FEDERAL TRADE COMMISSION

To Promote Innovation:
The Proper Balance of Competition and Patent Law and Policy

A Report by the Federal Trade Commission
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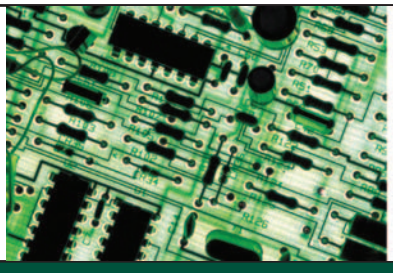

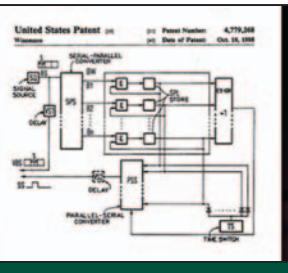

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The Commission thanks the Antitrust Division of the Department of Justice and the Patent and Trademark Office for participating in many of the panels at, and for recommending many of the participants in, the Hearings.

The Commission thanks the Competition Policy Center and the Berkeley Center for Law and Technology at the University of California at Berkeley for providing facilities to allow some of the Hearings to be held on the West Coast.

Cover:

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Patents: Front Cover
Patent No. 549,160 - Selden Road Engine
Patent No. 4,779, 268 - Frame Decoding for Digital Signal Transmission

Patents: Back Cover
Patent No. 4,302,281 - Method for Producing Pulp
Patent No. 4,805,654 - Sun Shield for Automobiles

TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY

EXECUTIVE SUMMARY

Innovation benefits consumers through the development of new and improved goods, services, and processes. An economy's capacity for invention and innovation helps drive its economic growth and the degree to which standards of living increase.[1] Technological breakthroughs such as automobiles, airplanes, the personal computer, the Internet, television, telephones, and modern pharmaceuticals illustrate the power of innovation to increase prosperity and improve the quality of our lives.

Competition and patents stand out among the federal policies that influence innovation. Both competition and patent policy can foster innovation, but each requires a proper balance with the other to do so. Errors or systematic biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness. This report by the Federal Trade Commission (FTC) discusses and makes recommendations for the patent system to maintain a proper balance with competition law and policy.[2] A second joint report, by the FTC and the Antitrust Division of the Department of Justice (DOJ) (forthcoming), will discuss and make recommendations for antitrust to maintain a proper balance with the patent system.

Competition and Patent Law and Policy Promote Innovation and Benefit the Public.

Competition through free enterprise and open markets is the organizing principle for most of the U.S. economy. Competition among firms generally works best to achieve optimum prices, quantity, and quality of goods and services for consumers. Antitrust law, codified in the Sherman Act, the FTC Act, and other statutes, seeks "to maximize consumer welfare by encouraging firms to behave competitively."[3]

Competition can stimulate innovation. Competition among firms can spur the invention of new or better products or more efficient processes. Firms may race to be the first to market an innovative technology. Companies may invent lower-cost manufacturing processes, thereby increasing their profits and enhancing their ability to compete. Competition can prompt firms to identify consumers' unmet needs and develop new products or services to

[1] Federal Reserve Board Vice Chairman Roger W. Ferguson, Jr., Patent Policy in a Broader Context, Remarks at 2003 Financial Markets Conference of the Federal Reserve Bank of Atlanta (April 5, 2003), *at* http://www.federalreserve.gov/boarddocs/speeches/2003/20030407/default.htm.

[2] The Federal Trade Commission issues reports pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f).

[3] I PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW : AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶100a at 4 (2000).

satisfy them.

Patent policy also can stimulate innovation. The U.S. Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[4] To obtain a patent, an invention (that is, a product, process, machine, or composition of matter) must be novel, nonobvious, and useful. Moreover, a patentee must clearly disclose the invention. A patent confers a right to exclude others from making, using, or selling in the United States the invention claimed by the patent for twenty years from the date of filing the patent application.

This property right can enable firms to increase their expected profits from investments in research and development, thus fostering innovation that would not occur but for the prospect of a patent. Because the patent system requires public disclosure, it can promote a dissemination of scientific and technical information that would not occur but for the prospect of a patent.

Like competition policy, patent policy serves to benefit the public. "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."[5] The public disclosure of scientific and technical information is part of the consideration that the inventor gives the public.[6]

Competition and Patents Must Work Together in the Proper Balance.

Competition and patents are not inherently in conflict. Patent and antitrust law "are actually complementary, as both are aimed at encouraging innovation, industry, and competition."[7] Patent law plays an important role in the property rights regime essential to a well-functioning competitive economy. For example, firms may compete to obtain the property rights that patents convey. Patents do not necessarily confer monopoly power on their holders,[8] and most business conduct with respect to patents does not unreasonably restrain or serve to monopolize markets. Even when a patent does confer monopoly power, that alone does not create an antitrust violation. Antitrust law recognizes that a patent's creation of monopoly power can be

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[4] U.S. CONST. art. I, § 8. Other sections of this constitutional provision authorize copyright law.

[5] *Brenner v. Manson,* 383 U.S. 519, 534-35 (1966). The consideration an inventor gives in return for a patent "is the benefit which he confers upon the public by placing in their hands a means through the use of which their wants may be supplied." 1 WILLIAM ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22 at 305 (1890), *cited in* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 361 (3d ed. 2002).

[6] *See* James E. Rogan, *Prepared Remarks of James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office* (2/6/02) 2, *at* http://www.ftc.gov/opp/intellect/rogan.htm.

[7] *Atari Games Corp. v. Nintendo of Am.,* 897 F.2d 1572, 1576 (Fed. Cir.1990).

[8] ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.4(b) at 21 (5th ed. 2001) ("Patent rights are not legal monopolies in the antitrust sense of the word. Not every patent is a monopoly, and not every patent confers market power.").

necessary to achieve a greater gain for consumers.

Analogously, the Supreme Court has recognized the importance of competition to the patent system.[9] "[F]ree competition" is "the baseline" on which "the patent system's incentive to creative effort depends."[10] By limiting the duration of a patent, "[t]he Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[11] The patentability requirements for novelty and nonobviousness "are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all."[12]

A failure to strike the appropriate balance between competition and patent law and policy can harm innovation. For example, if patent law were to allow patents on "obvious" inventions, it could thwart competition that might have developed based on the obvious technology. *See* Box 1. Conversely, competition policy can undermine the innovation that the patent system promotes if overzealous antitrust enforcement restricts the procompetitive use of a valid patent. *See* Box 2.

Box 1. ***An Invalid Patent on an Obvious Invention Can Harm Competition.***

In 1895, George Selden obtained a U.S. patent with a claim so broad that "it literally encompasse[d] most automobiles ever made." Yet the basic invention covered by that claim – putting a gasoline engine on a chassis to make a car – was so obvious that many people worldwide thought of it independently as soon as the most primitive gasoline engines were developed. The association that licensed the Selden patent collected hundreds of thousands of dollars in royalties – raising costs and reducing the output of automobiles – before Henry Ford and others challenged the patent, and the patent claim was judicially narrowed in 1911. *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 644-46.

The FTC/DOJ Hearings Examined the Balance of Competition and Patent Law and Policy.

To examine the current balance of competition and patent law and policy, the FTC and the DOJ held Hearings from February through November 2002. The Hearings took place over 24 days, and involved more than 300 panelists, including business representatives from large and small firms, and the independent inventor community; leading patent and antitrust organizations; leading antitrust and patent practitioners; and leading scholars in

[9] *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 146 (1989) (federal patent laws embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.").

[10] *Id.* at 156.

[11] *Id.* at 146.

[12] *Id.* at 156.

Box 2. ***Overzealous Antitrust Enforcement Can Undermine the Innovation that Patents Promote.***

In the 1970's, antitrust enforcers viewed grantbacks (*e.g.,* when a licensee has improved patented technology, it "grants back" to the original patentee access to the improvement) as automatically illegal. More recently, antitrust enforcers recognize that "[g]rantbacks can have procompetitive effects," for example, by encouraging a patentee to license its patent in the first place, thereby enabling the licensee's improvement. Antitrust enforcers now evaluate likely procompetitive and anticompetitive effects of grantbacks. Past antitrust rules may have deterred some procompetitive grantbacks, however, thus deterring some innovations using patented technology. *See* U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property § 5.6 (Apr. 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

economics and antitrust and patent law.[13] In addition, the FTC received about 100 written submissions. Business representatives were mostly from high-tech industries: pharmaceuticals, biotechnology, computer hardware and software, and the Internet.[14] This report discusses Hearings testimony and independent research, and explains the Commission's conclusions about and recommendations for the patent system.

CONCLUSIONS AND RECOMMENDATIONS

I. Although Most of the Patent System Works Well, Some Modifications Are Needed to Maintain A Proper Balance of Competition and Patent Law and Policy.

The patent system does, for the most part, achieve a proper balance with competition policy. The statutory standards of patentability appear largely compatible with competition; properly interpreted, they tend to award patents only when necessary to provide incentives for inventions, their commercial development, or their disclosure. Congress has enacted new statutes that protect competition by, among other things, facilitating disclosures of patent applications. The Court of Appeals for the Federal Circuit, the sole court for most patent law appeals, has brought stability and increased predictability to various elements of patent law. This has reduced legal uncertainty and facilitated business planning. The Patent and Trademark Office (PTO) has implemented initiatives to deal with new types of patents and has released a Strategic Plan for the 21st Century to improve patent quality (*i.e.,* reduce errors) and streamline procedures.[15] Hearings participants found much to praise in the current patent system.

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[13] The Commission thanks the DOJ and the Patent and Trademark Office for participating in many of the panels at the Hearings and for recommending many of the participants in the Hearings. For providing facilities to allow some of the Hearings to be held on the West Coast, the Commission thanks the Competition Policy Center and the Berkeley Center for Law and Technology at the University of California at Berkeley.

The Commission wishes to note the expertise and time contributed by Hearings participants. For all of their contributions, the Commission conveys its thanks.

[14] *See* Appendices A and B.

[15] *See* United States Patent and Trademark Office, The 21st Century Strategic Plan, *at* www.uspto.gov/web/offices/com/strat21/index.htm.

Nonetheless, many participants in and observers of the patent system expressed significant concerns that, in some ways, the patent system is out of balance with competition policy. Poor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can cause unwarranted market power and can unjustifiably increase costs. Such effects can hamper competition that otherwise would stimulate innovation. This report makes several recommendations for the legal standards, procedures, and institutions of the patent system to address such concerns.

II. Questionable Patents Are a Significant Competitive Concern and Can Harm Innovation.

A poor quality or questionable patent is one that is likely invalid or contains claims that are likely overly broad. Hearings participants raised concerns about the number of questionable patents issued.[16] Such patents can block competition, *see* Box 3, and harm innovation in several ways.

A. Questionable Patents Can Deter or Raise the Costs of Innovation.

One firm's questionable patent may lead its competitor to forgo R&D in the areas that the patent improperly covers. For example, firms in the biotech industry reported that they avoid infringing questionable patents and therefore will refrain from entering or continuing with a particular field of research that such patents appear to cover.[17] Such effects deter market entry and follow-on innovation by

Box 3. ***Blocking Patents***

The patents of others can block a patentee's ability to exploit its own invention. For example:

> "[S]uppose that Admiral Motors obtains a patent on an internal combustion engine for use in automobiles. Later, Betty Beta purchases an automobile marketed by Admiral Motors that embodies the patented invention. Beta experiments with her new car and develops a dramatically improved fuel injector useable only in the patented Admiral Motors engine. Even if Beta patents her improved fuel injector, she cannot practice that technology without infringing Alpha's basic patent. . . . Unless one of the parties licenses the other, Beta must wait until Admiral Motors' patent expires before practicing her own patented improvement invention." ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 20.1.1 at 462 (2003). If the blocking patent is invalid or overbroad, then no public benefits exist to justify its effects on follow-on innovation.

[16] For example, software firms raised concerns about patents that they believed should not have been granted, because the inventions were obvious based on preceding work in the area. While praising patents as the basis for their industry, biotech firms also raised concerns that some overbroad patents may discourage further innovation in some biotech areas. *See generally* Chs. 2 and 3.

[17] *See, e.g., FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, David J. Earp Testimony Feb. 26, 2002*, at pages 290-91, 238 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)); Blackburn 2/26 at 296; Caulfield 3/19 at 161.

competitors and increase the potential for the holder of a questionable patent to suppress competition.

If a competitor chooses to pursue R&D in the area improperly covered by the questionable patent without a license to that patent, it risks expensive and time-consuming litigation with the patent holder. If the competitor chooses to negotiate a license to and pay royalties on the questionable patent, the costs of follow-on innovation and commercial development increase due to unjustified royalties.

Another option is to find a legal means to invalidate the patent. PTO procedures allow only very limited participation by third parties, however. A lawsuit in federal court may not be an alternative, because a competitor may not sue to challenge patent validity unless the patent holder has threatened the competitor with litigation. If the competitor is not on the verge of marketing an infringing product, the patent holder may have no reason to threaten litigation. In these circumstances, as one biotech representative complained, "there are these bad patents that sit out there and you can't touch them."[18] If litigation does take place, it typically costs millions of dollars and takes years to resolve. This wastes resources.

B. In Industries with Incremental Innovation, Questionable Patents Can Increase "Defensive Patenting" and Licensing Complications.

In some industries, such as computer hardware and software, firms can require access to dozens, hundreds, or even thousands of patents to produce just one commercial product. One industry representative from a computer hardware firm reported that more than "90,000 patents generally related to microprocessors are held by more than 10,000 parties."[19] Many of these patents overlap, with each patent blocking several others. This tends to create a "patent thicket" – that is, a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[20]

Much of this thicket of overlapping patent rights results from the nature of the technology; computer hardware and software contain an incredibly large number of incremental innovations. Moreover, as more and more patents issue on incremental inventions, firms seek more and more patents to have enough bargaining chips to obtain access to others' overlapping patents.[21] One panelist asserted that the time and money his software company spends on creating and filing these so-called defensive patents, which "have no . . . innovative value in and of themselves," could have been better spent on developing new

[18] Blackburn 2/26 at 295-96.

[19] Detkin 2/28 at 667-68.

[20] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001).

[21] The forthcoming FTC/DOJ joint report will discuss the proper antitrust evaluation of licensing techniques used in such situations.

technologies.[22]

Questionable patents contribute to the patent thicket. In the context of a patent thicket, questionable patents can introduce new kinds of licensing difficulties, such as royalties stacked one on top of another, and can increase uncertainty about the patent landscape, thus complicating business planning. Questionable patents in patent thickets can frustrate competition by current manufacturers as well as potential entrants. Because a manufacturer needs a license to all of the patents that cover its product, firms can use questionable patents to extract high royalties or to threaten litigation.[23] For example, a questionable patent that claims a single routine in a software program may be asserted to hold up production of the entire software program. This process can deter follow-on innovation and unjustifiably raise costs to businesses and, ultimately, to consumers.

C. Recommendations to Improve Patent Quality and Minimize Anticompetitive Costs of the Patent System.

One recent article argues persuasively that because most patent applications involve claims of little economic significance, "it is much cheaper for society to make detailed [patent] validity determinations in those few cases [in which patents are challenged] than to invest additional resources examining patents that will never be heard from again."[24] Accordingly, the FTC's recommendations focus first on procedures and presumptions used in challenging questionable patents, because such challenges are more likely to involve patents of competitive significance.

Recommendation 1:

As the PTO Recommends, Enact Legislation to Create A New Administrative Procedure to Allow Post-Grant Review of and Opposition to Patents.

The PTO discusses patent applications only with the patent applicant. Until recently, third parties could only bring certain relevant documents to the attention of, and, in limited circumstances, file a written protest with, an examiner or to request the PTO Director to reexamine a patent. To address this situation, Congress passed legislation to establish limited procedures that allow third parties to participate in patent reexaminations. Recent amendments have improved those procedures, but they still contain important restrictions and disincentives for their use. Once a questionable patent has issued, the most effective way to challenge it is through litigation. Litigation generally is extremely

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[22] Greenhall 2/27 at 377, 420.

[23] "Large and small companies are increasingly being subjected to litigation (or its threat) on the basis of questionable patents." *United States Patent and Trademark Office Fee Modernization Act of 2003: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 108th Cong. 2 (2003) (Statement of Michael K. Kirk, Executive Director, American Intellectual Property Law Association), *available at* http://www.aipla.org/html/Legislative/108/testimony/FeeLeg.htm.

[24] Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1495, 1497 (2001).

costly and lengthy,[25] and is not an option unless the patent owner has threatened the potential challenger with patent infringement litigation.

The existing procedures attempt to balance two perspectives. On the one hand, third parties in the same field as a patent applicant may have the best information and expertise with which to assist in the evaluation of a patent application, and therefore might be useful participants in the process of deciding whether to grant a patent. On the other hand, the limited involvement of third parties in the issuance and reexamination of patents reflects genuine concern to protect patent applicants from harassment by competitors. This remains an important goal. To continue to protect against the possibility of competitors harrassing patent applicants, any new procedure should be available only after a patent issues.

Because existing means for challenging questionable patents are inadequate, we recommend an administrative procedure for post-grant review and opposition that allows for meaningful challenges to patent validity short of federal court litigation. To be meaningful, the post-grant review should be allowed to address important patentability issues.[26] The review petitioner should be required to make a suitable threshold showing. An administrative patent judge should preside over the proceeding, which should allow cross-examination and carefully circumscribed discovery, and which should be subject to a time limit and the use of appropriate sanctions authority. Limitations should be established to protect against undue delay in requesting post-grant review and against harassment through multiple petitions for review. The authorizing legislation should include a delegation of authority permitting the PTO's conclusions of law to receive deference from the appellate court. Finally, as is the case with settlements of patent interferences, settlement agreements resolving post-grant proceedings should be filed with the PTO and, upon request, made available to other government agencies.

Recommendation 2:

Enact Legislation to Specify that Challenges to the Validity of a Patent Are To Be Determined Based on a "Preponderance of the Evidence."

An issued patent is presumed valid. Courts require a firm that challenges a patent to prove its invalidity by "clear and convincing evidence." This standard appears unjustified. A plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application is filed. In addition, as many have noted, the PTO is underfunded, and PTO patent examiners all too often do not have sufficient time to evaluate patent applications fully. These circumstances suggest that an overly strong presumption of a patent's validity is inappropriate. Rather, courts should require only a "preponderance of the evidence" to rebut the presumption of validity.

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[25] A biotechnology case, for example, can cost between five and seven million dollars and take two or three years to litigate. *See* Ch. 3.

[26] At a minimum, patent challengers should be able to raise issues of novelty, nonobviousness, written description, enablement, and utility.

The PTO works under a number of disadvantages that can impede its ability to reduce the issuance of questionable patents. Perhaps most important, the courts have interpreted the patent statute to require the PTO to grant a patent application unless the PTO can establish that the claimed invention does not meet one or more of the patentability criteria. Once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise.

The PTO's procedures to evaluate patent applications seem inadequate to handle this burden. The patent prosecution process involves only the applicant and the PTO. A patent examiner conducts searches of the relevant prior art,[27] a focal point of the examination process, with only the applicant's submissions for assistance. The patent applicant has a duty of candor to the PTO, but that duty does not require an applicant to search for prior art beyond that about which the applicant already knows.[28] If the patent applicant makes assertions or files documentary evidence regarding certain facts, the PTO does not have facilities with which to test the accuracy or reliability of such information.

Moreover, presumptions in PTO rules tend to favor the issuance of a patent. For example, "[i]f the examiner does not produce a *prima facie* case [of obviousness], the applicant is under no obligation to submit evidence of nonobviousness."[29] Similarly, "[o]ffice personnel . . . must treat as true a statement of fact made by an applicant in relation to [the asserted usefulness of the invention], unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement."[30] Likewise, "[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed."[31]

The PTO's resources also appear inadequate to allow efficient and accurate screening of questionable patent applications. Patent applications have doubled in the last twelve years and are increasing at about 10% per year.[32] With yearly applications approximating 300,000,

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[27] "Prior art" consists of materials – often patents and publications, although affidavits and testimony also may present prior art – that reflect one or more of the features or elements of the claimed invention. An invention is "obvious" if it does not represent a sufficient step beyond the prior art.

[28] The PTO's Manual of Patent Examining Procedure (MPEP) states that the agency "does not investigate" duty of disclosure issues and "does not . . . reject" applications on that basis. *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 2010 (8th edition 2001) (explaining that such PTO determinations "would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest"), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (hereinafter MPEP).

[29] MPEP § 2142.

[30] United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1098-99 (2001).

[31] United States Patent and Trademark Office, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112 ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1105 (2001).

[32] Lerner 2/20 at 157; James Langenfeld, *Innovation, Competition, and Intellectual Property: Providing an Economic Framework* (2/20/02) (slides) at 6, at http://www.ftc.gov/opp/intellect/langenfeld.pdf.

they arrive at the rate of about 1,000 each working day.[33] A corps of some 3,000 examiners must deal with the flood of filings.[34] Hearings participants estimated that patent examiners have from 8 to 25 hours to read and understand each application, search for prior art, evaluate patentability, communicate with the applicant, work out necessary revisions, and reach and write up conclusions. Many found these time constraints troubling.[35] Hearings participants unanimously held the view that the PTO does not receive sufficient funding for its responsibilities.

Finally, the PTO grants patents based only on the "preponderance of the evidence." This standard applies in the context of an underlying presumption that the patent should be granted unless the PTO can prove otherwise. It does not seem sensible to treat an issued patent as though it had met some higher standard of patentability.

Defenders of the application of the "clear and convincing" evidence standard urged that a finding of patent validity by a neutral government agency using a knowledgeable examiner justifies placing a heavy burden on those who challenge a patent's validity. We disagree. Presumptions and procedures that favor the grant of a patent application, combined with the limited resources available to the PTO, counsel against requiring "clear and convincing evidence" to overturn that presumption. We believe the "clear and convincing evidence" burden can undermine the ability of the court system to weed out questionable patents,[36] and therefore we recommend that legislation be enacted to amend the burden to a "preponderance of the evidence."

Recommendation 3:

Tighten Certain Legal Standards Used to Evaluate Whether A Patent Is "Obvious."

Patent law precludes patenting if the differences between the claimed invention and the prior art[37] are such that "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."[38] "Nonobviousness asks whether a development is a significant enough technical advance to merit the award of a patent."[39] A proper application of this statutory requirement is crucial to prevent the issuance of questionable patents, including trivial patents and patents on inventions essentially already in the public domain. The courts have developed a variety of tests to evaluate the obviousness of a claimed invention. Two in particular –

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[33] Chambers 2/8 (Patent Law for Antitrust Lawyers) at 86 (hereinafter 2/8 (Patent Session)).

[34] Chambers 2/8 (Patent Session) at 84.

[35] *See, e.g.,* Dickinson 2/6 at 64-65 ("Patent examiners need more time to examine."); Kirschner 2/26 at 242-43 (time available "clearly inadequate" for a meaningful examination of a biotech patent application); Kesan 4/10 at 100 (time constraints do not allow adequate search for software prior art).

[36] *See* T.S. Ellis 7/11 at 119-20.

[37] *See supra* note 25.

[38] 35 U.S.C. § 103.

[39] *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 644.

the "commercial success test" and "the suggestion test" – require more thoughtful application to weed out obvious patents.

a. In applying the "commercial success" test, 1) evaluate on a case-by-case basis whether commercial success is a valid indicator that the claimed invention is not obvious, and 2) place the burden on the patent holder to prove the claimed invention caused the commercial success.

The Supreme Court has advised that, in some circumstances, courts may consider the commercial success of a claimed invention to indicate that it was not obvious. For example, in some cases early in the twentieth century, courts found the commercial success of an invention that satisfied a long-felt need that had resisted the efforts of others to solve the problem tended to show the claimed invention was not obvious.

Commercial success can result from many factors, however, some of which have nothing to do with the claimed invention. For example, marketing, advertising, or an incumbent's unique advantages may cause commercial success. An undue reliance on commercial success to show nonobviousness can raise a number of competitive concerns. Commercially successful inventions may be more likely than others to occur even without the prospect of a patent. Patents on commercially successful products are more likely to confer market power than those on less successful products.

Certain patent experts and other Hearings participants expressed concern that courts and juries sometimes fail to use a sufficiently searching inquiry when they conclude that commercial success demonstrates a claimed invention is not obvious. Under current standards, if the patent holder shows that the claimed features of the patent are coextensive with those of a successful product, then it is presumed that the invention – rather than other factors – caused the commercial success. The burden shifts to the challenger to present evidence to rebut that presumption.[40]

This test fails to ask, first, whether factors other than the invention may have caused the commercial success. By contrast, the PTO properly requires that commercial success be "directly derived from the invention claimed" and not the result of "business events extraneous to the merits of the claimed invention."[41] Second, the judicial standard too easily shifts the burden to the challenger. The patent holder is the best source of information on what has caused the commercial success of its product and should be required to show that, in fact, the claimed invention caused the commercial success.

b. In applying the "suggestion" test, assume an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art.

If the prior art already would have suggested the claimed invention, then the

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[40] *See* HARMON, PATENTS AND THE FEDERAL CIRCUIT at 169-70.

[41] MPEP § 716.03(b).

claimed invention is obvious. If not, then the claimed invention is not obvious. The "suggestion test" thus asks a helpful question – that is, to what extent would the prior art "have *suggested* to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success."[42] The Federal Circuit justifiably has sought to protect inventors from findings of obviousness based purely on hindsight. "Good ideas may well appear 'obvious' after they have been disclosed, despite having been previously unrecognized."[43] The Federal Circuit also has sought to ensure that the PTO provides an administrative record susceptible to judicial review.

Hearings participants expressed concern, however, with some recent applications of the suggestion test. To show that a claimed invention is obvious, some cases seem to require the PTO to point to particular items of prior art that concretely suggest how to *combine* all of the features of a claimed invention. Such an application of the suggestion test may have found that the claimed invention of the Selden patent – that is, putting a gasoline engine on a carriage – was not obvious, because there was no document that suggested that combination. The invention likely was obvious, however; "[e]verybody seemed to know that if you got a new engine of any kind, you would put it on a carriage."[44]

It is important to protect against the issuance of obvious patents that may confer market power and unjustifiably raise costs. Requiring concrete suggestions beyond those actually needed by a person with ordinary skill in the art,[45] and failing to give weight to suggestions implicit from the art as a whole and from the nature of the problem to be solved, is likely to result in patents on obvious inventions and is likely to be unnecessarily detrimental to competition. The Federal Circuit's most recent articulations of the suggestion test seem to signal greater appreciation of these issues and would better facilitate implementation of the test in ways sensitive to competitive concerns.

Recommendation 4:

Provide Adequate Funding for the PTO.

Participants in the Hearings unanimously expressed the view that the PTO lacks the funding necessary to address issues of patent quality. Presidential patent review committees have long advocated more funding for the PTO to allow it to improve patent quality.[46] As recently as 2002, the Patent Public Advisory Committee stated that the PTO "faces a crisis in funding

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[42] *Brown and Williamson Tobacco Corp. v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000) (emphasis added).

[43] *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997).

[44] Duffy 7/10 at 132-33.

[45] *Cf.* Barr 10/30 at 53-54 (arguing that current obviousness standards fail to reflect the skill of his company's engineers, who "every day" independently invent things that have been deemed nonobvious).

[46] *E.g.,* THE ADVISORY COMMISSION ON PATENT LAW REFORM, REPORT TO THE SECRETARY OF COMMERCE (Aug. 1992), *available at* http://world.std.com/obi/USG/Patents/overview; REPORT OF THE INDUSTRIAL SUBCOMM. FOR PATENT AND INFORMATION POLICY OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, REPORT ON PATENT POLICY (1979).

that will seriously impact . . . the quality of . . . issued patents."[47] The FTC strongly recommends that the PTO receive funds sufficient to enable it to ensure quality patent review.

Recommendation 5:

Modify Certain PTO Rules and Implement Portions of the PTO's 21st Century Strategic Plan.

a. Amend PTO regulations to require that, upon the request of the examiner, applicants submit statements of relevance regarding their prior art references.

Some Hearings participants asserted that, far from holding back information, patent applicants tend to provide an examiner with numerous prior art citations, resulting in lots of "information," but little "knowledge."[48] The 2002 version of the PTO's 21st Century Strategic Plan proposed requiring applicants that cited more than 20 prior art references to provide statements to explain the relevance of references, but the PTO has now withdrawn that proposal.[49] The FTC's proposal is more modest than the PTO's original proposal; it would require relevance statements only when the examiner requests them. These statements could materially enhance examiners' ability to provide quality patent examinations by drawing more fully on the patent applicant's knowledge base to identify the most relevant portions of prior art references.

b. Encourage the use of examiner inquiries under Rule 105 to obtain more complete information, and reformulate Rule 105 to permit reasonable follow-up.

PTO Rule 105 permits examiners to request "such information as may be reasonably necessary to properly examine or treat the matter [under examination]."[50] The Commission recommends that the PTO make a concentrated effort to use examiner inquiries more often and more extensively. As one panelist emphasized, "to get better quality and shrink the amount of work," there is a need to seek more knowledge in the possession of applicants, who typically "know more about the technology than the examiner does, and [know] where you might find something that might be relevant."[51] To be fully effective, however, Rule 105 should be amended so that applicants who reply that they do not know the answer to the examiner's inquiry, or that the necessary information "is not readily available to the party or parties from which it was requested" are *not* accepted as a complete reply,[52] as they are now, but rather are treated as responses on which the examiner may follow up.

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[47] PATENT PUBLIC ADVISORY COMMITTEE, ANNUAL REPORT 6 (Nov. 29, 2002), *available at* http://www.uspto.gov/web/offices/com/advisory/acrobat/ppacannual12-05-02.pdf.

[48] *E.g.,* Kesan 10/25 at 60-61.

[49] United States Patent and Trademark Office 21st Century Strategic Plan*, Mandatory Information Disclosure Statements (IDS)*, P-09 at 3 (June 3, 2002). *See* The 21st Century Strategic Plan, *available at* www.uspto.gov/web/offices/com/strat21/index.htm.

[50] 37 C.F.R. § 1.105.

[51] Kushan 4/11 at 89.

[52] *See* 37 C.F.R. § 1.105.

c. Implement the PTO's recommendation in its 21st Century Strategic Plan that it expand its "second-pair-of-eyes" review to selected areas.

Second-pair-of-eyes review allows the PTO quickly to flag issues that need further attention by the examiner or the examiner's supervisor. The PTO first used this method to improve the quality of business method patents, and it received good reviews from participants in the patent system. The Commission believes that expanding this program to fields with substantial economic importance, such as semiconductors, software, and biotechnology, as well as other new technologies as they emerge, could help to boost patent quality in areas where it will make the most difference.

d. Continue to implement the recognition that the PTO "forges a balance between the public's interest in intellectual property and each customer's interest in his/her patent and trademark."[53]

The PTO functions as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power, just as it should issue valid patents to encourage invention, disclosure, and commercial development.

Recommendation 6:

Consider Possible Harm to Competition – Along with Other Possible Benefits and Costs – Before Extending the Scope of Patentable Subject Matter.

Section 101 of the Patent Act states, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent."[54] Despite this broad mandate, courts have long held certain types of inventions unpatentable. Traditional common law exceptions include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter, and, for many years, business methods.

Over the past twenty-five years, however, the scope of patentable subject matter has expanded significantly. For example, the Supreme Court, through two landmark decisions in 1980, held that both man-made, living organisms and computer software constitute patentable subject matter pursuant to Section 101. In 1999, the Federal Circuit ruled that business methods can be patented. Some Hearings participants claimed that patents on computer software and business methods are not necessary to spur the invention, commercial development, or public disclosure of

[53] United States Patent and Trademark Office, *FY2002 Corporate Plan* 28 (2001) (describing role of PTO Under Secretary and Director), *at* http://www.uspto.gov/web/offices/com/corpplan/fy2002/index.html.

[54] 35 U.S.C. § 101.

software or business methods.[55] Others disagreed. Some Hearings participants contended that software and business method patents can raise significant competitive concerns and deter innovation, especially because so much of the innovation in those fields builds incrementally on preceding work. This may raise the potential for thickets of patents to hinder, rather than accelerate, innovation and commercial development.

The constitutional intention that patents "promote the Progress of Science and useful Arts" should be taken into account in interpreting the scope of patentable subject matter under Section 101. Decisionmakers should ask whether granting patents on certain subject matter in fact will promote such progress or instead will hinder competition that can effectively spur innovation. Such consideration is consistent with the historical interpretation of patentable subject matter, which implicitly recognizes that granting patent protection to certain things, such as phenomena of nature and abstract intellectual concepts, would not advance the progress of science and the useful arts. For future issues, it will be highly desirable to consider possible harms to competition that spurs innovation – as well as other possible benefits and costs – before extending the scope of patentable subject matter.

III. Other Patent Laws and Procedures Also Raise Competitive Concerns.

In addition to questionable patents, other portions of the patent system raise competitive concerns. This section briefly describes each issue and the Commission's recommendation(s) to address it.

Recommendation 7:

Enact Legislation to Require Publication of All Patent Applications 18 Months After Filing.

Until relatively recently, patents were published only when issued; patent applications were not published. During the time that would pass between the filing of a patent application and the issuance of a patent, an applicant's competitor could have invested substantially in designing and developing a product and bringing it to market, only to learn, once the patent finally issued, that it was infringing a rival's patent and owed significant royalties. This scenario disrupts business planning, and can reduce incentives to innovate and discourage competition.

A relatively new statute requires that most patent applications – all except those filed only in the United States – be published 18 months after filing. Patent applicants are protected from copying of their inventions by statutory royalty rights, if the patent ultimately issues. This new procedure appears to have increased business certainty and promoted rational planning, as well as reduced the problem of unanticipated "submarine patents" used to hold up competitors for unanticipated royalties. For these reasons, Hearings participants advocated expanding the 18-month publication requirement to include patents filed only domestically, because such

[55] *See generally* Ch. 3. *See also* Robert M. Hunt, *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the Economy?*, Q1 BUSINESS REVIEW 5, 14 (2001).

patents may well have competitive significance. Protection from copying similar to that already available for other published applications should be extended to those filing domestic patent applications as well, and any necessary protections for independent inventors also should be considered in terms of their likely costs and benefits.

Recommendation 8:

Enact Legislation to Create Intervening or Prior User Rights to Protect Parties from Infringement Allegations That Rely on Certain Patent Claims First Introduced in a Continuing or Other Similar Application.

After publication of its patent application, an applicant may continue to amend its claims. Through this claim amendment process, a patent that states broader claims than those published at 18 months can still emerge. If the applicant uses procedures such as continuing applications to extend the period of patent prosecution, the potential for anticompetitive hold up increases. Indeed, several panelists asserted that some applicants keep continuing applications pending for extended periods, monitor developments in the relevant market, and then modify their claims to ensnare competitors' products after those competitors have sunk significant costs in their products. Patent reform efforts have long focused on how to remedy opportunistic broadening of claims to capture competitors' products.

Legitimate reasons exist to amend claims and use continuing applications. Any proposed remedy for the opportunistic broadening of claims should also protect such legitimate uses. Creating intervening or prior use rights would most directly achieve this balance; it would cure potential competitive problems without interfering with legitimate needs for continuations. Such rights should shelter inventors and users that infringe a patent only because of claim amendments following a continuation or other similar application,[56] provided that the sheltered products or processes are developed or used (or the subject of substantial preparation for use) before the amended claims are published.

Recommendation 9:

Enact Legislation to Require, As a Predicate for Liability for Willful Infringement, Either Actual, Written Notice of Infringement from the Patentee, or Deliberate Copying of the Patentee's Invention, Knowing It to Be Patented.

A court may award up to three times the amount of damages for a defendant's willful infringement of a patent – that is, the defendant knew about and infringed the patent without a reasonable basis for doing so. Some Hearings participants explained that they do not read their competitors' patents out of concern for such potential treble damage liability. Failure to read competitors' patents can jeopardize plans for a noninfringing business or research strategy, encourage wasteful duplication of effort, delay follow-on innovation that could

[56] *See infra* Ch. 4(II)(C)(1) for a description of the types of filings that should be covered.

derive from patent disclosures, and discourage the development of competition.

It is troubling that some businesses refrain from reading their competitors' patents because they fear the imposition of treble damages for willful infringement. Nonetheless, infringers must not be allowed to profit from knowingly and deliberately using another's patented invention due to a low likelihood that the patent holder can afford to bring suit or obtain substantial damages. The FTC's recommendation would permit firms to read patents for their disclosure value and to survey the patent landscape to assess potential infringement issues, yet retain a viable willfulness doctrine that protects both wronged patentees and competition.

Recommendation 10:

Expand Consideration of Economic Learning and Competition Policy Concerns in Patent Law Decisionmaking.

The Supreme Court has made clear in several decisions that there is room for policy-oriented interpretation of the patent laws.[57] Indeed, to find the proper balance between patent and competition law, such policy-oriented interpretations are essential. Over the past twenty-five years, the incorporation of economic thinking into antitrust has provided significant insights that have substantially improved the development of antitrust law and competition policy. The Federal Circuit and the PTO may also benefit from much greater consideration and incorporation of economic insights in their decisionmaking.

IV. The FTC Will Pursue Steps to Increase Communication between Antitrust Agencies and Patent Institutions.

Many Hearings participants expressed concern that the patent and competition communities appear to exist in separate worlds, interacting infrequently at best. Patent practitioners and scholars further expressed concern that patent institutions do not always fully understand or accommodate economic learning or competition concerns. Increased interaction appears desirable to foster better understanding and communication between the patent and competition communities.

The FTC wishes to do its part to improve communication between the competition and patent communities. Accordingly, the FTC will pursue the steps listed below.

A. The FTC Will Increase its Competition Advocacy Role through Filing Amicus Briefs in Appropriate Circumstances.

The Commission will renew its commitment to the filing of amicus briefs in important patent cases that can affect competition, as well as in cases at the intersection of patent and antitrust law. When such cases have high stakes for the public, the Commission can serve the public interest by filing amicus briefs to present its perspectives regarding the implications of certain issues for consumer welfare.

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[57] *See, e.g., supra* notes 10-12; *Graham v. John Deere Co.,* 383 U.S. 1 (1966).

B. In Appropriate Circumstances, the FTC Will Ask the PTO Director to Reexamine Questionable Patents that Raise Competitive Concerns.

A collective action problem may frustrate business challenges to questionable patents. Instead of challenging a patent's validity, many firms may simply license it, because no single firm has the incentive to finance an expensive legal challenge that would benefit all of the affected firms, not just the challenger. An enforcement agency, however, can consider the cost of a questionable patent to an entire industry and to consumers and can solve this coordination problem. In appropriately narrow circumstances, the FTC will do so.

C. The FTC Will Encourage Increased Communication between Patent Institutions and the Antitrust Agencies.

One means of improving interagency communication would be the establishment of a Liaison Panel between the FTC and the DOJ's Antitrust Division (collectively, the Antitrust Agencies) and the PTO. Such a panel could function as a practical, policy-oriented group designed to permit the exchange of views on important issues as they arise. Another means would be to establish an Office of Competition Advocacy within the PTO. Such an office could, when appropriate, advise PTO policymakers about the likely competitive impact and economic consequences of policy decisions. A final means would be to request that Congress amend the membership categories of the Patent Public Advisory Committee ("P-PAC") to include competition experts and economists.

V. Conclusion

Both patents and competition make significant contributions to innovation, consumer welfare, and our nation's prosperity. We recognize the importance of the patent system; the recommendations in this Report are designed to increase the likelihood that the valid patents are issued and upheld. There is broad consensus on the significant role that these patents can play to spur innovation and to encourage the disclosure and commercial development of inventions.

The importance of competition as a spur to innovation also should be recognized. More patents in more industries and with greater breadth are not always the best ways to maximize consumer welfare. A questionable patent can raise costs and prevent competition and innovation that otherwise would benefit consumers. The FTC looks forward to working closely with the PTO and other patent organizations to increase communication and include all parties in discussion and implementation of the FTC's recommendations.

TABLE OF CONTENTS

CHAPTER 1 INTRODUCTION AND BACKGROUND

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Innovation benefits consumers through the development of new and improved goods and services, and spurs economic growth. An economy's capacity for invention and innovation helps drive its economic growth and the degree to which standards of living increase.[1] Indeed, the United States economy and the economies of other countries have enjoyed "huge productivity gains from the development and rapid adoption of new information and communication technologies."[2] The technological breakthroughs that introduced "automobiles, airplanes, radio, television, space travel, telephones, internet, modern pharmaceuticals, and the like" illustrate how innovation improves the quality of our lives in ways that are hard to measure and underscore the importance of stimulating innovation.[3]

The federal government has a profound impact on R&D in the U.S. First, the federal government funds certain R&D. In FY 2003, federal investment in R&D hit a new record of $117 billion, a 13.8 percent increase over FY 2002 and the largest dollar increase in history.[4] Many government agencies contribute to R&D funding, especially in national defense, health, and space.[5] Second, the federal government sets policies that influence how businesses and individuals invest many more billions of dollars in R&D. Tax and environmental policies, for example, all can influence which R&D companies undertake and how much they spend.

Competition and patents stand out among the federal policies that influence private R&D.[6] Competition among firms prods inventors to be first in the market with a new product or service at a price and quality that consumers want. Patent policy encourages prospective inventors to invest time and money in inventions, because a patent's grant of the exclusive right to make, sell, and use the invention for a certain period of time can allow inventors to realize

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[1] Federal Reserve Board Vice Chairman Roger W. Ferguson, Jr., Patent Policy in a Broader Context, Remarks at 2003 Financial Markets Conference of the Federal Reserve Bank of Atlanta (April 5, 2003), *at* http://www.federalreserve.gov/boarddocs/speeches/2003/20030407/default.htm.

[2] *Id*.

[3] American Bar Association Section of Antitrust Law, *The Economics of Innovation: A Survey* (Public Comment) 2, *at* http://www.ftc.gov/opp/intellect/0207salabasrvy.pdf (hereinafter ABA (Economics stmt)).

[4] Kei Koizumi & Paul W. Turner, *Congressional Action on Research and Development in the FY 2003 Budget*, American Association for the Advancement of Science 1 (2003), *at* http://www.aaas.org/spp/rd/ca03.pdf.

[5] For example, the Department of Defense (DOD) accounts for half the total federal R&D portfolio. Support for R&D makes up 97 percent of the budget of the National Institute of Health (NIH). The National Science Foundation (NSF) accounts for about 20 percent of federal support to academic institutions for basic research. The National Aeronautics and Space Administration (NASA) spends two-thirds of its budget (excluding the Space Shuttle program) on R&D. *See* Koizumi & Turner, *Congressional Action on Research and Development in the FY 2003 Budget* at 11-16; NFS website http://www.nsf.gov/home/programs; AAAS R&D Funding Update, *FY 2003 Omnibus Bill Complete NIH Doubling Plan; Large Increases for Bioterrorism R&D and Facilities* 1, 3 (Feb. 25, 2003), *at* http://www.aaas.org/spp/rd/nih03f.pdf.

[6] In the Hearings, panelists focused on patents and not other forms of intellectual property. Most of the antitrust cases involving intellectual property involve patents in particular. *See, e.g.,* 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 1.3c at 1-14 (2002) (hereinafter HOVENKAMP ET AL., IP AND ANTITRUST).

returns sufficient to encourage the initial investments.[7]

Competition and patent policy are bound together by the economics of innovation and an intricate web of legal rules that seek to balance the scope and effect of each policy. Errors or systematic biases in the interpretation or application of one policy's rules can harm the other policy's effectiveness. For example, patent law precludes the patenting of an "obvious" invention. If, however, patent law sets the bar for "obviousness" too low, and erroneously allows patents on "obvious" inventions, then patent law can thwart competition that otherwise might have developed based on the obvious technology. Conversely, competition policy – as implemented through antitrust law – prohibits only anticompetitive business conduct. If antitrust enforcement erroneously condemns efficient, welfare-enhancing conduct with respect to a valid patent, then antitrust enforcement can undermine the incentives the patent system creates to encourage innovation. A challenge for both policies is to find the proper balance of competition and patent protection.[8]

To understand better the current relationship between competition and patent law and policy, and whether it strikes the proper balance, the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) held a series of Hearings from February through November 2002. The Hearings took place over 24 days, with more than 300 panelists, including experienced business representatives from large and small firms, representatives from the independent inventor community, all of the leading patent and antitrust organizations, many of the leading antitrust and patent practitioners, and scholars in economics and antitrust and patent law. Care was taken to solicit all points of view, and the transcripts of the Hearings provide a wide spectrum of well-considered experience with and perspectives on patent and competition-related issues. In addition, written comments were solicited; the FTC received about 100 written submissions.

The FTC took the lead in examining the issues addressed in this report, which discusses what the FTC has learned and, as appropriate, makes recommendations for changes to patent law and policy to achieve a better balance with competition policy. The DOJ and the FTC worked together developing the record for a forthcoming joint report that will examine antitrust's approach to maintaining the proper balance with the patent system.

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[7] *See generally infra* Ch. 2(I).

[8] *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 146 (1989) ("From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."); Richard Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, 927 (2001) ("The patent and copyright laws try to strike the output-maximizing balance by giving the creator of intellectual property some but not complete protection from competition."); 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3b at 1-14 (patents can limit the reach of antitrust law, and antitrust constrains what a patentee can do with its patent).

I. THE RELATIONSHIP OF COMPETITION AND PATENT LAW AND POLICY

A. Each Policy Reflects Fundamental Assumptions about How Best to Organize an Economy and Encourage Innovation

1. Competition Policy and Antitrust Law

Competition through free enterprise and open markets is the organizing principle for most of the U.S. economy.[9] The United States generally has chosen antitrust law (rather than regulation) to provide the governing rules for competition. For the last twenty years, antitrust law has recognized enhancing consumer welfare as the single unifying goal of competition policy.[10] To serve that objective, competition policy and antitrust enforcement use a framework based on sound economics.[11]

Economics affirms that "[c]ompetition is good for a variety of reasons. Basic economics teaches that firms in competition will produce more and price lower than monopolists. Monopolists not only take money away from consumers by raising prices, but they impose a 'deadweight loss' on society by reducing their output below the level which consumers would be willing to purchase at a competitive price."[12] Thus, economics informs us that effective competition is the best mechanism for achieving the optimum mix of products and services in terms of price, quality, and consumer choice. Moreover, economic learning focuses on the importance of competition in enhancing consumer welfare not only with respect to existing products, but also the development of new and improved products and services.[13] Monopolists can have fewer incentives to innovate than do competitive firms.[14]

Antitrust law protects competition and the competitive process "by preventing certain types of conduct that threaten a free market."[15] Antitrust evaluates agreements among firms to determine whether they

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[9] *See, e.g.,* 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3a at 1-10 ("[A] fundamental principle of our economic system is the proposition that free market competition will best ensure an efficient allocation of resources in the absence of market failure.").

[10] *See, e.g.,* IIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW : AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 401 (2d. ed. 2002).

[11] *See, e.g.*, HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 2.3a (2d ed. 1999).

[12] 1 HOVENKAMP ET AL., IP AND ANTITRUST §1.2 at 1-5 through 1-6. *See also* William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 991 (1981).

[13] *See generally infra* Ch. 2(II)(A).

[14] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.2 at 1-6. Others emphasize that, depending on the circumstances, monopolists also can have greater incentives to innovate. *See infra* at Ch. 2(II)(A)(3).

[15] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.2 at 1-5. *See also Northern Pacific Railway v. United States*, 356 U.S. 1, 4 (1958) ("The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.").

"unreasonably restrain trade."[16] For example, antitrust prohibits naked agreements among competitors on the price they will charge or which customers each will serve. For most other agreements, antitrust evaluates likely procompetitive and anticompetitive effects.[17] Antitrust law also constrains the creation of market power through mergers,[18] and prohibits monopolization and attempts and conspiracies to monopolize.[19]

In recognizing consumer welfare as its proper goal, antitrust law has relinquished earlier doctrines that sought to protect competitors rather than competition. Indeed, the Supreme Court has held that the purpose of the antitrust laws is to protect competition, not competitors.[20] Thus, antitrust enforcement has ceased protecting individual firms in favor of protecting consumer welfare, because protecting individual firms often served to harm consumers by protecting firms from competition.[21] Antitrust's focus on consumer welfare also reveals that governmental impediments to, or exemptions from, competition can be as harmful to consumers as private business restraints.[22]

2. Patent Policy and Law

The U.S. economy also reflects the belief that limited exclusive rights in intellectual property – as distinguished from tangible property – can encourage innovation, which also benefits consumers.[23] Article I, Section 8 of the Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and

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[16] Sherman Act of 1890 § 1, 15 U.S.C. § 1; *Standard Oil Co. v. United States*, 221 U.S. 1, 59-69 (1911); *see also* Federal Trade Commission Act of 1914 § 5, 15 U.S.C. § 45.

[17] *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 8 (1979). *See generally* Federal Trade Commission and U.S. Department of Justice, Antitrust Guidelines for Collaborations Among Competitors § 2 (April 2000), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[18] Clayton Act of 1950 § 7, 15 U.S.C. § 18; 15 U.S.C. § 45. Market power arises when the "defendant (1) can profitably set prices well above its costs and (2) enjoys some protection against a rival's entry or expansion that would erode such supracompetitive prices and profits." IIA AREEDA & HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 501 at 90. *See also United States v. E.I. duPont de Nemours & Co.,* 351 U.S. 377 (1956); Federal Trade Commission and U.S. Department of Justice, Horizontal Merger Guidelines § 1.1 (1992), *available at* http://www.ftc.gov/bc/docs/horizmer.htm; *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, William E. Kovacic Testimony Feb. 8, 2002 (Antitrust Law for Patent Lawyers)*, at page 33 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)). Antitrust does not constrain all exercises of market power, however. *See infra* Ch. 1(I)(B).

[19] 15 U.S.C. § 2.

[20] *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) ("The antitrust laws, however, were enacted for the protection of *competition*, not *competitors*" (internal citations omitted)).

[21] *See generally* I PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶100 at 3-7 (2d ed. 2000).

[22] *See, e.g.,* HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 18.1a at 680.

[23] ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2 at 11 (5th ed. 2001) (noting that the exclusive right granted by a patent "was for the national purpose of advancing the useful arts – the process today called technological innovation[,]" and serves "the public interest in technological advancement." (Footnotes omitted)).

Inventors the exclusive Right to their respective Writings and Discoveries."[24] The patent statute[25] confers a right to exclude others from making, using, or selling in the United States the invention claimed by the patent for twenty years from the date of filing the patent application.[26]

Box 1-1. ***Two of the Basics of the Patent Document***

A patent contains a great deal of information. Among the most important are the patent's "specification" and "claims." The specification must provide a "written description of the invention, and of the manner and process of making and using it," and must disclose the "best mode" known to the inventor of carrying out the invention. 35 U.S.C. §§ 111, 112.

The patent's "claims" are "the portion of the patent document that defines the patentee's rights." *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 372 (1992). Since the claims essentially articulate the "metes and bounds" of the patentee's intellectual property, they are one of the most important parts of the modern patent document. *See generally* ROBERT MERGES & JOHN DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 25-26 (3d ed. 2002).

To obtain a patent, an invention (that is, a product, process, machine, or composition of matter) must be novel, nonobvious, and useful, and must meet certain requirements for the description of the invention.[27] A patentee must disclose the invention clearly enough so that one skilled in that art can make and use it without undertaking a great deal of experimentation;[28] must highlight or describe what the inventor claims so that others can easily discern the boundaries of the patent;[29] and must tell the public the inventor's "best mode" – most effective method – for practicing the invention.[30] *See also* Box 1-1.

Patent law reflects certain differences between intellectual property and tangible property. Problems of copying by third parties make it generally more difficult for holders of intellectual property to exclude others from its use than it is for holders of

[24] U.S. CONST. art. I, § 8 also authorizes Congress to establish the copyright system.

[25] The first U.S. patent statute was passed by the first U.S. Congress; it has been substantially revised from time to time. *See generally* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1-13 (3d ed. 2002) (reviewing history of patent law); ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS § 13.2 at 283-87 (2003) (reviewing history of patent law).

[26] 35 U.S.C. § 154(a)(2).

[27] 35 U.S.C. §§ 101-103, 112.

[28] *See* 35 U.S.C. § 112; *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S.124, 142 (2001) ("The disclosure required by the Patent Act is the *'quid pro quo* of the right to exclude'" (internal citations omitted)); MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 262; James E. Rogan, *Prepared Remarks of James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office* (2/6/02) 2 (disclosure for right to exclude is a "remarkable trade-off"), *at* http://www.ftc.gov/opp/intellect/rogan.htm (hereinafter Rogan (stmt)).

[29] 35 U.S.C. § 112. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 5.4 at 218 ("The inquiry under § 112¶ 2 focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the patentee's right to exclude."); MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 262.

[30] 35 U.S.C. § 112; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 263.

tangible property to do so.[31] Once third parties have learned about an invention, they may copy and use it.[32] Intellectual property is also "non-rivalrous" – that is, many people may use innovative technology, and they all may use it without diminishing others' ability to use it.[33] Many people may employ an innovation without depletion, and it is hard to identify and prevent those who will not pay for its use from using it.[34] In such circumstances, inventors are unlikely to have sufficient incentives to pursue and produce their inventions.[35]

To preserve incentives to invent, patent policy protects inventors from such misappropriation. "The principal basis for intellectual property protection in the United States is the utilitarian or economic incentive framework. That is, intellectual property in the United States is fundamentally about incentives to invent and create."[36] Patent policy serves consumer interests in innovation through other means as well.[37] By requiring disclosure of the patented invention in an issued patent,[38] the patent system can encourage further innovations if inventors forego keeping their inventions as trade secrets and instead disclose their inventions.[39] The patent system also can encourage further innovation by facilitating investment in the research, development, and marketing necessary to commercialize a product.[40] One

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[31] *See* 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.1 at 1-2.

[32] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.1 at 1-3 through 1-4; *see also* Thomas 2/8 (Patent Session) at 14-15.

[33] HAL VARIAN, MICROECONOMIC ANALYSIS 414-415 (3d ed. 1992); 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.1 at 1-2; *see also* DonPaul Olshove, *Comments Regarding Competition & Intellectual Property* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/olshovedonpaul.htm.

[34] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.1 at 1-3 through 1-4. *See generally*, Thomas 2/8 (Patent Session) at 14-15.

[35] SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK § 13.4.1 at 288 (noting that, if inventions can easily be duplicated or exploited by free riders, "[t]he resulting inability of inventors to capitalize on their inventions would lead to an environment where too few inventions are made." (Footnote omitted.)).

[36] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.1 at 1-2.

[37] *See generally infra* Ch. 2(I)(A)(2), (I)(A)(3).

[38] *See* 35 U.S.C. § 112.

[39] *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 259 (explaining that by the late eighteenth century, many viewed the primary benefit of the patent system as "the technological know-how behind the inventor's patent. . . . This was a major change in the economic role of patents, for it shifted the emphasis from the introduction of finished products into commerce to the introduction of new and useful *information* to the technical arts[.]" (emphasis in original)); R. Levin 2/6 at 100 (research has shown the disclosure requirement is "quite procompetitive"); SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.4 .1 at 288 (noting that "[t]rade secrets do not enrich the collective knowledge of society, . . ., nor do they discourage others from engaging in duplicative research."); Donald S. Chisum, *Comment: Anticipation, Obviousness, Enablement: An Eternal Golden Braid*, 15 AIPLA Q.J. 57 (1987) (explaining that primary purpose of disclosure requirement is to "put[] the invention in full possession of the public so the invention may be freely made and used after expiration of the patent").

But see infra Ch. 2(II)(A)(2) (firms sometimes favor trade secrecy over patents as an appropriation mechanism) and Ch. 3(IV)(D) (firms sometimes obtain patents only when they view trade secrecy as impossible).

[40] HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2 at 11; SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.4.1 at 289. *See infra* Ch. 2 (I)(A).

patent scholar has described the public purposes of the patent grant as "an incentive to invention, investment, and disclosure."[41]

B. Competition and Patent Policy Both Promote Consumer Welfare Over Time, and Competition and Patent Policy Generally Work Well Together

Patent and antitrust law "are actually complementary, as both are aimed at encouraging innovation, industry, and competition."[42] In introducing these hearings, FTC Chairman Muris emphasized that "properly understood, IP law and antitrust law both seek to promote innovation and enhance consumer welfare."[43] Then-Assistant Attorney General Charles James similarly noted that "intellectual property and antitrust law share the common purpose of promoting dynamic competition and thereby enhancing consumer welfare."[44] Likewise, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office James Rogan stated that "patent law and competition law . . . are highly compatible and serve many similar ends."[45] Others have also observed that antitrust and patent law "are complementary efforts to promote an efficient marketplace and long-run, dynamic competition through innovation."[46] Both doctrines can function to promote consumer welfare.[47]

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[41] HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.4(b) at 22.

[42] *Atari Games Corp. v. Nintendo of Am.,* 897 F.2d 1572, 1576 (Fed. Cir.1990). *See also* R. Hewitt Pate, *Refusals to Deal and Intellectual Property Rights*, 10 GEO. MASON L. REV. 429, 429 (2002) ("Intellectual property and antitrust laws share a common objective – to encourage innovation, industry, and competition.").

[43] Timothy J. Muris, Competition and Intellectual Property Policy: The Way Ahead, Before American Bar Association Antitrust Section, Fall Forum 2 (Nov. 15, 2001), *at* http://www.ftc.gov/speeches/muris/intellectual.htm (hereinafter The Way Ahead).

[44] Charles A. James, *Opening Day Comments, Joint DOJ-FTC Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* 1 (Feb. 6, 2002), *at* http://www.usdoj.gov/atr/public/speeches/10162.htm (hereinafter *Opening Day Comments*).

[45] Rogan (stmt) 3.

[46] 1 HOVENKAMP, JANIS, & LEMLEY, IP AND ANTITRUST § 1.3 at 1-12 through 1-13. *See also* M. Thompson 2/25 at 7; American Bar Association Section of Antitrust Law, *Statement* 6-7, *at* http://www.ftc.gov/opp/intellect/020628busey.pdf (hereinafter ABA Antitrust Section (stmt)); Sheila F. Anthony, *Antitrust and Intellectual Property Law: From Adversaries to Partners*, 28 AIPLA Q.J. 1 at 1, 7 (2000), *at* http://www.ftc.gov/speeches/other/aipla.htm.

Antitrust and patent law show similarities and differences in each's consideration of short and long run effects on consumer welfare. "Patent law and the incipiency elements of antitrust law are similar in that they both are ultimately based on inherently uncertain predictions of what is going to happen in the future. The difference is that in the antitrust regime, we sometimes are concerned about conduct that in the short term may be benign or even helpful to consumers, but that may be harmful in the long run, whereas in the patent regime we are willing to tolerate immediate consumer harm [e.g., monopoly pricing] in the expectation that in the long run it will benefit consumers by encouraging innovation." Thomas B. Leary, The Patent-Antitrust Interface, Remarks before the ABA Section of Antitrust Law Program, Philadelphia, Pennsylvania 3-4 (May 3, 2001), *at* http://www.ftc.gov/speeches/leary/ipspeech.htm.

[47] WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL, 2-3 (1973); 1 HOVENKAMP, JANIS, & LEMLEY, IP AND ANTITRUST § 1.3 at 1-11 ("[W]hen one departs from the static view of markets and takes a longer-run approach, it is even plausible that intellectual property and the antitrust laws share a common goal").

In most cases, competition and patent policy work in tandem toward this goal.[48] Competition advocates understand that "an effective legal regime defining and protecting property rights is essential to a well-functioning competitive economy[,]" and that "[patent] law plays an important role in this overall property rights regime."[49] The patent system spurs competition to innovate, because it can increase the potential rewards to successful innovators by limiting the competition that may arise from the innovation. As the Supreme Court has noted, "free competition" is "the baseline" on which "the patent system's incentive to creative effort depends."[50] Moreover, patents protect intellectual property that firms use as inputs to compete. Thus, as a general matter, competition spurs the creation of patents, and patents protect inputs that firms use in the competitive process.

Analogously, patent policy recognizes the value of competition. The Supreme Court has pointed out that, by limiting the duration of a patent, "[t]he Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[51] The patentability requirements for novelty and nonobviousness "are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all."[52] Thus, patent policy recognizes that certain limits on patents are necessary to avoid unnecessarily restraining competition.[53]

Competition and patent policy approach these issues through different means to achieve their congruent goals, however.[54] Antitrust concerns about harm to competition typically flow from the creation or exercise of monopoly power in a relevant antitrust market.[55] "Intellectual property,

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[48] *See, e.g.,* American Intellectual Property Law Association (AIPLA), *AIPLA Testimony* (Public Comment) 2-4 ("we view the two sets of laws as fully sharing common, not conflicting, goals and acting together in balance"), *at* http://www.ftc.gov/os/comments/intelpropertycomments/aipla.pdf (hereinafter AIPLA (stmt)).

[49] Muris, The Way Ahead at 2; *see also* American Bar Association Section of Antitrust Law and Section of International Law and Practice, Comments and Recommendations on the Competition Elements of the Doha Declaration, Before the United States Trade Representative 12 (2003) (noting that a "functional system for the definition, protection and exchange of common forms of tangible and intangible property (including intellectual property)" is necessary for a "successful market economy" based on competition), *at* http://www.abanet.org/antitrust/comments/doha.doc.

[50] *Bonito Boats*, 489 U.S. at 156.

[51] *Bonito Boats*, 489 U.S. at 146.

[52] *Bonito Boats*, 489 U.S. at 156.

[53] *See, e.g.,* HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2 at 12 ("It should not be supposed, however, that there are no public costs associated with the right to exclude. These include inflated prices (invariably absorbed by the consumer), which frequently accompany exclusive rights, and overinvestment. The patent system seeks to maintain an efficient balance between incentives to create and commercialize and the public costs engendered by these incentives." (Footnotes omitted)).

[54] BOWMAN, PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL at 2; 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3b at 1-13.

[55] Although cases under Sections 1 and 2 of the Sherman Act may distinguish between "monopoly power" and "market power," this report uses the terms interchangeably, because the distinction is not important for present purposes. The creation or exercise of monopoly power does not always violate the antitrust laws. *See infra* Ch. 1(I)(B).

while it does not generally create a monopoly, may in some cases permit or even encourage monopoly in order to give incentives for invention."[56] As Judge Pauline Newman noted, "[p]atents are directed at innovation. That's their purpose, and of course they affect competition. That's how they work. That's the only way they work, and that's why we're here today."[57] The existence of a patent may enable a firm to charge monopoly prices or otherwise limit competition.[58]

Patents do not always or even frequently confer monopoly power on their owners.[59] Indeed, most patents do not confer monopoly power on their holders,[60] and most business conduct with respect to patents does not "unreasonably restrain" or serve to monopolize markets. Even when a patent does confer monopoly power, that alone does not create an antitrust violation. Antitrust law recognizes that a patent's creation of monopoly power can be necessary to achieve a greater gain for consumers.[61] Moreover, antitrust law does not outlaw monopoly in all circumstances. For example, monopoly achieved solely with "superior skill, foresight, and industry" does not violate the antitrust laws.[62]

C. Tension Can Arise Between Competition and Patent Law and Policy in Certain Limited Circumstances

Nevertheless, there are opportunities for tension between competition and patent law and policy. Broadly speaking, this tension most typically arises in two settings. The first involves the grant of a patent; the second involves business conduct with respect to a patent. Competition and patent policymakers may reach different conclusions about whether each policy has adequately accommodated the other's concerns.

1. Grant of a Patent

Competition policy asks two questions in connection with the grant of a patent. The first question is whether the patent is warranted. Patent policy, of course, as set through statutes and decisional law, also seeks to ensure that the Patent and

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[56] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3b at 1-13.

[57] Newman 2/6 at 38. *See also* 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3a at 1-9 through 1-10 ("Indeed, in order for the intellectual property laws to succeed in giving authors and inventors an incentive to create, the law *must* give them some power over price." (emphasis in original)).

[58] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3a at 1-10.

[59] HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.4(b) at 21 ("Patent rights are not legal monopolies in the antitrust sense of the word. Not every patents is a monopoly, and not every patent confers market power." (Footnote omitted.)). *See also* ABA Antitrust Section (stmt) 11-12; Kovacic 2/8 (Antitrust Law for Patent Lawyers) at 32-33 (hereinafter Antitrust Session); Tom 2/8 (Antitrust Session) at 50.

[60] AIPLA (stmt) 21; Cohen 2/20 at 63; Dickinson 2/6 at 52-53; Pitofsky 2/6 at 29-30.

[61] BOWMAN, PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL at 3, n. 2.

[62] *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) ("The successful competitor, having been urged to compete, must not be turned upon when he wins." *Id.*). *See also U.S. v. Grinnell Corp*., 384 U.S. 563, 571 (1996) (the offense of monopoly is distinct from "growth or development as a consequence of a superior product, business acumen, or historic accident"); ABA Antitrust Section (stmt) 12.

Trademark Office (PTO) does not grant, and the courts do not uphold, invalid patents. The second question is whether the patent conveys market power. The patent system does not ask this question. We introduce each question here and discuss the issues in more depth throughout this report.

a. Is the Patent Warranted?

The PTO must issue a patent unless it can establish a *prima facie* case for rejection of the patent application.[63] Patent law establishes the standards of patentability against which the PTO measures a patent application. These standards ask whether the claimed invention is patentable subject matter[64] that is novel,[65] nonobvious,[66] and useful,[67] and whether the application meets the disclosure requirements.[68]

Competition policy and economic perspectives would ask a somewhat different question, one that focuses on whether and how the patent is necessary to encourage innovation. For example, one could ask whether the claimed invention would have emerged in roughly the same time frame "but for" the prospect of a patent. Judge Posner articulated this view as follows:

> [I]f a court thinks an invention for which a patent is being sought would have been made as soon or almost as soon as it was made even if there were no patent laws, it must pronounce the invention obvious and the patent invalid.[69]

Analogously, one could ask whether other measures through which patent law can encourage innovation – disclosure or commercial development of an invention[70] – would have occurred as soon "but for" the patent.[71]

This question asks whether a patent is necessary to achieve one of the means through which the patent system encourages innovation. If not, then, in theory, a patent

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[63] *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967), *cert. denied*, 389 U.S. 1057 (1968).

[64] 35 U.S.C. § 101 (basically, processes, machines, manufactures, and compositions of matter).

[65] 35 U.S.C. § 102. "The invention must . . . not be wholly anticipated by the so-called 'prior art,' or public domain materials such as publications and other patents." SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.1 at 282 (footnote omitted).

[66] 35 U.S.C. § 103. "The nonobviousness requirement is met if the invention is beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field." SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.1 at 282 (footnote omitted).

[67] 35 U.S.C. § 101. "An invention is judged as useful if it is minimally operable towards some practical purpose." SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.1 at 282 (footnote omitted).

[68] 35 U.S.C. § 112. "Patent applications must include a specification that so completely describes the invention that skilled artisans are enabled to practice it without undue experimentation. The patent application must also contain distinct, definite claims that set out the proprietary interest asserted by the inventor." SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHT, PATENTS AND TRADEMARKS § 13.1 at 282 (footnotes omitted.).

[69] *Roberts v. Sears, Roebuck & Co.,* 723 F.2d 1324, 1346 (7th Cir. 1983) (Posner, J., dissenting from judgment remanding for a new trial rather than finding the claimed invention obvious as a matter of law).

[70] *See supra* Ch. 1(I)(A)(2) and *infra* Ch. 2(I)(A) (discussing purposes of the patent law).

[71] *See generally infra* Ch. 2(I), (III) (discussing purposes of patent law from economic perspective).

should not be granted, because patents can impose costs on the public.[72] By disallowing a patent if it is not necessary to elicit an invention (or disclosure or commercial development of the invention), this "but for" approach would leave room for competition policy to spur innovation and provide consumers with what they want at optimal prices, quantity, and quality.[73]

From a theoretical perspective, the "but for" approach represents the right way to assess whether to grant a patent.[74] It is not usually possible, however, to use a "but for" approach to analyze whether individual patents should be granted.[75] For example, any property rights system must be administrable; finding the answer to the "but for" question in most individual cases would not be administrable.[76] Instead, the more manageable standards of the patent statute have evolved to serve as the means by which to measure when to grant a patent. Nonetheless, for conceptual purposes, one way to assess the alignment between competition and patent law and policy, and to assess policy choices for an appropriate blend of competition and patents, is to examine whether the patent system's standards of patentability ask questions likely to produce results similar to those obtained by asking the "but for" question.[77]

b. Does the Grant of the Patent Confer Market Power on the Patentholder or Unnecessarily Increase Transaction Costs?

If an unwarranted patent confers market power on a patentholder, it can deprive consumers of the benefits of competition without compensating value.[78] Moreover, even if an unwarranted patent

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[72] *See, e.g.,* 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3a at 1-10 ("Because intellectual property rights impose costs on the public, the intellectual property laws can be justified by the public goods argument *only to the extent that the laws on balance encourage enough creation and dissemination of new works to offset those costs*." (Emphasis added.)); *see also* HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2 at 12 (costs to the public can include inflated prices); *see infra* Ch. 1(IV)(B)(5) (discussing process costs and costs of uncertainty to businesses).

[73] The Supreme Court's decision in *Bonito Boats* provides an analogy. There, a unanimous Supreme Court held a Florida statute offering patent-like protection for a boat hull molding process to be preempted by the Supremacy Clause. "By offering patent-like protection for ideas deemed unprotected under the present federal scheme, the Florida statute conflicts with the 'strong federal policy favoring free competition in ideas which do not merit patent protection.'" *Bonito Boats,* 489 U.S. at 168, *citing Lear, Inc. v. Adkins*, 395 U.S. 653, 656 (1969). A "but for" approach analogously would protect free competition in areas where a patent was not necessary to elicit the invention (or its disclosure or commercial development).

[74] Many view the perspective that patents should be granted only if the invention would not have emerged "but for" the patent system as the "defining proposition" for standards of patentability. *See, e.g.,* Merges 2/28 at 579; Greenhall 2/27 at 421-22; Farrell 2/28 at 596-97; Musacchia 4/9 at 25-26; Scherer 7/10 at 54; Lunney 7/10 at 97-104; Wamsley 7/10 at 139; Gambrell 10/25 at 41; Stoner 10/30 at 37; Kitch 10/30 at 50-51 ("but for" inquiry the right thing to think about as a matter of "metatheory"); Barr 10/30 at 53.

[75] Most concede that the "but for" standard, although conceptually correct, cannot practically be applied in individual cases. *See generally infra* Ch. 4(II)(A)(2).

[76] In many cases, it is likely unknowable whether the claimed invention would have emerged in roughly the same time frame absent the prospect of a patent. Even if knowable, the costs of examining that question would generally far outweigh any benefits from obtaining a more precise measure of whether a patent should be granted.

[77] *See generally infra* Ch. 4(II)(A)(2) (discussing standards of patentability in relation to "but for" question).

[78] The issuance of invalid patents that do not confer market power may also raise societal costs even if they do not raise competition issues.

does not confer market power, a proliferation of trivial patents can harm competition.

The patent system, quite properly, does not examine whether the grant of a patent would likely create market power. As Under Secretary of Commerce for Intellectual Property and Director of the USPTO James Rogan pointed out on the first day of the Hearings, "[p]atent examination does not include an analysis of the potential commercial impact of the patent. It does not determine the relevant market in which the invention may be marketed or sold. No patent examiner projects the economies of scale to be achieved through the invention."[79] In other words, patent examination does not include an assessment of the likely competitive significance of a patent.[80]

This is as it should be, especially given the early point at which patent applications typically are filed.[81] At that point, any attempt to assess the likely competitive significance of a patent would usually devolve into mere speculation. Nonetheless, the likelihood of market power problems may be greater in some areas of the economy than others, and that increased likelihood may justify closer scrutiny of patent applications in those areas.[82]

In addition, the issuance of unwarranted patents can injure competition even if they do not confer market power. A proliferation of trivial patents can be detrimental. Innovators "must expend resources both in searching such patents to avoid infringement and in negotiating patent licenses to use the technology. For patents covering significant developments, it may be assumed that those additional social costs are relatively small compared to the social benefits associated with the advance in the art. But that assumption becomes less plausible if the advance is relatively trivial. . . . Thus, in aggregate, the search and transaction costs associated with numerous trivial patents may outweigh the relatively small benefits associated with such patents."[83]

2. Business Conduct with Respect to a Patent

Patent policy generally asks two questions about antitrust enforcement in connection with a patent. The first question is whether antitrust enforcement is warranted, or erroneously condemns welfare-enhancing conduct that should be permitted. Antitrust enforcers, of course, are also very concerned to ensure that antitrust enforcement properly distinguishes between anticompetitive and procompetitive conduct. The second question is whether antitrust enforcement limits the rights conferred by a patent to undermine the incentives that the patent system creates. This is a question that also concerns antitrust enforcers. We introduce each question and discuss both

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[79] Rogan (stmt) 2.

[80] *Id.*

[81] Hughes 2/28 at 611-12, 618.

[82] *See infra* Chs. 3 (III), (IV) and 4 (II)(E) (business method patents; semiconductors (patent thicket)). *But see supra* Ch. 1(I)(B) (antitrust does not object to patent that conveys market power if the patent is necessary to elicit an invention that otherwise would likely not have issued at all or as soon).

[83] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 647.

more thoroughly throughout the report.

a. Is Antitrust Enforcement Warranted?

Antitrust law can constrain what a patentee can do with its patent, depending on the conduct at issue.[84] A patentee may use a patent to obtain unwarranted market power[85] or interfere with competition in a variety of ways.[86] The question for antitrust policymakers is how best to distinguish between procompetitive and anticompetitive conduct with respect to patents. A proper answer depends in part on understanding the role of patents in innovation and competition in particular industries. As this report will discuss, patents play different roles in different industries.[87] Moreover, to avoid errors, antitrust enforcement needs to understand the efficiencies that businesses may realize through particular types of patent-related conduct. The Antitrust Agencies have addressed this in part by issuing *Antitrust Guidelines for the Licensing of Intellectual Property*.[88] The Guidelines outline a framework for antitrust analysis of licensing practices and identify some of the efficiencies that businesses may seek through particular licensing practices.[89]

b. Does Antitrust Enforcement Undermine the Incentives Created by the Patent System?

Antitrust scrutiny is more likely if business conduct involves a patent that confers market power on the patentholder than if the patent does not confer market power. A patent that confers market power, however, can fulfill precisely the goals of the patent system: to preserve incentives to innovate.[90] Patents thus present an additional concern to antitrust enforcers: mistaken antitrust enforcement may undermine the incentives the patent system creates. If patentees find that antitrust enforcement unwarrantedly limits their conduct with respect to their patents, then such enforcement may reduce incentives to invent. Thus, patent perspectives emphasize the need for antitrust enforcement to take care in distinguishing anticompetitive from procompetitive conduct, particularly when the patent confers market power.

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[84] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3b at 1-14. *See also United States v. Microsoft Corp*., 253 F.3d 34, 63 (2001) (The court rejected appellant's assertion that because intellectual property rights have been lawfully acquired, their subsequent use cannot result in antitrust liability. *Id*. "That is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability." *Id*.); Tom 2/8 (Antitrust Session) at 53-54.

[85] This description does not capture all of the possible anticompetitive conduct, of course. For example, certain limited conduct with respect to a patent may be summarily condemned, without an examination of market power, due to its obvious anticompetitive effects. *See* Second Report (forthcoming).

[86] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3b at 1-13. *See* Second Report (forthcoming).

[87] *See generally infra* Ch. 2(II)(A)(2) and Ch. 3.

[88] U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (Apr. 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm (hereinafter IP Guidelines).

[89] *Id*. at § 3.3. How these Guidelines are working in practice will be discussed in the second, forthcoming report.

[90] *See supra* Ch. 1(B).

3. Enhancing Consumer Welfare Requires a Proper Balance of Competition and Patent Law and Policy

The Hearings record provides ample evidence of both the tensions and the potential for greater congruence between competition and patent law and policy. On the one hand, panelists noted antitrust's increased appreciation of the role of patents in fostering innovation and increased understanding of the efficiencies to be gained through patent licensing and other practices.[91] On the other hand, economists also emphasized that ever greater intellectual property protection is not necessarily socially beneficial.[92] Among other things, stronger intellectual property protection carries the potential for less price competition.[93] From a broad policy perspective, policymakers can maximize consumer welfare at a level of IP protection certainly greater than zero, but less than absolute.[94] Because both competition and intellectual property protection may foster innovation, these policy tools must be blended to achieve consumer welfare.[95]

II. VIEWS ON HOW BEST TO BALANCE COMPETITION AND PATENTS TO ACHIEVE CONSUMER WELFARE HAVE VARIED WIDELY OVER TIME

A. For Much of the Twentieth Century, Patent and Antitrust Law Have Traded Ascendency with Each Other

Despite the common goals of patent and antitrust law, the doctrines historically have traded ascendancy between each other.[96] Broadly speaking, throughout much of the twentieth century, courts and federal agencies considered patents to confer monopoly power and, correspondingly, viewed antitrust as always opposed to monopoly power.[97] Some have argued that this perceived conflict led courts to believe that, in any given case, they had to find that either patents or antitrust took precedence.[98] In general, when courts were favoring patents, they were usually disfavoring antitrust, and vice versa. A variety of factors appear to have shaped these shifts, including perceptions about the power of big business,

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[91] *See, e.g.,* James, *Opening Day Comments* at 1-2; Pitofsky 2/6 at 29-30; Tom 2/8 (Antitrust Session) at 47-50.

[92] *See*, *e.g.*, Farrell 2/28 at 596-97; Langenfeld 2/20 at 10-13, 64.

[93] *See, e.g.,* HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.2 at 12.

[94] *See generally* James Langenfeld, *Intellectual Property and Antitrust: Steps Toward Striking a Balance*, 52 CASE W. RES. L. REV. 91, 96-98 (2001); William Landes & Richard Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325 (1989).

[95] *See generally infra* Ch. 2(II), (III).

[96] 1 HOVENKAMP ET AL., IP AND ANTITRUST at § 1.3c at 1-15.

[97] *See, e.g., Crown Die & Tool Co. v. Nye Tool & Mach. Works,* 261 U.S. 24, 37 (1923), *citing Continental Paper Bag Co. v. Eastern Paper Bag Co.,* 210 U.S. 405 (1908) (patents as monopolies); R. Hewitt Pate, Antitrust and Intellectual Property, Before the American Intellectual Property Association, 2003 Mid-Winter Institute (Jan. 24, 2003), *at* http://www.usdoj.gov/atr/public/speeches/200701.pdf.

[98] Anthony, 28 AIPLA Q.J. at 4.

the competitive significance of various patent licensing practices, the nature and role of patents, and the best ways to achieve economic and technological growth.

1. 1890-1930: Patents Receive Little Antitrust Scrutiny

Passage of the Sherman Act in 1890 – one hundred years after passage of the first Patent Act in 1790 – set the stage for courts to begin construing how these two doctrines should interact. Although both patent and antitrust have antecedents dating back farther than the enactment of those two statutes,[99] courts did not give significant attention to the intersection of patents and antitrust until the early 1900s.[100] Early court opinions generally refrained from subjecting patent-related conduct to antitrust scrutiny,[101] most typically because the "very object of these [patent] laws is monopoly. . . ."[102] Courts often seemed "to immunize from antitrust scrutiny the conduct of firms holding patents,"[103] even including patent pools with outright price fixing.[104] Some contend that patent owners engaged in "what was arguably rather substantial overreaching" during this time by seeking to impose restrictions beyond the first sale of a patented product.[105]

2. 1930-1980: Antitrust Is Generally Ascendant

An antitrust backlash began in 1917,[106] when the Supreme Court rejected on antitrust and patent misuse grounds certain licensing restrictions that movie exhibitors had imposed.[107] By the 1930s, a stronger role for antitrust, and a correspondingly weaker role for patents, were emerging. During that time, some saw

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[99] Robert Merges and John Duffy point out that Aristotle discussed (and rejected) a proposal for a patent-like system in the fourth century B.C.; they trace the history of the core concepts of patent law from that time through the present. *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1-13. One can also find 'abuse of patent' cases in England going back to 1600. 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3c at 1-14 & n. 10, *citing* Lewis Edmonds, THE LAW AND PRACTICE OF LETTERS PATENT FOR INVENTIONS 7-8 (1890) (relating a case in which two people were stripped of patents and imprisoned for abusing their patent in the seventeenth century). Analogously, English courts wrestled with competition law early on, and, for example, rejected a monopoly granted by Elizabeth I. The Case of Monopolies, 11 Co. Rep. 84b, 77 Eng. Rep. 1260 (1603). Other competition law issues, such as restraint of trade cases, with parties demonstrating cartel behavior, were brought as contract cases. Courts in England and the United States refused to uphold such contracts, long before the Sherman Act was written. *See generally* John E. Lopatka, *The Case for Legal Enforcement of Price Fixing Agreements*, 38 EMORY L.J. 1 (1989).

[100] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3c at 1-14 through 1-15.

[101] *See, e.g., Bement v. National Harrow Co.,* 186 U.S. 70 (1902); *Heaton-Peninsular Button-Fastner Co. v. Eureka Specialty Co.,* 77 F. 288 (6th Cir. 1896); *Strait v. National Harrow Co.,* 51 F. 819 (N.D.N.Y. 1892).

[102] *Bement v. National Harrow Co.*, 186 U.S. at 91. *See also Strait v. National Harrow Co*., 51 F. 819 (N.D.N.Y. 1892); Tom 2/8 (Antitrust Session) at 38.

[103] Anthony, 28 AIPLA Q.J. at 5.

[104] Anthony, 28 AIPLA Q.J. at 5 (citing *Bement v. National Harrow Co*., 186 U.S. 70 (1902)).

[105] 1 HOVENKAMP ET AL, IP AND ANTITRUST § 1.3c at 1-15.

[106] *Id*.

[107] *Motion Picture Patents Co. v. Universal Film Mfg. Co.,* 243 U.S. 502 (1917). Movie exhibitors mandated that their patented film projection equipment only be resold at a specified price, and that the projectors only be used with the licensor's patented film.

patent procedures as favoring "the powerful and the unscrupulous," noting, among other things, the potential for "dragnet" patent applications, through which firms could amend their patent claims during lengthy procedures at the patent office and thereby capture competitors' most recent developments.[108] Others attacked patents more broadly.[109] Although not all commentary was anti-patent,[110] an "anti-business" tenor of the times apparently contributed to antitrust's more active role in constraining patent-related conduct.[111]

Another significant factor was the state of economic learning. Courts limited the scope of any exemption from antitrust for patent-related conduct. The Supreme Court ruled there was no exemption from antitrust "beyond the limits of the patent monopoly."[112] As this quotation and other cases made clear, courts generally continued to view patents as automatic sources of monopoly power.[113]

Around the same time, courts also weakened patent rights, "most notably by imposing a high standard of 'invention' as a condition of patentability."[114] For example, in *Cuno Engineering Corp. v. Automatic Devices Corp.,* the Supreme Court reversed a lower court's judgment that respondent had a valid patent that was infringed, reasoning that "the new device, however useful it may be, must reveal *the flash of creative genius*, not merely the skill of the calling. If it fails, it has not established its right to a private grant on the public domain."[115] The anti-patent posture of the Supreme Court at that time led one dissenting U.S. Supreme Court Justice to observe that "the only patent that is valid is one which this Court has not been able to get

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[108] Alfred E. Kahn, *Fundamental Deficiencies of American Patent Law*, 30 AM. ECON. REV. 475, 485-86 (1940). *See infra* Ch. 4(II)(C)(1), for a discussion of the current competitive significance of continuation procedures at the PTO. *See also* FRITZ MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM, SUBCOMM. ON PATENTS, TRADEMARKS, & COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 85TH CONG., 2D SESS. 40-42 (Comm. Print 1957) (discussing charges that "the patent system operates in favor of economic concentration and bigness") (hereinafter MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM).

[109] *See* MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM at 28-29 (quoting from various articles attacking patents to one degree or another). Machlup's report also outlines many arguments in favor of patents.

[110] *See, e.g.,* JOHN BATES CLARK, ESSENTIALS OF ECONOMIC THEORY 360 (1927) (describing why inventors need patents to maintain incentives to innovate), *cited in* MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM at 37.

[111] *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 10.

[112] *United States v. Line Material Co.,* 333 U.S. 287, 308 (1948). *See also Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S. 488, 492 (1942).

[113] *See, e.g.,* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1349 ("During the middle part of the twentieth century, the courts tended to associate patents with monopolies, and hence to view them as narrow exceptions to the nation's antitrust laws. This view [was] especially prominent in the Supreme Court cases from the 1930s until the 1960s, ...").

[114] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3c at 1-16; s*ee also* SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 17.3.1 at 376 ("The anti-monopoly sentiments that arose during the Depression era did not bode well for the patent system. Courts began to apply an increasingly stringent 'invention' standard that found most patents wanting.").

[115] 314 U.S. 84, 91 (1941) (emphasis added); *see also* Gerald Sobel, *Patent Scope and Competition: Is the Federal Circuit's Approach Correct?,* 7 VA. J. OF LAW & TECH. 3, 16-17 (2002).

BOX 1-2. REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM (1966) "TO PROMOTE THE PROGRESS OF . . . USEFUL ARTS"

In 1965, President Johnson established a Commission on the Patent System, which examined the patent system in light of six objectives: raising the quality and reliability of U.S. patents; shortening the period of patent pendency; accelerating the public disclosure of technological advances; reducing the expense of obtaining and litigating a patent; harmonizing the U.S. patent system with that of other major countries; and preparing the patent system to cope with future technological developments.

In 1966, the Commission issued its report containing 35 recommendations that addressed a wide range of subject areas. Two areas of recommendation are particularly noteworthy as they underscore society's ongoing efforts to increase the value of patent disclosures and to decrease the possibility the system could be gamed so as to undermine the value of those disclosures.

Publication. The Commission concluded that early publication of patent applications "could prevent needless duplication of the disclosed work, promote additional technological advances based on the information disclosed, and apprise entrepreneurs of their potential liability." They recommended publication of all pending applications "eighteen to twenty-four months after its earliest effective filing date. . . ."

Continuations. Continuations are one means by which claims can be broadened after publication. The difficulty continuations pose is that "unclaimed disclosures in a published application . . . might be protected by broader claims in [a] subsequently issued patent." The Commission believed an absolute bar on continuations was not feasible but, instead, recommended the imposition of certain limits on an applicant's ability to file continuations.

its hands on."[116]

Congress responded to these judicial trends by passing the Patent Act of 1952, which limited the doctrine of patent misuse and strengthened the patent system.[117] Congress issued a lengthy study in 1957 on "The Patent System and the Modern Economy,"[118] consisting of reports prepared by a variety of experts. Most references to the study note only the conclusion of economist Fritz Machlup that insufficient empirical economic evidence exists to justify either abolishing or creating a patent system, but Machlup also provided useful insights about how patents and competition each might function to achieve the purposes of the patent system.[119] A 1966 Presidential Commission on the Patent System endorsed patents as offering a "unique service," although the Commission also recommended 35 changes to the patent system. *See* Box 1-2 (1966 Presidential Commission). Also in 1966, the Supreme Court articulated an objective test for nonobviousness, based on Section 103 of the Patent Act of 1952, which, over time, has replaced the more subjective "invention"

[116] *Jungerson v. Ostby & Barton Co.,* 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

[117] 35 U.S.C. §§ 1 et seq.

[118] STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 84TH CONG., 2D SESS. (1957).

[119] *See* MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM at 80 ("If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."); *id.* at 76-79 (discussing rationales for patent system, such as providing incentives to invent, disclose, or invest, and comparing theories suggesting that competition alone could serve those purposes with theories that patents are necessary in some cases to achieve those purposes); Merges 2/28 at 577-79.

approach the Court had used earlier.[120]

Overall, however, antitrust dominated and patents were disfavored during the 1960s and 70s.[121] "Most litigated patents were held invalid during this period."[122] Courts of appeal "diverged widely both as to doctrine and basic atittudes toward patents."[123] Some contend that, for that reason, "industry downplayed the significance of patents."[124] Overzealous antitrust enforcement culminated in the Department of Justice's "Nine No-Nos," a list of nine licensing practices that the Justice Department generally viewed as automatically illegal.[125] Most now believe that antitrust's ascendency during this period lacked both a sound economic foundation and a sufficient appreciation of the incentives for innovation that patents and patent licensing can provide.[126]

B. 1980-1990: Congress and the Courts Strengthen Patents, and Antitrust Incorporates an Updated Economic Framework

By the late 1970s, two factors were converging to reverse the cycle of antitrust's dominance and patents' weakness. First, general concern about industrial stagnation and a lack of significant technological innovation spurred reassessments of the patent system. Second, scholars, many associated with the "Chicago School of Economics," spurred a general rethinking of antitrust, including its approach to patents. Although these two factors were not the only ones that influenced trends in the 1980s, each played a central role.

1. Congress and the Courts Strengthen Patents

a. Congress Creates the Court of Appeals for the Federal Circuit

In 1978, President Carter appointed an Advisory Committee to perform a domestic review of industrial innovation. *See* Box 1-3 (1979 Commission report on patents). Government officials and policymakers had grown concerned with an overall weakening of R&D and other signs

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[120] *See* SCHECHTER & THOMAS, THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS, § 17.3.2 at 377-80 (discussing *Graham v. John Deere Co.,* 383 U.S. 1 (1966) in relation to 35 U.S.C. § 103 (1952)); HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.2(a) at 137-39 (same).

[121] *See, e.g.,* Pate, Antitrust and Intellectual Property at 6.

[122] 1 HOVENKAMP ET AL., IP AND ANTITRUST § 1.3c at 1-16. In 1971, the Second Circuit reported that appeals courts found more than 80% of the patents reviewed to be invalid. *Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.,* 443 F.2d. 867, 872 (2d Cir. 1971), *cert. denied*, 412 U.S. 929 (1973). *See also* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 10 (during 1960s and early 1970s, "[i]t was difficult to get a patent upheld in many federal courts").

[123] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 10-11. *See infra* Ch. 6(II)(A).

[124] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 11.

[125] *See* Bruce B. Wilson, Deputy Assistant Attorney General, Antitrust Division, Remarks before the Michigan State Bar Antitrust Law Section (September 21, 1972), *reprinted in* 5 CCH Trade Reg. Rep. 50,146 (transfer binder) (DOJ official's speech articulating what came to be called the "Nine No-Nos").

[126] *See, e.g.,* Muris, The Way Ahead at 1; Pate, Antitrust and Intellectual Property at 7; Pitofsky 2/6 at 29-30 ("'Nine No-Nos . . .' a far, far cry from where we are today").

BOX 1-3. REPORT OF THE INDUSTRIAL SUBCOMMITTEE FOR PATENT AND INFORMATION POLICY OF THE ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION: REPORT ON PATENT POLICY (1979)

In 1978, President Carter appointed an Advisory Committee to perform a domestic review of industrial innovation. In 1979, the Patent and Information Policy Subcommittee (Subcommittee) of the Advisory Committee issued its REPORT ON PATENT POLICY. The report had five key proposals, four of which (at pages 153-55) are relevant to this report:

Proposal I. *Upgrade the Patent and Trademark Office.* The Subcommittee observed that the quality of the patent system depends on the quality of the underlying PTO examination, which in turn depends upon "the search of the prior art by the examiner." The Subcommittee recommended the PTO be "given the funds and resources to improve its examination procedure. . . ."

Proposal II. *Provide for Reexamination of Patents.* The Subcommittee recognized the need for a "fast, inexpensive method for increasing the certainty as to the enforceability and scope of patents over prior art not considered by the PTO." Under the proposal, any party could request reexamination during the life of the patent. The proposed system would provide for the submission of written arguments by interested parties and expedited review by the PTO to provide a "simple, inexpensive method" to improve the quality of patents with demonstrated commercial value.

Proposal III. *Provide a Specialized Appellate Court for Patent Cases.* The Subcommittee advocated, "a centralized national court with exclusive appellate jurisdiction (subject to Supreme Court review) over patent-related cases as a vehicle for insuring more uniform interpretation of the patent laws."

Proposal IV. *Reduce Cost of Patent Litigation.* The Subcommittee concluded that decreasing "the cost and time involved in resolving patent infringement and validity disputes through litigation" would improve the patent system. The Subcommittee urged, among other things, that Federal courts "exercise a high degree of control over the conduct of patent litigation, with particular concern for the time and expense of discovery."

of economic trouble. One question for the Advisory Committee was whether, and to what extent, patent policies contributed to these circumstances. Judge Newman, a member of the Advisory Committee, recalled the "low point" at which they found the U.S. economy: "Investment in basic science in applied research had disappeared . . . . Our production in the United States was no longer competitive. Old technologies were stagnant. New [technologies] were dormant. . . ."[127] Among other problems, Committee members attributed these conditions to "a diminished patent incentive" in the U.S..[128]

The *Report on Patent Policy* that emerged recommended "a centralized national court with exclusive appellate jurisdiction (subject to Supreme Court review) over patent-related cases as a vehicle for insuring more uniform interpretation of the patent laws."[129] Committee members concluded that increased uniformity and reliability in patent decisions would "contribute meaningfully to decisions to file patent applications and to commercialize invention, thereby improving industrial innovation[.]"[130] During the 1970s, others also discussed the problem of

[127] Newman 2/6 at 39-42.

[128] *Id.*

[129] REPORT OF THE INDUSTRIAL SUBCOMM. FOR PATENT AND INFORMATION POLICY OF THE ADVISORY COMM. ON INDUSTRIAL INNOVATION, REPORT ON PATENT POLICY 155 (1979).

[130] *Id.*

Box 1-4. ***Congressional Activity.***

Congress has actively legislated in the field of patent law since 1980. Congress passed amendments to the Patent Act in 1980 that required the payment of maintenance fees (35 U.S.C. § 154), made provision for third parties to cite prior art to the PTO (35 U.S.C. § 301) and created reexamination procedures (35 U.S.C. § 302). In 1982, Congress created the Court of Appeals for the Federal Circuit (35 U.S.C. § 141, 28 U.S.C. § 1295). Two years later, Congress passed the Hatch Waxman Amendments which, among other things, permitted an extension of patent term to compensate for delay in securing FDA approval to sell new drugs for humans (35 U.S.C. § 156) and consolidated the Boards of Patent Appeals and Interferences into a single Board of Patent Appeals and Interferences (35 U.S.C. § 141). In 1988, Congress passed the Patent Misuse Reform Act, which governs the application of certain patent misuse defenses to patent infringement claims (35 U.S.C. § 271(d)). In 1994, Congress passed the Uruguay Round Agreements Act which, among other reforms, changed the patent term to 20 years from the earliest date on which the application was filed (35 U.S.C. § 154) and allowed the filing of provisional applications (35 U.S.C. § 111). Congress passed the American Inventors Protection Act in 1999, which made multiple changes to patent law, such as requiring that patent applications be published after 18 months where equivalent applications are published abroad (35 U.S.C. § 122), creating an *inter partes* reexamination procedure (35 U.S.C. §§ 311-313), and granting a prior user right for business method patents (35 U.S.C. § 273). Congress reformed certain features of the *inter partes* reexamination procedure in 2002.

significant inconsistency in patent decisions and the idea that a centralized appellate court for patent matters might ease that problem.[131]

In 1982, Congress created the Court of Appeals for the Federal Circuit.[132] The Federal Circuit has exclusive jurisdiction of all appeals from final district court decisions in civil actions "arising under any Act of Congress relating to patents."[133] "[T]he creation of the Federal Circuit was a watershed event in the history of the U.S. patent system."[134] Most commentators find that, as a general matter, the Federal Circuit strengthened patent rights significantly,[135] upholding patent validity

[131] *See, e.g.,* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 11 (during 1970s, idea of a single, unified court of appeals for patent cases discussed as "way to return patents to a more central position in the commercial world").

[132] 28 U.S.C. § 1295. The United States Court of Appeals for the Federal Circuit was created through the merging of two specialized courts of limited subject matter but nationwide jurisdiction – the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals.

[133] 28 U.S.C. § 1338(a). The Supreme Court has interpreted the "arising under" clause to require a determination of whether the patent allegation forms part of the "well-pleaded complaint," in that patent law either (1) "creates the cause of action" (generally referred to as "arising under" jurisdiction), or (2) is a "necessary element of one of the well-pleaded claims," such that "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law" (generally referred to as "substantial question" jurisdiction). *Christianson v. Colt*, 486 U.S. 800 (1988). In *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), the Supreme Court concluded that "arising under" jurisdiction does not give jurisdiction to the Federal Circuit, when only a patent counterclaim exists, and the complaint does not assert any claim arising under federal patent law. *See generally infra* Ch. 6(II)(B)(1)(a).

[134] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 11.

[135] "Since the creation of the Federal Circuit, . . . [i]t is also much easier to get an injunction against an infringer. And money damages have soared too, both on average and in the highest-visibility cases." MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 11. *Cf.* ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 147, 161 (Supp. 2002) (original assessment of Federal Circuit as pro-patentee; more recently, court is moving toward "a more neutral position").

"more frequently than in the anti-patent era of the 30s to the 70s."[136]

b. The Supreme Court Interprets Patentable Subject Matter Broadly

In *Diamond v. Chakrabarty*,[137] the Supreme Court held that a live, human-made microorganism was patentable subject matter under 35 U.S.C. § 101.[138] In reaching this decision, the Court noted that the Committee Reports accompanying the 1952 Patent Act "inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[139] The Court distinguished "laws of nature, physical phenomena, and abstract ideas," which have been held not patentable,[140] from the patentee's "new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility."[141] "His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."[142] The description of patentable subject matter as "anything under the sun that is made by man" conveyed a broad sense of the potential scope of patents and, in particular, provided a significant boost to the biotech industry. Indeed, Hearings participants from the biotech industry generally credited the Court's decision in *Chakrabarty* as the beginning of their industry, without which genetic engineering would not have made nearly as much progress.[143]

In the 1981 case, *Diamond v. Diehr*,[144] the Supreme Court held that a process claim that included use of a computer program was patentable subject matter, concluding that "a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program,

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[136] "Since the creation of the Federal Circuit, patents have been held valid more frequently than in the anti-patent era of the 30s to the 70s." MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 11 (footnotes omitted). *See also* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation,* 76 CAL. L. REV. 803, 820-21 (comparing pre- and post-Federal Circuit era statistics); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents,* 26 AIPLA Q. J. 185 (1998) (providing a statistical survey of validity decisions from 1989-1996). *See generally infra* Ch. 6(II)(C).

[137] 447 U.S. 303 (1980).

[138] Section 101 states that "[w]hoever invents or discovers any new or useful *process, machine, manufacture, or composition of matter,* or any new or useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (emphasis added).

[139] 447 U.S. at 309, *citing* S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

[140] 447 U.S. at 309. "[A]n *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection[,]" however. *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

[141] 447 U.S. at 310.

[142] *Id*. The Court's decision was 5-4, with Justice Brennan writing the dissent, which described the patent laws as "attempt[ing] to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress[,]" and argued that both congressional intent and public policy militated against finding that living organisms could be patentable subject matter. *Id*. at 318-19.

[143] Kirschner 2/26 at 239; Beier 2/26 at 322; Chen 2/28 at 628; American Bar Association Section of Intellectual Property Law, *Statement of Robert P. Taylor on Behalf of Section of Intellectual Property Law American Bar Association on Competition and Intellectual Property Law and Policy In the Knowledge-Based Economy* (7/11/02) 7, *at* http://www.ftc.gov/opp/intellect/020711robertptaylor.pdf.

[144] 450 U.S. 175 (1981).

or digital computer."[145] The Court "view[ed the patentees'] claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."[146] The Court repeated the observation that patentable subject matter can "include anything under the sun that is made by man,"[147] and once again conveyed a broad sense of the potential scope of patents.

2. Antitrust Incorporates an Updated Economic Framework

During the 1970s, change was brewing in antitrust as well. Debates took place between those who focused primarily on market structure and market power, and those who, broadly speaking, saw more efficiencies than market power in the U.S. economy.[148] The new economic learning, associated with many of those who were called "Chicago School" economists and lawyers, brought an updated economic framework to antitrust that, among other things, emphasized the importance of seeking to understand the efficiencies, as well as possible anticompetitive effects, associated with particular business conduct. Over time, the courts and agencies have largely adopted this updated economic framework.[149]

New economic learning led to a more complex and pro-patent understanding of how antitrust should view conduct with respect to patents. In 1981, Antitrust Division Deputy Assistant Attorney General Abbott B. Lipsky, Jr., renounced the Nine No-Nos as "contain[ing] more error than accuracy," and reviewed in some detail the possible efficiency justifications for each licensing practice that the Nine No-Nos previously had condemned automatically.[150] The then-Chief of the Intellectual Property Section of the Antitrust Division, Roger Andewelt described how patents can benefit competition:

> The availability of exclusive patent rights increases the possible reward for R&D. It thereby results in the development of some inventions that otherwise would not have been discovered or developed at all or, at least, not nearly as early as they were. For such inventions it is illogical to talk in terms of the patent

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[145] *Id*. at 187. Once again, the decision was 5-4, with the dissent by Justice Stevens noting, among other things, that it was not at all clear that patent protection was essential for the growth of the software industry. *Id.* at 217. For discussion of the ongoing controversy about the role of patents in the computer industry, *see infra* Ch. 3(III), (IV).

[146] 450 U.S. at 191. The dissenting justices viewed the case as having greater implications for the patentability of computer programs generally and would have adopted a much narrower rule for when a program-related invention could constitute patentable subject matter. *Id.* at 219.

[147] *Id*. at 182.

[148] *See generally* Harold Demsetz, *Two Systems of Belief about Monopoly*, *in* INDUSTRIAL CONCENTRATION: THE NEW LEARNING 164-84 (Harvey J. Goldschmid et al. eds. 1974).

[149] *See generally* William E. Kovacic & Carl Shapiro, *Antitrust Policy: A Century of Economic and Legal Thinking*, 14 J. ECON. PERSPECTIVES 43, 54-55 (2000). One of the first decisions to use the new learning was *Continental T.V., Inc. v. GTE Sylvania Inc.,* 433 U.S. 36 (1977), which upheld a supplier's restriction on the geographic area in which its distributor could sell. The Supreme Court found that consumers would benefit from a restriction on competition that prevented competitors from "free riding" on a firm's promotional efforts. *Id.* at 54-55.

[150] Abbott B. Lipsky, Jr., *Current Antitrust Division Views on Patent Licensing Practices,* 50 ANTITRUST L.J. 515, 517-24 (1981).

> grant conflicting with a competitive economic system. If there were no patent grant these inventions would not have reached the marketplace; therefore, the availability of a patent served only to benefit competition – to make additional or less expensive choices available to consumers.[151]

In 1985, Deputy Assistant Attorney General for Antitrust Charles F. Rule commented on prior failures of the courts and the Department of Justice "to recognize some fundamental facts about the nature of intellectual property and the beneficial role that technology licensing plays in a healthy, competitive economy."[152] The 1988 DOJ *Antitrust Enforcement Guidelines for International Operations* elaborated on these earlier policy statements with a section on intellectual property licensing arrangements that outlined consumer benefits from intellectual property licensing[153] and specifically adopted a rule of reason approach to intellectual property licensing issues, absent sham.

Thus, by the end of the 1980s, congressional and court-driven changes had significantly strengthened patents. Antitrust's incorporation of updated economic thinking led to a generally more favorable view of how conduct with respect to patents influences competition. This incorporation of economics held the potential for both competition and patent policy to develop a greater integration and balance.

III. COMPETITION AND PATENT POLICY CONTINUE TO SEEK A PROPER BALANCE, AND GROWTH OF THE KNOWLEDGE-BASED ECONOMY ADDS NEW CHALLENGES

A. Antitrust and Patent Policy Have Worked to Achieve Better Balance

1. Antitrust Policy Has Continued to Implement New Economic Learning in Addressing the Intersection of Antitrust and Patents

Antitrust policymakers and enforcers continue to apply the new economic learning that gained precedence in the 1980s. In 1995, the Antitrust Division of the Department of Justice and the Federal Trade Commission jointly issued *Antitrust Guidelines for the Licensing of Intellectual Property (IP Guidelines).* Like the 1988 Guidelines, the 1995 IP Guidelines identify and discuss potential efficiencies associated with many licensing practices and

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[151] Roger B. Andewelt, Basic Principles to Apply at the Patent-Antitrust Interface, Remarks to the Houston Patent Law Association 4-5 (Dec. 3, 1981).

[152] Charles F. Rule, Technology Licensing and the Second American Revolution: Storming the Ramparts of Antitrust and Misuse, Before the John Marshall Law School 5 (Feb. 22, 1985). Rule emphasized the role of patents in preventing free riding: "Unless the 'free rider' problem is somehow addressed, those who might otherwise undertake risky and expensive R&D will not do so. Fewer technologies will be developed and consumers will face higher prices and fewer choices." *Id.* at 6. *See also* Charles F. Rule, The Antitrust Implications of International Licensing: After the Nine No-No's, Remarks before the Legal Conference sponsored by the World Trade Association and the Cincinnati Patent Law Association (Oct. 21, 1986), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,131. 3, 1981.

[153] 1988 International Guidelines at §§ 3.6, 3.61.

emphasize that the vast majority of licensing practices are analyzed under the rule of reason.[154]

The IP Guidelines "embody three general principles[.]"[155] The first is that "for the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property[.]"[156] Some have expressed concern that this statement may mean that antitrust sees no difference between intellectual property and other types of property.[157] The IP Guidelines themselves belie this characterization, explaining that:

> [i]ntellectual property has important characteristics, such as ease of misappropriation, that distinguish it from many other forms of property. These characteristics can be taken into account by standard antitrust analysis, however, and do not require the application of fundamentally different principles. [footnote omitted][158]

Second, "the Agencies do not presume that intellectual property creates market power in the antitrust context[.]"[159] This observation eliminates the automatic conflict between patents and antitrust that courts perceived by assuming that patents always create monopoly power in the hands of the patent holder. As noted earlier, patents may enable the holder to exercise market power,[160] but the Antitrust Agencies do not assume that is necessarily the case.

Third, "the Agencies recognize that intellectual property licensing allows firms to combine complementary factors of production and is generally procompetitive."[161] The IP Guidelines explicitly recognize the efficiencies that firms can gain through intellectual property licensing, which can "benefit[] consumers through the reduction of costs and the introduction of new products."[162] Further, the IP Guidelines note that, "[b]y potentially increasing the expected returns from intellectual property, licensing also can increase the incentive for its creation and thus promote greater investment in research and development."[163] Similarly, the IP Guidelines note that "various forms of

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[154] The 1995 IP Guidelines superceded the 1988 International Guidelines. The 1988 International Guidelines specified that "[b]ecause they hold significant procompetitive potential, unless the underlying transfer of technology is a sham, the Department analyzes restrictions in intellectual property licensing arrangements under a rule of reason [footnote omitted]." § 3.62. The 1995 Guidelines provide for a slightly greater possibility of *per se* treatment, *see* IP Guidelines § 3.4, but still make clear that the Agencies use the rule of reason "[i]n the vast majority of cases." IP Guidelines § 3.4.

[155] IP Guidelines § 2.0.

[156] *Id.*

[157] *See, e.g.,* Langenfeld 2/20 at 6-8.

[158] IP Guidelines § 2.1. *See* Tom 2/8 (Antitrust Session) at 50-52. The IP Guidelines further note that the power to exclude others from the use of intellectual property may vary substantially, and that "[t]he greater or lesser legal power of an owner to exclude others is also taken into account by standard antitrust analysis." IP Guidelines § 2.1, n. 9.

[159] IP Guidelines § 2.0.

[160] *See supra* Ch. 1(I)(C)(1) .

[161] IP Guidelines § 2.1.

[162] *Id.* § 2.3.

[163] *Id.*

exclusivity"[164] can give a licensee the incentive to invest in commercializing and distributing products that embody the intellectual property by "protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor."[165] Overall, the 1995 IP Guidelines, like the *1988 International Guidelines*, signal an approach that is far more positive toward patent licensing than earlier antitrust perspectives.

In the same vein, since 1997, the Antitrust Division of the Department of Justice has issued four Business Review Letters that analyze the antitrust issues raised by the proposed patent pools and discuss the features that reduce competitive concerns about those pools.[166] Each letter explicitly recognizes that patent pools can provide competitive benefits by promoting the dissemination of technology.[167] In each case, based on the descriptions of the patent pools the parties provided, the Antitrust Division declined to initiate enforcement action.[168]

The FTC challenged one patent pool; the allegations were resolved through a consent order that bars continuation of the pooling arrangement.[169] The FTC's challenge elicited controversy, especially with regard to what the facts actually showed, but the FTC's complaint provides a useful comparison to the types of arrangements reviewed by the Antitrust Division to reveal which types of patent pools are more likely to pose significant antitrust concerns.[170] Once again, the Antitrust Agencies have viewed patent pools that offer legitimate efficiencies far more favorably than in the past.

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[164] The guidelines give as examples field-of-use and territorial restrictions. IP Guidelines § 2.3.

[165] *Id*.

[166] *See* Letter from Joel I. Klein, Acting Assistant Attorney General, Antitrust Division, Department of Justice, Letter to Garrard R. Beeney, Esq. (June 26, 1997), *at* http://www.usdoj.gov/atr/public/busreview/1170.htm (hereinafter MPEG Pool Letter); Letter from Joel I. Klein, Assistant Attorney General, Antitrust Division, Department of Justice, to Garrard R. Beeney, Esq. (Dec. 16, 1998), *at* http://www.usdoj.gov/atr/public/busreview/2121.htm (hereinafter Phillips DVD Pool Letter); Letter from Joel I. Klein, Assistant Attorney General, Department of Justice, to Carey R. Ramos, Esq., counsel to Hitachi, Ltd. (June 10, 1999), *at* http://www.usdoj.gov/atr/public/busreview/2485.htm (hereinafter Hitachi DVD Pool Letter); Letter from Charles A. James, Assistant Attorney General, Antitrust Division, Department of Justice, to Ky P. Ewing, Esq. (Nov. 12, 2002), *at* http://www.usdoj.gov/atr/public/busreview/200455.htm. *See also* James, *Opening Day Comments* at 2.

[167] *See* MPEG Pool Letter at 5; Phillips DVD Pool Letter at 5; Hitachi DVD Pool Letter at 5.

[168] *See* MPEG Pool Letter at 9-10; Phillips DVD Pool Letter at 9; Hitachi DVD Pool Letter at 10.

[169] *See In re* Summit Tech., Inc. & VISX, Inc., No. 9286 (FTC Mar. 24, 1998) (complaint), *available at* http://www.ftc.gov/os/1998/03/summit.cmp.htm (*Summit* Complaint); *In re* Summit Tech., Inc. & VISX, Inc., No. 9286 (FTC Aug. 21, 1998) (Agreement Containing Consent Order To Cease And Desist As To Summit Tech., Inc.), *available at* http://www.ftc.gov/os/1998/08/d09286suagr.htm; *In re* Summit Tech., Inc. & VISX, Inc., No. 9286 (FTC Aug. 21, 1998) (Agreement Containing Consent Order To Cease And Desist As To VISX, Inc.), *available at* http://www.ftc.gov/os/1998/08/d09286viagr.htm.

[170] *See* Anthony, 28 AIPLA Q.J. at 18-19.

2. Patent Policy Has Implemented Certain Reforms and Rules that Can Lessen Anticompetitive Conduct and Increase Competition

a. Congress Enacted the American Inventors Protection Act of 1999 (AIPA)

(i). Disclosure of Most Patent Applications after Eighteen Months Can Reduce Opportunistic Hold Ups through Submarine Patents

Over the years, companies have complained about problems caused by "submarine patents." The basic scenario is that a patent applicant allows its application to languish in the PTO while watching another company make substantial investments in a technology or product that will infringe the yet-to-be-issued patent. Once the other company's sunk costs are large, the patent applicant obtains the patent, asserts infringement, and "holds up" the other company, demanding supra-competitive royalties for a license to the "submarine patent."[171] The company must agree to supra-competitive royalties or forego its production or innovation. As a result, consumers will either pay higher prices for the company's goods, or will never get the benefit of the innovation that the company had to abandon.[172]

Partly in response to problems created by submarine patents, and partly to conform U.S. practice to international practice, the AIPA now requires publication of a patent application eighteen months after filing, unless the applicant certifies that the invention will not be the subject of any foreign or international application in jurisdictions that provide for eighteen-month publication.[173] The PTO reports that roughly 90 percent of all pending patent applications are published at eighteen months.[174] This new publication requirement can assist inventors and businesses to some extent in avoiding hold up and making more informed decisions about where (and where not) to spend R&D resources.[175] As several

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[171] *See, e.g.*, Shapiro 11/6 at 15-16, 175-76; *see also infra* Ch. 2(B)(3)(b)(1) (discussing hold up in the context of patent thickets) and Second Report (forthcoming).

[172] *See infra* at Ch. 2(B)(3)(b)(1) (discussing this scenario in more detail).

[173] 35 U.S.C. § 122. *See* John Love 2/28 at 647 (18-month publication part of AIPA is response to problem of submarine patents); MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 62-63 (AIPA brings United States into conformity with many other countries that require publication of application eighteen months after filing).

[174] John Love 2/28 at 647.

[175] Gable 3/20 at 118-19 (describing how AIPA can "go a long way" to prevent plight of individual small inventors who "put a lot of money and a lot of effort into this process and two or three years down the line, typically, in the course of the prosecution of their own patent they found out another patent has issued that covers their invention and they're barred from using it."); John Love 2/28 at 647 (AIPA gives businesses "an idea of what patent applications are pending and . . . an indication of where the technology is going also."); Ronald Myrick, *FTC/DOJ Hearings on IP and Antitrust: Testimony of Ronald Myrick* (3/19/02) 20 (eliminating the right to opt-out of application publication at eighteen months would "partially eliminate the potential for 'surprise' or 'hold up' about which some have expressed concern."), *at* http://www.ftc.gov/opp/intellect/020319ronmyrickpreparedtestimony.pdf. *But see* Thomas 4/10 at 192-93 (asserting that the AIPA provides no benefit, because it requires only the publication of patent applications that already are published in Europe at the same time; may "save[] a translation fee on occasion"); Katsh 4/10 at 193 (noting that 18-month publication does not give notice of what additional claims will be sought in continuation practice; 18-month publication does not give complete notice and

panelists noted, patent disclosures may stimulate competition to design around a patent.[176]

(ii). Patent Quality: Reexaminations of Questionable Patents

Patent prosecutions – that is, the administrative procedures through which a patent application becomes a patent – take place *ex parte*. At the PTO, only the patent applicant and the patent examiner(s) discuss the patent application; no third parties are involved in that discussion.[177] In 1980, Congress established an *ex parte* reexamination procedure[178] intended to "strengthen[] investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents."[179] Congress hoped this reexamination procedure would allow an efficient resolution of questions of patent validity and thus would obviate to some extent the need for lengthy and costly patent litigation.[180] This *ex parte* reexamination procedure affords little opportunity for participation by third parties, however;[181] for the most part, it is conducted *ex parte* in the same manner as the initial patent examination. It has not become a substitute for patent litigation, and some argue that it has been used as frequently by patentees to strengthen their patents as by challengers to weed out invalid patents.[182]

To afford a greater opportunity for third-party participation in the reexamination process, Congress enacted an *inter partes* reexamination system as part of the AIPA.[183] *See also* Box 1-5 (1992 Advisory Commission on Patent Law Reform). Due to certain limitations, however, third parties had used the procedure only four times since its enactment, as of the date of the Hearings.[184] In the fall of 2002, Congress revised the procedure in hopes that third parties would use it more frequently.[185] Some remain skeptical that the revisions were sufficient to encourage greater use of the procedure because one important disincentive to its use remains.[186] Nevertheless, the availability of

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leaves uncertainty).

[176] *See, e.g.,* Banner 10/30 at 70-71 (discussing design-around competition that disclosure of issued patents spurs); *see generally infra* at Ch. 3(III)(D)(1)(b) and Ch. 5(II)(C)(4) for discussion of limitations on the role of patent application disclosures at eighteen months and disclosures of issued patents in facilitating business planning and encouraging design-around competition.

[177] *See infra* Ch. 5(II)(B).

[178] 35 U.S.C. §§ 302-07.

[179] H.R. REP. NO. 96-1307, at 3, *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462.

[180] H.R. REP. NO. 96-1307, at 3, *reprinted in* 1980 U.S.C.C.A.N. at 6463.

[181] 35 U.S.C. §§ 304, 307 (if a third party has requested the reexamination, it has a right to reply to the patentee's opening statement on the reexamination issue, but no right to participate beyond that).

[182] *See* Mowery 2/27 at 408; Hall 2/28 at 760-61; Merrill 10/25 at 123; *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1210-11 ("the confirmation of a patent in reexamination is accorded a great deal of respect by courts, and hence a reexamination can bolster the 'strength' of a patent.").

[183] 35 U.S.C. §§ 311-18.

[184] *See* Kunin 7/10 at 70.

[185] 35 U.S.C. § 315(b) (as amended Nov. 2, 2002).

[186] *See infra* Ch. 5(III)(A), (B)(1).

BOX 1-5. THE ADVISORY COMMISSION ON PATENT LAW REFORM: A REPORT TO THE SECRETARY OF COMMERCE (1992)

In 1990, Secretary of Commerce Robert Mosbacher established an Advisory Commission regarding the state of the patent system and the need for any reform. In 1992, the Commission issued its report containing recommendations in three areas:

(1) Harmonization-Related Issues. The Commission recommended publication of all patent applications within 24 months from the earliest priority date claimed by the applicant, along with certain protections for patentees.

(2) Patent Enforcement-Related Issues. *Litigation*. The Commission recognized that "an essential relationship [exists] between the value of patent rights [ ] and the cost of patent litigation." More specifically, the Commission sought "to ensure that transactional costs do not prejudice the rights of patentees or the rights of the public through the process of patent enforcement." The Commission also noted that "[i]ncreased quality of examination will strengthen the presumption of validity, which in turn will decrease the number of unwarranted challenges to patent validity. This will also increase the confidence of the courts in applying the statutory presumption of validity."

Alternatives to Litigation. The Commission advocated modifications to the reexamination system "to provide third parties with a greater opportunity to participate." For example, it recommended that the basis and scope of reexamination include all aspects of 35 U.S.C. § 112 (i.e., written description, enablement, claim definiteness), except best mode.

(3) Unique Issues Facing the Patent System. This series of recommendations addressed issues ranging from the protection of computer-related inventions to PTO funding through user fees. Recommendations relevant to the FTC/DOJ Hearings are addressed elsewhere in this report.

inter partes reexamination adds a new mechanism through which to address competition concerns about the validity of patents associated with market power.[187]

b. The Federal Circuit Has Increased Business Certainty and Has Noted Competition Concerns in Certain Contexts

Many panelists at the Hearings agreed that the Federal Circuit has increased consistency in the application of many aspects of patent law.[188] This trend has important implications. Consistency in the application of the law can reduce the costs of business uncertainty and can facilitate business planning about how best to compete.

In addition, in different contexts, the Federal Circuit has interpreted the statute in ways that support the "notice function" of patents[189] – that is, the requirement that a

[187] *See also infra* Ch. 5(III)(B), (C) for discussion of pros and cons of reexamination and post-grant opposition proceedings as means to address questionable patents.

[188] *See, e.g.,* Mossinghoff 2/6 at 76-78 (adds certainty and consistency); Myrick 3/19 at 17 (credits Federal Circuit with uniformity and certainty of patent law); Armbrecht 3/19 at 54-55 (informal poll of members of Industrial Research Institute found general agreement that the Federal Circuit has brought greater stability and predictability to the patent process across industries); Weil 7/11 at 150-51 (Federal Circuit has brought consistency to many areas of patent law). *But see generally* Ch. 6(II)(C) (discussion of areas in which some argue that the Federal Circuit has increased uncertainty or other costs of the litigation process).

[189] *See, e.g., Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("Where there is an equal choice between a broader and

patent's "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[190] The notice function serves an important purpose in the framework of competition: "The object of the patent law in requiring the patentee [to distinctly claim his invention] is not only to secure to him all to which he is entitled, *but to apprise the public of what is still open to them*."[191] Accurate notice of the scope of a patent's claims can encourage competition in the area not covered by the patent. Although the Supreme Court in one context has found that the interest in ensuring appropriate incentives for innovation can override the notice function,[192] the Federal Circuit's general attentiveness to the role of notice in ensuring that competitors know what a patent does and does not protect serves to encourage and protect competition outside the scope of a valid patent.

c. The PTO Has Implemented Certain Reforms that Can Aid Competition

(i). Utility Guidelines

A claimed invention must be "useful" to receive a patent. From time to time, some have raised concerns about whether patents have been granted for research "too close to the laboratory bench" – that is, basic research not yet "useful" enough to deserve a patent.[193] During the 1990s, some raised this concern with regard to biotech patents in particular.[194] The PTO responded by issuing and then revising a set of Utility Examination Guidelines,[195] which, ultimately, have been generally well-

narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.").

[190] 35 U.S.C. § 112.

[191] *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891) (emphasis added). *See also General Electric Co. v. Wabash Appliance Corp.,* 304 U.S. 364, 369 (1938) (primary purpose of notice is "to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.").

[192] In *Festo v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722 (2002), the Court reviewed a case involving the doctrine of equivalents, under which "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo*, 535 U.S. at 732. In that case, the Court conceded that "the doctrine of equivalents renders the scope of patents less certain [and that it] may be difficult to determine what is, or is not, an equivalent to a particular element of an invention. If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. In addition the uncertainty may lead to wasteful litigation between competitors, suits that a rule of literalism might avoid." *Id*. The Court noted, however, that "[t]hese concerns with the doctrine of equivalents . . . are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule." *Id. See also Festo v. Shoketsu Kinzoku Kogyo Kabushiki*, No. 95-1066, 2003 U.S. App. LEXIS 19867 (Fed. Cir. Sept. 26, 2003).

[193] Thomas 2/8 (Patent Session) at 42.

[194] *See, e.g.,* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 106-07, 138 (1999); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Investions Associated with the Identification of Partial CDNA Sequences,* 23 AIPLA Q. J. 1, 4-20 (1995).

[195] United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (2001), revising interim guidelines published at 64 Fed. Reg. 71440 (1999), which in tern superseded an earlier version, 60 Fed. Reg. 36263 (1995).

received.[196] Well-considered PTO guidelines can prevent invalid patents that capture basic ideas and research and thus thwart competition in emerging fields.[197]

(ii). Business Methods Patent Initiatives

In *State Street Bank & Trust v. Signature Financial Group,*[198] the Federal Circuit ruled that business methods can be patented. This decision has generated a fair amount of controversy, as has the PTO's subsequent issuance of hundreds of business method patents.[199] From a competition standpoint, one could ask whether and, if so, when a business method should be patented; for example, a patented business method may stand in the way of Internet competition in some circumstances.[200] In addition, it is often very difficult to locate and identify all relevant prior art with respect to a claimed business method invention, because much of the relevant prior art does not exist in the patent literature, the traditional source of relevant prior art.[201] Prior art is the primary way that patent examiners determine whether a claimed invention is nonobvious, one of the requirements of the patent statute.

The PTO responded to concerns about the possible issuance of many questionable business method patents by undertaking the "Business Method Initiative."[202] The primary goals of this initiative were to identify sources of non-patent prior art and to create mandatory fields of search for examiners.[203] In addition, the PTO adopted another level of review for business method patents; this level of review involves a "second pair of eyes" – that is, a more senior examiner or an examination panel takes a look at each business method patent application.[204] Since the PTO introduced this program, the allowance rate for business method patents has decreased, and the PTO believes that this decreased allowance rate indicates improved PTO searches for prior art.[205] Such PTO action can prevent the issuance of invalid patents that may contribute to market power and restrain competition in unwarranted ways.

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[196] *See infra* Ch. 4(II)(D)(1).

[197] *See generally* Ch. 4(II)(D)(1) for further discussion of the PTO's Utility Guidelines.

[198] 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied,* 525 U.S. 1093 (1999).

[199] *See infra* Ch. 4(II)(E).

[200] *See*, *e.g.*, Musacchia 4/9 at 24-25; Young 4/11 at 61, 63-64; Thomas 4/11 at 59-60; Richard C. Levin, *Testimony* (2/6/02) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/levinrichardc.htm; Langenfeld 2/20 at 18; Kushan 4/11 at 114.

[201] *See* Thomas 4/11 at 111; *see infra* Ch. 4(II)(E)(2).

[202] John Love 2/27 at 467-68.

[203] *Id*.

[204] *Id.* at 470.

[205] *Id*. at 470-71. *See generally infra* at Ch. 4(II)(E) for discussion of issues surrounding business method patents.

B. The Growth of the Knowledge-Based Economy Creates Ongoing Controversy and Challenges Competition and Patent Policy to Continue Seeking a Better Balance

As discussed above, both antitrust and the patent system have responded to the challenges posed by the knowledge-based economy and sought to improve the balance between competition and patent policy. Nonetheless, the Hearings revealed that much controversy remains about whether competition and patent policy have yet responded adequately to the knowledge-based economy or found a proper balance. The joint FTC/DOJ report (forthcoming) will address the issues related to the balance between antitrust law and policy and patents that were raised at the Hearings. This report discusses issues related to the balance between patent law and policy and competition that were raised at the Hearings.

The growth of the knowledge-based economy presents several challenges to the patent system. One is the sheer number of patents sought and received. As Under Secretary of Commerce for Intellectual Property and Director of the USPTO James Rogan stated at the outset of these Hearings, there is an "unprecedented explosion of patent applications" today.[206] Other aspects of the knowledge-based economy also render the PTO's mission more difficult. For example, pendency may assume particular importance in fast-moving technologies (such as software); prior art may be more difficult to locate for technologies that were previously unpatented or unpatentable (such as business methods); and increasingly complex technologies (such as biotechnology) must be evaluated.

Many panelists at the Hearings raised concerns that the patent system is not keeping up with these challenges. They asserted that dubious patents, and costly patent procedures and litigation to determine whether such patents are valid or infringed, are stifling competition unnecessarily. Panelists observed that issues of patent quality seem to arise more frequently than is desirable.[207] In recent testimony before the House Judiciary Committee's Subcommittee on Courts, the Internet, and Intellectual Property, the AIPLA stated that "[l]arge and small companies are increasingly being subjected to litigation (or its threat) on the basis of questionable patents."[208] As noted earlier, invalid patents that confer market power unnecessarily thwart competition. *See also* Box 1-6 (blocking patents).

Panelists pointed out that a number of factors determine patent quality. Substantive standards of patent law determine whether the PTO and the courts evaluate the validity and scope of patents under proper standards. Procedures and presumptions at the PTO and in the courts

[206] Rogan (stmt) 3.

[207] *See, e.g., infra* Chs. 3(II), (IV) and Ch. 5(I).

[208] *United States Patent and Trademark Office Fee Modernization Act of 2003: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 108th Cong. 2 (2003) (Statement of Michael K. Kirk, Executive Director, American Intellectual Property Law Association), *available at* http://www.aipla.org/html/Legislative/108/testimony/FeeLeg.htm.

Box 1-6. ***Blocking Patents***

The patents of others can block a patentee's ability to exploit its own invention without a license to the others' patents. Schechter and Thomas provide an example:

> "[S]uppose that Admiral Motors obtains a patent on an internal combustion engine for use in automobiles. Later, Betty Beta purchases an automobile marketed by Admiral Motors that embodies the patented invention. Beta experiments with her new car and develops a dramatically improved fuel injector useable only in the patented Admiral Motors engine. Even if Beta patents her improved fuel injector, she cannot practice that technology without infringing Alpha's basic patent. . . . Unless one of the parties licenses the other, Beta must wait until Admiral Motors' patent expires before practicing her own patented improvement invention." SCHECHTER & THOMAS, THE LAW OF COPYRIGHTS, PATENTS & TRADEMARKS § 20.1.1 at 462.

If the alleged blocking patent is questionable, business costs, which ultimately may be passed on to consumers, can increase unjustifiably, with the owner of an improvement patent forced to choose between paying royalties on a questionable patent or engaging in expensive patent litigation. *See generally infra* Ch. 5(III).

further affect the ability to weed out unwarranted patents either before or after they are granted. Panelists raised several issues concerning patent quality and how it affects the proper balance between competition and patent policy. We identify a few.

1. Follow-On Innovation, Product Commercialization, and Patent Proliferation

The simplest economic model of the patent system assumes that innovation is a "one-time" event.[209] Of course, in the real world, innovation is an ongoing process, with one invention frequently providing a building block for the next. The ongoing nature of innovation poses difficult questions about how best to preserve adequate incentives for an initial innovator and maintain adequate incentives for competition to become the next innovator. These questions implicate substantive standards for determining the proper breadth of patent claims.

The real world adds other complexities as well. In a simple economic model of innovation and patents, each invention requires access to only one or a few patents to commercialize the patented product. Certain industries, such as pharmaceuticals, have tended to follow this model.[210] Some suggest, however, that more and more industries are moving toward the model in which, for commercialization, a product requires access to many patents – dozens, hundreds, or even thousands.[211] Reports indicate that this phenomenon can increase transactions costs substantially and lead to additional problems such as royalty

[209] *See generally infra* Ch. 2(I).

[210] *See, e.g.,* Browder 3/19 at 174; Gregory J. Glover, *Competition in the Pharmaceutical Marketplace* (3/19/02) 8, *at* http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf.

[211] *See, e.g.,* R. Levin 2/6 at 98-99; Cohen 2/20 at 29.

stacking and patent thickets.[212] These issues have implications for both patent and competition policy. *See also* Box 1-7 (difficulties in claim drafting and interpretation).

Box 1-7. ***Complexities Added by the Difficulty of Drafting and Interpreting Claims***

When a firm determines whether it needs access to one or more patents held by others, it evaluates its planned business activities in relation to the rights established in others' patents. Each patentee's exclusive rights are based upon the invention, as recited in the claims of the patent. Each claim consists of one sentence that verbally portrays a method, product or process; a patent may contain one or many claims. Sometimes, a patent may contain claims that overlap other claims in that patent, or that overlap claims in other patents.

The inquiring firm reviews the claims set forth in patents it believes it might infringe without a license. A firm's activities may infringe only one, many, or all of the claims of the patent. In some cases, a review of the claims in others' patents may yield uncertain answers. Although drafting claims sounds straightforward, experience has shown that it is often a very difficult task. As a corollary, issues can arise with some frequency regarding how claims should be interpreted. *See generally* SCHECTER & THOMAS, THE LAW OF COPYRIGHTS, PATENTS & TRADEMARKS § § 18.2 and 20.2 at 404-20, 474-75. Claim interpretation issues can add to the complexity that firms may confront in determining whether their planned activities would infringe absent licenses to use others' patents.

2. Procedures that Third Parties Can Use to Challenge Questionable Patents

Procedures that third parties can use to challenge questionable patents may be insufficient.[213] Third parties rarely use *inter partes* reexamination procedures;[214] moreover, participants in the patent system generally view patent litigation as too costly and time consuming. Substantial concerns about patent quality, however, have led to calls for improving existing or developing new procedures through which third parties can challenge questionable patents. These issues, including their relationship to competition policy, are discussed in depth in this report.[215]

3. Patent Prosecutions and Examinations within the PTO

A variety of pressures that arise from the nature of recent technological change and innovation confront the PTO. Sometimes these pressures may conflict; for example, pressure to reduce the pendency of patent applications may conflict with pressure to provide additional time for examinations of particularly complex patent applications. Indeed, patent applicants in different industries may take different views

[212] Royalty stacking describes the phenomenon whereby disparate owners of complementary technologies demand higher aggregate royalties than they would if they acted as a group. *See infra* Ch. 2(III)(C)(3). A patent thicket is a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001). *See infra* Ch. 2(III)(C) (describing economics of patent thickets); *see generally* Ch. 3(II)(D)(4) (describing instances of royalty stacking and patent thickets).

[213] *See generally infra* Ch. 5(I), (III).

[214] *See generally infra* Ch. 5(III).

[215] *See generally infra* Ch. 5(I), (III).

of which of these issues is most important.[216]

Increasing Complexity and Limited Time for Patent Examiners. Throughout the Hearings, panelists lamented the PTO's inability to provide examiners with sufficient time to undertake their review.[217] The increasing complexity of patents compounds this challenge. One panelist noted, for example, that typically new examiners have 25 hours, and more experienced examiners have 20 hours, to examine a biotechnology patent. He felt these time constraints were "clearly inadequate given the complexity and difficulty of biotechnology patents. . . ."[218] This panelist recommended not only that the PTO double the time allocated for such patent examinations, but also that the PTO provide examiners with more training.[219] Expertise comes not only from education but also from experience.[220]

Opportunities to Broaden Claims. Some believe that an opaque process for patent prosecution at the PTO can allow firms unfairly to disadvantage their competitors. For instance, some assert that applicants can anticompetitively game patent continuations to capture subject matter already developed by a competitor.[221] This raises significant issues for both patent and competition policy.

Patent Pendency. Faster technology evolution and shorter product life cycles have increased the pressure on the PTO to reduce pendency times.[222] As the U.S. House of Representatives Committee on Science/Subcommittee on Technology recognized: "In a growing number of industries - such as computer hardware and software . . . - the pace of advancement has begun to challenge the ability of the patent office to process applications in a time frame that is functionally useful to the inventor."[223] In fast moving fields, such as electronics,

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[216] *See generally infra* Ch. 3(III)(D)(2), (V)(B) (compare biotech representatives expressing views that more thorough examinations are more important than reducing pendency times with software representatives expressing concern that patents emerge only after they no longer have any commercial value).

[217] *See*, *e.g.*, Dickinson 2/6 at 64; Gable 3/20 at 121.

[218] Kirschner 2/26 at 243.

[219] Kirschner 2/26 at 244.

[220] The PTO has sometimes suffered from a "crippling attrition rate," due to more experienced examiners going to higher paying private sector jobs; more recently, the attrition rate at the PTO has been falling. *See Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary*, 107th Cong. 2 (2002) (Statement of James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office), *available at* http://www.uspto.gov/web/offices/com/speeches/househrg2002.htm. *See also* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 607-8 (1999). *See also* Gable 3/20 at 121 ("There is a very significantly high turnover in the examiners particularly . . . in the biotech area as well as the software, method of doing business area.").

[221] *See generally infra* Ch. 4(II)(C)(1).

[222] *Cf.* FTC Staff Report, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace,* Ch. 6 at 15 (May 1996) ("Competition to be first on the market has resulted in shortening product life cycles, at least in high-tech industries."), *available at* http://www.ftc.gov/opp/global/report/gc_v1.pdf.

[223] *The Patent System and Modern Technology Needs: Meeting the Challenges of the 21st Century, Hearing Charter Before the Subcomm. on Technology of the House Comm. on Science,* 104th Cong. (1996), *available at* http://www.house.gov/science/patchrt.htm.

semiconductor, and telecommunications, patents granted years after filing may be of "little value."[224]

4. Patent Quality and Patentable Subject Matter

Many at the Hearings noted the continuing expansion of what can constitute patentable subject matter.[225] The transition of subject matter from a status of "generally open to free competition" to a status in which an inventor may obtain a patent on it can raise questions for competition policy.[226] In addition, panelists explained that the expansion of patentable subject matter can cause difficult transition periods for patent policy. The courts and the PTO must determine how best to apply existing patent doctrines to the newly patentable subject matter.

IV. THE HEARINGS EXAMINED THE CURRENT BALANCE OF COMPETITION AND PATENT LAW AND POLICY IN FOSTERING INNOVATION

As noted earlier, the growth of the knowledge-based economy means that increasingly complex questions confront antitrust enforcers, and increasingly numerous and challenging patent applications and patent issues confront the patent system. Some claim that these challenges have led to problems in the patent system that cause unnecessary harm to competition and may even require antitrust solutions. Others assert that these challenges have confounded antitrust and require even greater deference to patents. The FTC and the Antitrust Division of the Department of Justice convened these Hearings to learn more about these and other questions.

A. The Hearings Did Not Address Certain Fundamental Questions or Issues with International Ramifications

The Hearings did not address certain fundamental questions. For example, the Hearings did not ask whether there should be a patent system. Some panelists noted a correlation between a strengthened patent system during the 1980s and subsequent robust performance of the U.S. economy; they suggested a causal link between those

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[224] Michael Kirk, *AIPLA/FICPI Colloquium on Pendency Reduction* 9-10 (2001), *at* http://www.aipla.org/html/ficpi/2001/ficpi1119.pdf. Though not addressing the pendency issue explicitly, one panelist discussed the consequences of increasing technological change and the value of intellectual property protection as a practical matter. Burk 3/20 at 141 (If a product has a "very, very short life," then "some intellectual property protections, as they now exist, just are not terribly helpful in your business plan." Instead, such companies sell the product "for six months until our competitors copy it" and then sell something else.).

[225] *See generally infra* Ch. 4(II)(E)(3).

[226] *See generally infra* Ch. 4(II)(E) (discussion of business method patents).

events.[227] Regardless of whether and to what extent such a link exists, there is no gainsaying the innovation that businesses report that the patent system has spurred.[228]

The Hearings also did not ask whether the duration of a patent is optimal; Congress and international organizations have recently spoken on the legal length of patents.[229] Similarly, the Hearings did not address various questions – such as whether to use a first-to-file or first-to-invent standard – that are in discussion among the United States and other countries in international fora.[230]

B. The Hearings Examined the Appropriate Balance of Competition and Patent Law and Policy from a Competition and Economic Perspective

The Hearings addressed questions about the appropriate balance of competition, antitrust, and patent law and policy. The joint FTC/DOJ report will address the appropriate balance of antitrust law and policy with patents. This report applies a competition and economic perspective to identify the following policy goals for a proper balancing of patent law and policy with competition concerns.

1. The Legal System Should Provide Efficient Incentives for All Types of Innovation, Including Both Single-Stage and Follow-On Innovation

Single-stage Innovation. Efficient incentives for innovation begin with assuring adequate appropriability for single-stage innovation. By conferring a right to exclude, the patent system can enhance appropriability and increase incentives to innovate.[231] Patents also may be important bases for attracting financial support, particularly for small, new firms without tangible assets and reliable cash flow.[232] Patents can thereby facilitate entry and innovation.[233] The relative importance of patents for appropriability, however, varies

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[227] *See, e.g.,* Newman 2/6 at 40-41, 49; s*ee also* Pate, Antitrust and Intellectual Property at 16.

[228] *See generally infra* Ch. 3.

[229] To comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), the United States in 1995 enacted the Uruguay Round Agreement Act, providing, among other things, a patent term of twenty years from the patent application's filing date. *See* 35 U.S.C. § 154(a)(2); *see also* SCHECHTER AND THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.3.3 at 288.

[230] *See, e.g.,* Adam I. Hasson, *Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization*, 25 B.C. INT'L & COMP. L. REV. 373 (2002).

[231] *See, e.g.,* Thomas 2/8 (Patent Session) at 13-15; Langenfeld 2/20 at 7-8; Stoner 2/26 at 108; Taylor 2/27 at 489-90; Duffy 7/10 at 107; Chambers 10/25 at 30; ABA (Economics stmt) 17-18; Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 4, at http://www.ftc.gov/os/comments/intelpropertycomments/ipo.pdf (hereinafter IPO (stmt)).

[232] *See, e.g.,* Merges 2/28 at 577-78; Scherer 7/10 at 53; Hoerner 7/11 at 54; Barton 2/26 at 212.

[233] *See, e.g.,* Lerner 2/20 at 186; Hall 2/26 at 179, 183, 191; Ziedonis 3/20 at 17-18, 87-88.

from industry to industry.[234]

Follow-on Innovation. Innovation often is a cumulative process, with each stage building on its predecessors. To the extent that follow-on innovation flows from sources independent of the initial innovator, it is vital that efficient incentives to innovate exist for the original and for follow-on innovators.[235]

2. Safeguard the Patent System's Disclosure Function

In exchange for receiving a patent, a patentee must disclose the nature of the invention; disclosure is the basic *quid pro quo* of the system.[236] Disclosure can provide the public with knowledge that otherwise might have been kept a trade secret.[237] The public may apply that knowledge in non-infringing uses, and, after the patent expires, the invention becomes part of the public domain.

3. The Patent System Should Avoid Creating or Upholding Unwarranted Patents that Confer Market Power

"We should be wary of creating unwarranted market power by granting unwarranted patents."[238] Unwarranted market power can produce supracompetitive pricing, deter competition to spur innovation, and cause other harms to consumers.[239] From a patent perspective, an unwarranted patent is one that does not meet the statutory standards for patentability. From an economic perspective, however, unwarranted market power can arise from unwarranted patents – that is, patents for inventions that would have emerged in roughly the same time frame, and for which disclosure and commercial development would have occurred, even without the prospect of a patent.[240]

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[234] *See infra* Ch. 2(II)(A)(2). Testimony indicated that patents are likely to have greatest significance as appropriability mechanisms when R&D costs are high relative to the size of the market, and imitation is quick and easy. *See id.*

[235] *See* Scotchmer 2/26 at 128-29. *See generally infra* Ch. 2(III) for a discussion of different theories about how best to address this issue. *Design-around innovation.* Some stress that the patent system directs R&D away from imitative and toward innovative efforts by forcing competitors to design around patents. Others respond that design-around may be technically impossible or economically impractical and may entail costly efforts essentially to duplicate the patentee's invention. *See infra* Ch. 2(III)(B)(1) for a discussion of design-around innovation.

[236] *See, e.g.,* Rogan 2/6 at 21; Cohen 2/20 at 35; Myrick 3/19 at 18. *See generally* Stoner 2/26 at 109-10. Indeed, some viewed disclosure as the system's central feature. *See* Myrick 10/30 at 25 (describing focus on disclosure as "really what the patent system is all about").

[237] *But see infra* Ch. 3 (Hearings record mixed on whether businesses use patents when they can keep inventions as trade secrets instead).

[238] R. Levin 2/6 at 102. Recognition of potential market power effects was a theme echoed by many other participants. *See, e.g.,* ABA (Economics stmt) 11 (describing the exercise of market power as a possible cost of patent protection); Langenfeld 2/20 at 10-13; Stoner 2/26 at 108-09; Hall 2/26 at 181, 184; Farrell 2/28 at 596; Katsh 4/10 at 25-26; Gambrell 10/25 at 38-39.

[239] *See, e.g., infra* Ch. 2(I)(B).

[240] As noted earlier, many view this perspective – that patents should be granted only if the invention would not have emerged "but for" the patent system – as the "defining proposition" for standards of patentability. *See* Merges 2/28 at 579. Most concede, however, that the "but for" standard cannot practically be applied in individual cases. *See generally infra* Ch. 4(II)(A).

4. The Patent System Should Rely on Substantive Standards and Procedures that Minimize the Sum of Error and Process Costs and the Detrimental Effects of Uncertainty

All legal regimes should consider the extent to which they are subject to error – that is, false negatives and false positives.[241] In the antitrust context, this translates into under-enforcement (failing to challenge anticompetitive conduct) versus over-enforcement (erroneously condemning efficient, welfare-enhancing conduct).[242] In the patent context, this translates into denying a patent that should have been granted versus granting an unwarranted patent.[243] Legal systems also should consider the extent to which they create or minimize costs or business uncertainty through the use of specific procedures and presumptions.[244] Among other problems, uncertainty can thwart effective business planning and increase costs of capital for business investments.[245] Trade-offs may be necessary among the accuracy, transparency, and manageability of substantive standards[246] and the error rates and process and uncertainty costs of different approaches toward quality control.[247] The goal is to minimize the sum of error and process costs and the detrimental effects of uncertainty.

C. Organization of the Report

We begin with what economics can teach us about the relationship of competition and patent policy to innovation and then review business testimony about specific industries. We next examine patent approaches that may ameliorate perceived

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[241] *See generally* Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974).

[242] *See, e.g.,* CHARLES J. GOETZ & FRED S. MCCHESNEY, ANTITRUST LAW: INTERPRETATION AND IMPLEMENTATION 67-69 (2nd ed. 2002) (discussing approach of antitrust law to Type I (false positive) and Type II (false negative) error); Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 15-16 (1984).

[243] *See* Erik S. Maurer, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter,* 95 NW. U. L. REV. 1057, 1094-96 (2001) (arguing that analysis of Type I and Type II errors supports broader scope for patentable subject matter).

[244] *See generally* Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974).

[245] *See, e.g.*, Teece 2/26 at 202-04 ("the greater the ambiguity around intellectual property rights the less likely that the market will be able to work"); Friedman 2/27 at 411-12 (patent uncertainties undermine R&D planning, add to risks, and frustrate innovation incentives); Quillen 3/19 at 29 (patent uncertainty raises innovation capital costs); IPO (stmt) 3 (uncertainty adds costs and impairs business planning).

[246] *See, e.g.,* Dreyfuss 7/10 at 142-43; Pooley 10/30 at 55-57; *see generally* Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L. J. 557 (1992).

[247] *See, e.g.,* Taylor 10/25 at 51-52; F. Scott Kieff, *Summary of Proposed Testimony* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/harvardlaw.pdf; *see generally* Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEG. STUDIES 399 (1973). Issues could include whether a patent challenger should need "clear and convincing evidence" to rebut a patent's presumption of validity (the presumption of validity can save process costs, but may erroneously protect invalid patents) or whether cases should be decided by only one specialized court or by numerous regional courts of appeal (use of one specialized court may save process costs and may contribute to stability in the law, but may lead to more errors in the development of the case law, which has not had the benefit of as many different perspectives on and insights into the issues at hand).

problems. We conclude with a discussion of recommendations for antitrust and patent institutions.

The following chapters discuss these issues:

Chapter 2: What can we learn from theoretical and empirical economics about the general relationship between competition policy, patents, and innovation?

Chapter 3: What can we learn from the examination of individual industries about areas in which the balance between competition and patents seems to be working well or, conversely, might be off-kilter?

Chapter 4: What suggestions for substantive patent law reform might address problematic issues raised at the Hearings?

Chapter 5: What suggestions for procedural patent law reform might address problematic issues raised at the Hearings?

Chapter 6: What suggestions might facilitate greater interaction between antitrust and patent institutions about the issues discussed in this report?

In four appendices, we also provide a list of contributors to the Hearings (App. A), a list of public comments (App. B), a glossary of patent terms (App. C), and a list of selected federal statutes (App. D).

CHAPTER 2 THE ROLE OF COMPETITION AND THE PATENT SYSTEM IN SPURRING INNOVATION

CHAPTER 2 THE ROLE OF COMPETITION AND THE PATENT SYSTEM IN SPURRING INNOVATION

Introduction. Competition and patent policy play complementary roles in enhancing economic welfare over time.[1] This chapter explores the economic learning – based on economic theory and empirical economic evidence – about the effects that patent policy and competition can have on innovation and economic welfare.[2]

Patents and Stand-Alone Innovation. It is easy to see how patent awards affect *stand-alone* innovations, and the discussion below begins with that clear case.[3] The award of patent rights can spur stand-alone innovations by limiting free riding, facilitating commercialization of innovations, and encouraging disclosure of new ideas.[4] Pharmaceutical companies, for example, rely on patents to prevent free riding, recoup their R&D investments, and learn about new technological breakthroughs, according to many panelists.[5] Biotechnology start-ups rely on their ability to patent their innovations to attract investment and continue innovating, some panelists stated.[6]

Awarding patent rights, however, is not costless. An innovator whose patent confers market power can raise prices or depress output[7] (and, as developed below, broad initial patent rights can sometimes interfere with follow-on innovation[8]). These effects may be the price of progress, if the promise of a patent grant is necessary to elicit an invention, its disclosure, or investment in it. If invention, disclosure, or investment would have occurred even without the promise of a patent award, however, these costs hurt consumers

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[1] *See supra* Ch. 1(I)(B). *See also* JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 390-92, 400 (1988) (discussing different incentives for innovation).

[2] The scope of the inquiry here is limited and omits some of the complexities of different types of innovation and regulation. For example, the discussion does not distinguish between "process" and "product" innovation. (The former term refers to changing the production process to reduce the costs of making a product, and the latter involves improving the quality of the product itself. *See, e.g.,* American Bar Association Section of Antitrust Law, *The Economics of Innovation: A Survey* (Public Comment) 4 (reporting that more than three-fourths of R&D expenditure in the United States is on product innovation), *at* http://www.ftc.gov/opp/intellect/0207salabasrvy.pdf (hereinafter ABA (Economics stmt)). Similarly, this discussion does not elaborate upon the important point that – in addition to granting intellectual property rights – the U.S. government takes other steps to increase innovation. *See supra* Ch. 1. Nor does this chapter discuss the optimal length of patent protection. *See, e.g.,* ABA (Economics stmt) 14-15 (summarizing literature on the optimal patent length). (The current patent term of twenty years from the filing of the patent application, *see supra* Ch. 1(I)(A)(2), derives from statutorily implemented international obligations.)

[3] *See infra* Ch. 2(I) (discussing patents' effects on stand-alone innovation). Patent policies can also affect follow-on innovation, to be sure. For ease of exposition, however, this chapter focuses first on the simpler case of stand-alone innovation. For a discussion of other effects that patent policies have on follow-on innovations, *see infra* Ch. 2(III).

[4] *See infra* Ch. 2(I)(A) (discussing how patents can spur stand-alone innovation).

[5] *See infra* Ch. 3(II)(C). More information about this and other real-world illustrations of the economic phenomena described in this chapter follow, in Chapter 3.

[6] *See infra* Ch. 3(III)(D).

[7] *See infra* Ch. 2(I)(B) (discussing costs of patents).

[8] *See infra* Ch. 2(III) (discussing patents' effects on follow-on innovation).

unjustifiedly.[9]

Competition and Initial and Follow-On Innovation. Like patent policy, competition also affects innovation. On the one hand, competition can spur innovation in a wide variety of ways. As an initial matter, competition to win a patent right may drive a race to innovate. Indeed, firms competing to innovate may approach research problems differently, increasing the chances of successful innovation. Moreover, in some circumstances, an innovator may reap the benefits of its work simply by exploiting its head start on its competitors. For example, empirical studies have demonstrated that in the semiconductor and communications equipment industries, patents are less important than other means of exploiting innovation, means such as maintaining secrecy, taking advantage of lead time, investing in complementary manufacturing processes, and offering complementary sales and services.[10] This chapter explores these and other ways in which competition can drive innovation.[11]

On the other hand, competition alone is not a perfect engine of innovation. As noted above, competition, standing alone, does little to limit free riding on others' innovations,[12] and competition-driven innovation races can generate duplicative research, which some deem wasteful.[13]

Patents and Follow-On Innovation. The analysis concludes with a discussion of the effects of patent grants on *follow-on* innovation.[14] Admittedly, the categories of initial and follow-on innovation are hardly hermetically sealed. The progression of innovation is often continuous. Today's follow-on innovation often becomes the foundation for a future advance.[15] In keeping with much of the scholarly analysis and for ease of exposition, however, this chapter analyzes initial and follow-on innovation separately and discusses the various issues in the context in which they have the greatest significance.

Some at the Hearings argued that broad initial patent grants facilitate follow-on innovation by allowing the *patentee* to organize research flowing from its innovation.[16] By contrast, others contended that broad initial patent rights can sometimes impede follow-on innovation that would otherwise emerge from entities *independent of* the patentee. A patentee's refusal to license an initial patent on technology needed for follow-on research can hinder

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[9] *See infra* Ch. 2(I)(B) (discussing costs and limits of patents' power to spur stand-alone innovation); Ch. 2(III) (discussing patents' effects on follow-on innovation).

[10] *See infra* Ch. 2(II)(A)(2) (discussing these studies).

[11] *See infra* Ch. 2(II)(A) (discussing competition's power to spur innovation).

[12] *See infra* Ch. 2(II)(B)(1) (discussing appropriability problems).

[13] *See infra* Ch. 2(II)(B)(2) (discussing costs of duplication of efforts).

[14] *See infra* Ch. 2(III) (analyzing patents' effects on follow-on innovation).

[15] *See, e.g.*, *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Suzanne Andersen Scotchmer Testimony Feb. 26, 2002*, at page 170 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)).

[16] *See infra* Ch. 2(III)(A)(1) (discussing follow-on innovation organized by the initial innovator).

follow-on innovation, according to some. Others, however, stressed the potential benefits of design-around activities and the availability of licenses.[17] For example, the fact that the ulcer-treating drug Tagamet was patented forced others to design around it, leading to the development of another successful product, Zantac, according to some Hearing testimony.[18]

Some panelists expressed concern that researchers who require access not just to a single patent but to *multiple* patents may find their work impeded by high transaction costs,[19] royalty stacking,[20] hold up in patent thickets,[21] and oligopolists seeking to bar new entry.[22] Panelists made clear that these are not merely hypothetical concerns. For example, some panelists noted that the plethora of patents in the computer hardware industry makes it "virtually impossible to search all potentially relevant patents, review the claims," and evaluate the infringement risk;[23] and panelists from the software industry complained of the risk of hold up, noting that the owner of any one of the multitude of patented technologies constituting a software program can hold up production of innovative new software.[24]

In short, panelists noted that both competition and patent grants can spur innovation, but both can have adverse effects on innovation as well. This chapter aims to outline the costs and benefits of each approach to enhancing economic welfare.

I. PATENTS' EFFECTS ON STAND-ALONE INNOVATION

A. Patents Can Spur Stand-Alone Innovation

As noted in Chapter 1, intellectual property is particularly susceptible to misappropriation, also known as "free riding." Patents can limit free riding and also facilitate commercialization of the intellectual property the patent protects. This chapter addresses each of these scenarios below. It also explores how patent policy encourages disclosure, and how that disclosure can stimulate further innovation.[25]

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[17] *See infra* Ch. 2(III)(B)(1) (discussing design-around innovation); Ch. 2(III)(B)(3) (discussing licenses).

[18] *See infra id.* (discussing examples of design-around innovation).

[19] *See infra* Ch. 2(III)(C)(1) (discussing transaction costs).

[20] *See infra* Ch. 2(III)(C)(3) (discussing royalty stacking and the Cournot complements problem).

[21] *See infra* Ch. 2(III)(C)(2) (discussing hold up in the patent thicket).

[22] *See infra* Ch. 2(III)(C)(4) (discussing oligopoly and group boycotts).

[23] Robert Barr, *Statement* (2/28/02) 1, *at* http://www.ftc.gov/opp/intellect/barrrobert.doc (hereinafter Barr (stmt)).

[24] *See infra* Ch. 3(V)(E).

[25] Patents, like other property rights, can also serve as an underpinning of competition and thereby spur innovation. For example, firms may use patent rights, like other property rights, to compete with each other on innovation. *Cf.* U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property § 1.0 (Apr. 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132 ("The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products [and of] more efficient processes."), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

1. Internalize Externalities and Protect Against Free Riding

Economists recognize that without patent protection, "innovators [that produce intellectual property] cannot appropriate the full benefits of their innovation; some of the benefits go to 'free riders' without payment."[26] If innovators know that they cannot exclude imitators and appropriate the fruits of their R&D efforts, then they may lack sufficient incentives to undertake the innovation in the first place.[27] The problem is especially acute when the original innovator's efforts entail substantial fixed costs, and the imitators can copy the innovation cheaply.[28] Patent rights mitigate this problem by granting exclusive rights in innovations, enhancing appropriability.[29] Economic theory suggests that by conferring such rights to exclude, the patent system increases incentives to innovate.[30]

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[26] ABA (Economics stmt) 10-12 (discussing "invention motivation" rationale for patent protection); *see also* Stoner 2/26 at 108. Even with a patent, patent holders may be unable to appropriate the full benefits of their innovation because patent protection is limited. For instance, others can learn of the invention and make use of the knowledge as long as they do not infringe the patent claims.

[27] *See, e.g.,* Alstadt 3/19 at 39 (noting that his client will not pursue concept for new alloy unless patent protection is available). Langenfeld 2/20 at 8 ("[i]f you have an idea and you can't protect it adequately, other people will steal it and use it and that, obviously, deters your incentive to develop those ideas yourself."); Duffy 7/10 at 107 (discussing inventors' disincentives to innovate absent assurances that they can recover R&D costs); Chambers 10/25 at 30 (noting that his clients have foregone pursuing "areas or . . . products" because of lack of assurance that "they were going to have a clear ownership right").

[28] *See, e.g.,* Scherer 7/10 at 52 (stating that patents are most likely to be important when R&D costs are "high relative to the size of the potential market but imitation can be quick and easy, that is, with imitator R&D costs much lower than those incurred by the innovator"); Taylor 2/27 at 489-90 (patent system is "absolutely essential" for industries in which firms must expend "high front-end costs" and in which "their products are easily copied and attract[] free riders").

[29] ABA (Economics stmt) 10-12 (discussing "invention motivation" rationale for patent protection); *see also* Stoner 2/26 at 108-09; Thomas 2/8 (Patent Session) at 15, Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipo.pdf.
Panelists discussed the degree to which such protection from free riding helps entrants. *Compare* Greenstein 2/20 at 143-47 (discussing entrant's ability to use patent to prevent imitation by incumbent); Hall 2/26 at 179, 183, 191 (patents may facilitate entry by helping with securing financing and by allowing firm to exploit its innovation), Hall 2/26 at 190-91 (patents facilitate vertical disintegration and entry by firms with only intangible assets); Arora 2/25 at 72 (patents permit small firms to compete in R&D without having extensive downstream assets); Merges 2/28 at 578 (in the raising of capital, the marginal importance of patent grows as size of business declines); Nydegger 2/27 at 525-26 (smaller firms acquire patents to protect innovative technologies and "hopefully put them on a somewhat level playing field with larger competitors"); Scherer 7/10 at 53 (patents important to small, new firms without reliable internal cash flow); Taylor 2/27 at 490 (reward essential to attract capital); Hoerner 7/11 at 54 (patents particularly important for start-ups needing financing) *with* Cohen 10/30 at 78 (with imperfect capital markets for investment in legal resources, small firms and entrants may have less ability to enforce their patents); Barton 2/26 at 213 (small firms often cannot afford to litigate). *Cf.* Liebowitz 2/20 at 233-34 (contrasting this traditional goal of patent ownership with other goals).

[30] It is unlikely that there is too much innovation from the viewpoint of economic welfare. Innovation often generates "large positive spillovers" that the inventor cannot appropriate; as a result, there is a general "underinvestment in innovative activities." Thomas M. Jorde & David J. Teece, *Rule of Reason Analysis of Horizontal Arrangements: Agreements Designed to Advance Innovation and Commercialize Technology*, 61 ANTITRUST L.J. 579, 584 (1993); *see also id.* at 583-88 (summarizing empirical evidence showing that "the social returns to innovation are markedly greater than the private returns"); Dennis Carlton, *Antitrust Policy Toward Mergers When Firms Innovate: Should Antitrust Recognize the Doctrine of Innovation Markets?*, Testimony

This view of the role of patents assumes that invention is "a one-time stationary phenomenon, not a cumulative process whereby inventions build on each other."[31] When innovation is not cumulative, enhancing appropriability raises few concerns about any "offsetting retardation of innovation that could come from the increased risk of infringement by followers in the cumulative chain."[32] When innovation is cumulative, however, allowing the initial innovator to appropriate more of the rewards from its invention may hinder independent follow-on innovation. Independent firms seeking to build on the initial innovation would have to bear the risk of infringement or the cost of negotiating and paying for licenses. Thus, the granting of strong patent rights may carry costs.[33]

Appropriability mechanisms other than patents – such as trade secrecy, first-mover advantages, and learning-curve advantages – may also protect the innovator from free riding. Indeed, a number of studies have shown that such measures typically are more important than patents for protecting appropriability in many industries.[34] In other industries, however, these alternatives may be less readily available.

2. Facilitate Commercialization

Some inventions lack commercial capability at first. Only substantial development can turn them into commercially viable products. Economic theory posits that patent rights make it easier for inventors to develop relationships with others to invest in that development.[35] Patents can make information a tradeable commodity by reducing transaction costs and enabling licensing negotiations.[36] Without patent rights, inventors might have to rely on secrecy to prevent free-riding on their innovation; by shielding inventors from such free-riding, patents allow them to discuss their work with other firms that can help commercialize the invention.[37] If firms had to rely on trade secrets to protect their inventions, it would be "very difficult to . . . efficiently transfer information from the

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Before the FTC Hearings on Global and Innovation-Based Competition 6 (Oct. 25, 1995) (noting that the "social rate of return [on innovation] exceeds the private one, suggesting that more R&D would be desirable"), *at* http://www.ftc.gov/opp/global/carlton.htm; Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569, 593-94 n. 60 (1995) (noting evidence that "the private return to R&D is much less than the social return").

[31] Stoner 2/26 at 108-109.

[32] *Id.*

[33] *See infra* Ch. 2(III) (discussing patents' effects on follow-on innovation).

[34] *See infra* Ch. 2(II)(A)(2) (discussing races to innovate); *see also* Cohen 2/20 at 25-26; Scherer 7/10 at 51-52. In particular, Prof. Teece has noted that problems in the patent system are sometimes the reason that firms use non-patent means of appropriating value from their innovations. *See* Teece 2/26 at 206.

[35] *See generally* ABA (Economics stmt) 12.

[36] *See, e.g.,* Bronwyn H. Hall, *Patents and Innovation* (2/26/02) (slides) at 8 (patents allow trade in knowledge), *at* http://www.ftc.gov/opp/intellect/020226bronwynhhall.pdf. Other kinds of intellectual property, such as trade secrets, can likewise facilitate trade in information. *See, e.g.,* ROGER M. MILGRIM, 2 MILGRIM ON TRADE SECRETS § 9.01[4], 9-13–9-24 (2003) (noting that trade secrets may be licensed).

[37] *See, e.g.,* Kitch 2/20 at 84 (patents enable contracting to transfer information); Arora 2/25 at 72 (patents "enhance the efficiency of knowledge transfer").

inventor or even the investor to . . . the entity that [is] best able to exploit and develop it."[38] As one panelist put it, without patent rights,

> [y]ou can imagine the basic problem. An independent inventor goes to a large firm [and says,] 'Hey, I've got a great invention.' And the large firm says, 'Well, what is it?' Well, without a property right the conversation might stop.[39]

Rendering innovation a tradeable commodity also helps foster specialization. A small firm that has invented something need not do alone all the things necessary – from the advertising and warranties to sales and service – to bring the invention to market.[40] Instead, it can license or sell its invention to another firm, which can then do whatever tasks are needed to develop and market the invention.[41] In these ways, the patent system facilitates the commercialization of inventions.

3. Encourage Disclosure

The patent system also promotes innovation, some panelists noted, by demanding disclosure. Patent law requires applicants to disclose the inventions for which they receive patents.[42] This disclosure obligation is a quid pro quo for obtaining the right to exclude others from making, using, offering for sale, or selling an invention.[43] The purpose of the disclosure obligation is to foster further innovation by enabling a person skilled in the particular art to learn from another's invention.[44] Thus, an issued patent "communicates a considerable amount of information that can help other would-be inventors, including rival firms."[45] Although some questioned whether the

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[38] Kobak 7/11 at 60.

[39] Thomas 2/8 (Patent Session) at 17 (noting further that contracts and nondisclosure agreements are imperfect).

[40] *See, e.g.,* Thomas 2/8 (Patent Session) at 18; Teece 2/26 at 201 (patents allow small firms to specialize in invention).

[41] *See, e.g.,* Thomas 2/8 (Patent Session) at 18-19 (discussing how patent system reduces need for vertical integration).

[42] *See infra* Ch. 4(II)(B) (describing statutory requirements). *See also* Rogan 2/6 at 21 (the quid pro quo for receiving patent rights is disclosure); Myrick 3/19 at 18-19 (stating that "[p]atenting . . . serves the public interest by encouraging still more innovation, which in turn must be publicly disclosed to be entitled to patent protection"). Since 1999, patent law has also required the publication of certain patent applications 18 months after they are filed, *see infra* Ch. 4(II)(C)(1); however, through the use of continuations, a patent may issue that contains broader claims than publication initially revealed, *see id.*

[43] *See* Rogan 2/6 at 21; J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S.124, 142 (2001) ("The disclosure required by the Patent Act is the 'quid pro quo of the right to exclude'" (internal citations omitted)); Merges & Duffy, Patent Law and Policy: Cases and Materials at 262.

[44] *See, e.g.,* R. Levin 2/6 at 100 (stating that disclosure function is important and pro-competitive); Cohen 2/20 at 23, 34-35 (noting that patent policy aims through disclosure to promote innovation); Kushan 10/25 at 131 (stating that disclosure promotes innovation); Thomas 2/8 (Patent Session) at 15; Merges 2/28 at 577; Frankel 4/10 at 6; Scotchmer 4/10 at 65 (noting that disclosure obviates need for reverse engineering); Chambers 10/25 at 177 (arguing that patents permit inventor to talk more freely about invention); Chambers 2/8 (Patent Session) at 83-84 (patents encourage less trade secrecy); *cf.* Dreyfuss 7/10 at 197 (if society makes it really hard to get patents, there will be more trade secrecy).

[45] Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUDIES 247, 267 (1994); *see also* Newman 2/6 at 39 (describing patents as "the major if not the only source of technical information" in "virtually all fields of technology"); Armbrecht 3/19 at 51-52.

disclosures that patent law demands are adequate,[46] others noted that their adequacy might vary by industry.[47] In Japan, patents are reportedly a more significant source of new technical information than in the United States.[48]

B. Costs Of, and Limits To, Patents' Power to Spur Stand-Alone Innovation

Most patents do not confer market power on their holders,[49] but when they do, they carry costs. For example, an innovator whose patent confers market power can cause prices of goods and services to be above (and quantities to be below) competitive levels. The creation of a patent monopoly can "lead[] to restriction of production, a supracompetitive price, and what economists call an efficiency or deadweight loss."[50]

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[46] Arora 2/25 at 73 (concern over whether disclosures are adequate).

[47] *See, e.g.,* Kahin 10/25 at 133 (arguing that patents induce meaningful disclosure in pharmaceuticals industry but not in software industry); Friedman 2/27 at 354-55 (contending that patent disclosures are too slow to be of use in software industry); Thomas 10/30 at 184-85 (in many post-industrial fields, the claim is an abstract behavioral protocol and there is not much worth learning from the description). *See also infra* Ch. 4(II)(B)(3) (questions about whether software disclosures are adequate, because no requirement to disclose source code).

[48] *See* Cohen 2/20 at 36-39; Wesley M. Cohen, *Patents: Their Effectiveness and Role* (2/20/02) (slides) at 24, *at* http://www.ftc.gov/opp/intellect/cohen.pdf (hereinafter Cohen Presentation), Cohen 10/30 at 84-85, 123-24 (finding patents to be the most important R&D information source in Japan but just "in middle of pack" in the United States); Wesley Cohen et al., *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RESEARCH POLICY 1349, 1355-56 (2002) (survey findings suggest that patents more effectively serve the information disclosure function in Japan than in the U.S.); Janusz Ordover, *A Patent System for Both Diffusion and Exclusion*, 5 J. OF ECON. PERSP. 43, 45 (1991) (stating that the Japanese patent system is designed to induce earlier disclosure than the American patent system). The Japanese patent system apparently induces disclosure by a variety of means. For example, it awards patent rights to those who file first, inducing innovators to disclose their inventions in patent applications earlier than does the American system of awarding patent rights to the first to invent. *See, e.g.,* Ordover, 5 J. OF ECON. PERSP. at 45; Cohen 10/30 at 123. Moreover, Japan's patent system also generally grants narrower patents, such that there are "more patents per product" – fostering more cross licensing and related negotiations and information sharing – than in the United States. Cohen 2/20 at 37; *see also* Cohen et al., 31 RESEARCH POLICY at 1356-62; Ordover, 5 J. OF ECON. PERSP. at 48. Two other explanations that affected survey results – Japan's pre-grant opposition system and its publication of patent applications 18 months after filing, *see* Cohen 10/30 at 123; Cohen et al., 31 RESEARCH POLICY at 1356; Ordover, 5 J. ECON. PERSP. at 45-46 – may no longer be relevant. Japan has abandoned pre-grant opposition, and the United States has begun publishing most patent applications 18 months after filing.

[49] *See infra* Ch. 1(III)(A)(1). *See also* Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property,* 53 VAND. L. REV. 1727, 1729-38 (2000).

[50] Dam, 23 J. LEGAL STUDIES at 248; *see also* Langenfeld 2/20 at 10-13, 64-66 and James Langenfeld, *Innovation, Competition, and Intellectual Property: Providing an Economic Framework* (2/20/02) (slides) at 4 (arguing that strong IP rights reduce price competition, and that partial IP protection would maximize economic welfare), *at* http://www.ftc.gov/opp/intellect/langenfeld.pdf; Farrell 2/28 at 596 (stating that IP rights can come at the cost of monopoly price); Kushan 10/25 at 131 (inventors pursue patents to try to "exploit exclusivity to a commercial advantage"). Many other participants recognized such potential market power effects. *See, e.g.,* ABA (Economics stmt) 11 (describing the exercise of market power as a possible cost of patent protection); Stoner 2/26 at 108-09; Hall 2/26 at 181, 184; Farrell 2/28 at 596; Katsh 4/10 at 25-26; MacKie-Mason 5/1 at 171; Gambrell 10/25 at 38-39; Farrell 11/6 at 109-11; Ordover 11/6 at 114; Hans Lennros, *Question Regarding Competition & Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lennroshans.htm; *see also* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1821-23 (1984) (noting that "the patentee's reward is made possible through monopolistic restrictions" and discussing the difficulty of striking a balance between rewarding patent holders and limiting anticompetitive harm).

Moreover, in the rational exercise of its self-interest, a patentee may sue would-be rivals for infringement, deterring entry to compete. Patentee suits against entrants for infringement can "tax" entry.[51] The threat of being sued for infringement by an incumbent – even on a meritless claim – may "scare . . . away" venture capital financing.[52] Likewise, according to panelists, a patentee may prolong its market power by precluding access to technology necessary for the next generation of products to emerge.[53]

To the extent that the promise of patent protection is necessary to stimulate invention, disclosure, or investment, then society accepts these costs as necessary to maximize long-term economic welfare.[54] If the promise of patent protection is not necessary for those purposes, however, then the costs – which may include higher prices or retarded follow-on innovation – may cause unjustified injury to consumers.[55] "[T]his economy is founded on the privilege to compete. That is the fundamental, bedrock principle of our capitalist economy. . . . [W]e simply must be very concerned when we manipulate our markets to restrain competition."[56] For these reasons, one panelist cautioned that "[w]e should be wary of creating unwarranted market power by granting unwarranted patents."[57]

II. COMPETITION'S EFFECTS ON INITIAL AND FOLLOW-ON INNOVATION

Like patent policy, competition plays an important role in spurring the development of technologies and sequences of related, follow-on technology.[58] This section discusses how a greater level of competition can affect the level of innovation, holding patent policy constant.

Panelists noted that competition can spur innovation in several ways, but that economic theory and empirical evidence suggest that the effect of an increase in competition on innovation will vary from

[51] Lerner 2/20 at 158-61, 187; *see also* Weinstein 2/27 at 451-52 (discussing patents as barriers to entry); Stoner 10/30 at 9 (discussing patents as potential entry barriers); Stallman 4/9 at 21, 38 (arguing that patents can exclude firms from standards); Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J. LAW & ECON. 463, 465, 489-490 (1995) (finding that high litigation costs deter biotechnology firms from seeking patents when rivals already hold patents).

[52] Lerner 2/20 at 189.

[53] *See* Arrow 2/25 at 59-61, 64-65; *see also infra* Box 2-1.

[54] *See, e.g.,* Hall 2/26 at 181 (noting the trade-off between short-term monopoly in return for incentive to innovate and disclose); Lunney 7/10 at 97-98 (noting that traditional trade-off balances incentives to innovate against monopoly deadweight loss). *See also supra* Ch. 1(I)(C)(1)(a) (recognizing that statutory standards for patentability govern, and that in any event, it would not usually be possible to use a "but for" test for patentability).

[55] *See, e.g.,* Farrell 11/6 at 109-11 (noting that costs of temporary monopoly become a matter for concern if the patents in some sense are not valid or deserved); Farrell 2/28 at 596-97 (because protecting intellectual property is a "costly way" to stimulate innovation since it sometimes allows monopoly pricing, IP protection should be used "judiciously").

[56] Thomas 4/11 at 56.

[57] R. Levin 2/6 at 102.

[58] *See, e.g.,* Partha Dasgupta & J.E. Stiglitz, *Uncertainty, Industrial Structure and the Speed of R&D*, 11 BELL J. ECON. 1, 25 (1980) (finding that competition in research and development raises the level of R&D).

one context to another.[59] For example, some panelists stated that firms in a competitive market generally have greater incentives to innovate than a monopolist who does not face the threat of entry.[60] Likewise, competition may drive a race to innovate, spurring invention faster. The firm that innovates first may gain a patent that allows it to exclude others, or may reap the benefits of its work by taking advantage of its competitive lead (at least when, among other things, copying the innovation is expensive or time-consuming).[61] Some panelists critiqued – and others defended – the so-called Schumpeterian hypothesis that large firms innovate more than small firms, and that firms in concentrated markets innovate more than firms in competitive markets.[62] Finally, some noted that firms competing to innovate will approach research problems differently, increasing the chances of successful innovation.[63] There are costs and limits, however, to competition's power to spur innovation. Patent grants are sometimes crucial to avoiding the kind of free riding that could erode incentives to innovate.[64] Moreover, the innovation races that competition can incite can lead firms to duplicate each others' research, which some believe to be a wasteful process.[65] Each point is addressed in turn below.

A. Competition Can Spur Innovation, Whether Initial or Follow-On

1. Cannibalization

Competition can drive innovation, and its power to do so may depend on market structure. To be sure, even a monopolist that faces no competition has an incentive to innovate to expand the demand for its products and to reduce its costs. Other things being equal, however, a monopolist that does not face the threat of entry has less incentive to engage in costly R&D to develop new products than does a firm facing competition, some contend. To the extent that new products would cannibalize the monopolist's existing sales, the monopolist would be less likely to find R&D expenditures worthwhile, they maintain.[66] By contrast, firms in a competitive market have incentives to innovate in hopes of acquiring market power, some argue.[67] Similarly, the monopolist that does face a threat of entry may have more incentive to invest in R&D

[59] *See, e.g.,* Nelson 2/20 at 123-36 (summarizing the literature and concluding that "there is no simple relationship").

[60] *See infra* Ch. 2(II)(A)(1) (discussing cannibalization).

[61] *See infra* Ch. 2(II)(B)(2) (discussing races to innovate).

[62] *See infra* Ch. 2(II)(B)(3) (discussing Schumpeterian hypothesis and its critics).

[63] *See infra* Ch. 2(II)(A)(4) (discussing diversity of R&D efforts).

[64] *See infra* Ch. 2(II)(B)(1) (discussing appropriability problems).

[65] *See infra* Ch. 2(II)(B)(2) (discussing duplication of effort).

[66] *See generally* Kenneth J. Arrow, *Economic Welfare & the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609, 619 (1962), Nelson 2/20 at 126.

[67] *See, e.g.,* Shane Greenstein, *Market Structure and Innovation: A Brief Synopsis* (2/20/02) (slides) at 2, *at* http://www.ftc.gov/opp/intellect/greenstein.pdf (hereinafter Greenstein Presentation).

than a prospective entrant would have, because the monopolist may have more to lose from entry than a potential entrant has to gain.[68]

2. Races to Innovate

The role of competition in stimulating R&D expenditures is perhaps most obvious when there is a race to patent, as, for example, when two companies are attempting to solve the same problem and the one that solves it first can win a patent and exclude the other from the market. Lured by this possibility, potential inventors may race to innovate.[69]

A number of studies have examined different settings where competitors race to achieve innovations and have concluded that the results vary by context. For example, analyses indicate that the effects of competition on innovation will vary according to the nature of the inventive process[70] and a firm's efficiency level relative to that of its rivals.[71] One commentator who has studied the disk drive industry has concluded that its patterns regarding competition and innovation show that "firms that trail the leader innovate more."[72] On the other hand, some state that races to innovate may lead to wasteful expenditures and risky cutting of corners, and they are not necessarily efficient.[73]

Some panelists observed that when imitation is costly or time-consuming, a firm can reap substantial benefits from innovation by exploiting its head start on competitors to further develop the innovation and the means to market it. It might enjoy a short-term monopoly on the innovation until other firms can copy it, and even after they enter, the innovator's established position may help it maintain market share.[74] In some industries, it is enough if an innovation "permit[s] the firm to reach the market first with a product (or in most industries a new

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[68] *See, e.g.,* Greenstein 2/20 at 140-141; Greenstein Presentation at 2; FTC Staff Report, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace*, Ch. 6, p. 12, n. 54 (May 1996) (summarizing testimony of Prof. Carlton that monopolists who fear the loss of their monopoly profits have an even greater incentive to innovate than a competitive firm), *available at* http://www.ftc.gov/opp/global/report/gc_v1.pdf.

[69] *See, e.g.,* GEORGE E. FROST, THE PATENT SYSTEM AND THE MODERN ECONOMY, STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 84TH CONG., 2D SESS. 34 (Comm. Print 1957).

[70] *Compare* Richard J. Gilbert & David M. G. Newbery, *Preemptive Patenting and the Persistence of Monopoly*, 72 AM. ECON. REV. 514, 515-17 (1982) (arguing that when invention follows without uncertainty from investment, a monopolistic incumbent has an incentive to out-bid entrants in a race to invent) *with* Jennifer Reinganum, *Uncertain Innovation and the Persistence of Monopoly*, 73 AM. ECON. REV. 741 (1983) (arguing that with uncertainty in the relationship between investment and the success of innovation efforts, potential entrants have greater incentives than incumbents to seek "drastic" (revolutionary) innovations).

[71] *See, e.g.,* Jan Boone, *Competitive Pressure: The Effects on Investments in Product and Process Innovation*, 31 RAND J. ECON. 549 (2000).

[72] Josh Lerner, *An Empirical Exploration of a Technology Race*, 28 RAND J. ECON. 228 (1997).

[73] *See infra* Ch. 2(II)(B)(2).

[74] *See, e.g.,* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCIENCE 173, 176 (1986) (noting that patents might not seem worthwhile in industries in which imitation is costly or difficult); Stoner 2/26 at 111 (noting that a simple head start on a product can yield large profits); Michael L. Katz & Carl Shapiro, *Systems Competition and Network Effects*, 8 J. ECON. PERSP. 93, 105-07 (1994).

feature of an established product); other firms are sure to follow, but only after the time required for copying or reverse engineering."[75]

Empirical study has shown that in some industries, firms often innovate to exploit first-mover advantages, learning-curve advantages, and other advantages, not to gain patent protection. One early study showed that in only two of the twelve surveyed industries – pharmaceuticals and chemicals – did the firms believe patents to be essential for developing or introducing thirty percent or more of the inventions.[76] "[I]n office equipment, motor vehicles, rubber, and textiles, the firms were unanimous in reporting that patent protection was not essential for the development or introduction of any of their inventions during this period."[77] By contrast, pharmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection.[78] A later study found that lead time, learning curve advantages, complementary sales or service efforts, and secrecy were all more effective means of protecting the competitive advantages of new processes than patents were.[79] With regard to new products, patents ranked ahead of secrecy but behind the other three mechanisms.[80] Again, the results showed substantial variation among industries, with patents proving particularly useful with regard to pharmaceutical drugs, pesticides, and industrial organic chemicals.[81]

The most recent study confirms the earlier findings; it found that patents trailed secrecy, lead time, investments in complementary manufacturing capabilities, and investments in complementary sales and services as appropriability mechanisms that businesses preferred.[82] "[P]atents are unambiguously the least central of the major appropriability mechanisms overall," the study concludes.[83] Again, patent significance varied sharply by industry. For example, in the medical equipment and pharmaceutical drug industries patents were effective appropriability mechanisms for more than 50% of all product innovations, but for semiconductors and communications equipment patents were effective less than

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[75] Dam, 23 J. LEGAL STUDIES at 263.

[76] *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCIENCE 173 (1986). This study involved a random sample of 100 firms (excluding very small firms) from twelve broadly defined industries from 1981-1983.

[77] *Id*. at 174.

[78] *Id.* at 175.

[79] *See* Richard C. Levin et al., *Appropriating the Returns from Industrial R&D*, *in* BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783 (1987). This study analyzed survey responses from 650 R&D managers representing 130 lines of business.

[80] *Id*. at 794-95.

[81] *Id*. at 795-96.

[82] *See* W.M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Econ. Research Working Paper No. 7552, 2000), *at* http://papersdev.nber.org/papers/w7552 (hereinafter COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS).

[83] *Id*. at 9 (discussing product innovations), Figures 1 and 2 (reporting similar results for product and process innovations).

Box 2-1. ***Competition for monopoly.*** Allowing price to rise above marginal cost through a succession of temporary monopolies can spur dynamic competition, some have asserted. Some analysts argue that rapid innovation, increased importance of declining average costs, and network externalities have created conditions ideal for "dynamic" competition for monopoly, in which temporary monopolies rise and fall in the rhythms of rapid entry and exit. *See, e.g.*, Janusz A Ordover, *Antitrust for the New Economy or New Economics for Antitrust* (2/20/02) 5, *at* http://www.ftc.gov/opp/intellect/020220januszordover.pdf (hereinafter Ordover (stmt)); Richard A. Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, 929-30 (2001). This type of competition can increase innovation, according to some observers. Low barriers to entry are critical to many of these analyses. As noted above, several observers have stated that a monopolist threatened by entry has more to lose than any potential entrant has to gain and will therefore invest more in innovation. *See* Greenstein 2/20 at 140-141; DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 538-40 (3rd ed. 1999). *See generally* Dasgupta & Stiglitz, 11 BELL J. ECON. at 25 (finding that the threat of entry may lead a monopolist to increase the pace of research). Another panelist explained that an incumbent monopolist can create barriers to entry by acquiring broad patents on critical technology. The very existence of such barriers to entry may have offsetting effects, however, because the value of winning the better-protected monopoly rises and the prospect of successful entry becomes more attractive. Kenneth Arrow, *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (2/25/02) 1, *at* http://www.ftc.gov/opp/intellect/020225kennethjarrow.pdf; Arrow 2/25 at 64-65.

27% of the time.[84]

These points do not suggest that patents are unimportant. Research regarding the relationship between patent effectiveness and R&D investments indicates that "[w]hile patents are not as featured as other mechanisms, they do stimulate R&D broadly, though more in some industries than others."[85] These three studies do suggest, however, that competition also plays an important role in spurring innovation.[86]

3. Schumpeterian Hypothesis and its Critics

Panelists debated the hypothesis, originally espoused by Joseph Schumpeter, that "large and often monopolistic enterprises" are "the principal engines of technological progress."[87] Participants discussed two dimensions of Schumpeter's hypothesis: larger firms innovate more than smaller firms, and firms in concentrated markets innovate more than firms in competitive markets.[88] Economists developing Schumpeter's ideas have noted that

[84] *Id.* at Table 1.

[85] Cohen 2/20 at 43. *See* ASHISH ARORA ET AL., R&D AND THE PATENT PREMIUM 35 (National Bureau of Econ. Research Working Paper No. 9431, 2003), *at* http://www.nber.org/papers/w9431. For evidence of a strong correlation between R&D investment and patenting activity, *see* Zvi Griliches, *Patent Statistics as Economic Indicators: A Survey*, 28 J. OF ECON. LITERATURE 1661, 1673-74 (1990); *see also* Evenson 2/20 at 51-52 (surveying international data).

[86] *Cf.* Hoerner 7/11 at 54 (stating that many companies would engage in the same level of R&D even without the patent system, because they must innovate to continue offering products that attract consumers away from rivals).

[87] *See* JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY (1942); *see also* DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 532-33 (3rd ed. 1999); Jennifer Reinganum, *The Timing of Innovation: Research, Development, and Diffusion*, *in* 1 HANDBOOK OF INDUSTRIAL ORGANIZATION 849 (Richard L. Schmalensee & Robert D. Willig, eds. 1989).

[88] ABA (Economics stmt) 29.

economies of scale may make innovation less costly for a large firm.[89] Specifically, they contend, large firms sponsoring considerable R&D can reduce the marginal costs of innovation by using "more specialized resources;" can spread the fixed costs of any R&D over a wider base of output; can spread the risk of unsuccessful R&D efforts by sponsoring many R&D projects simultaneously; and have access to inexpensive investment capital, drawn from the firm itself or from capital markets.[90] Moreover, some commentators state that large firms benefit from their own innovative efforts more than smaller firms do: large firms can apply their process innovations to large production operations, gaining greater savings; the chances that an innovation will be useful to one of their many businesses is greater; and their abilities to market their innovations to others may be greater.[91] Studies also have revealed a positive correlation between concentration and industry R&D/sales ratios, although that correlation may break down at high levels of concentration.[92]

Some panelists critiqued the Schumpeterian hypothesis directly. They noted, for example, that venture capital breaks the link between innovation and the financial resources of a firm, undermining the argument that large firms have unique access to investment capital.[93] Moreover, a number of studies have found that R&D spending rises proportionally to firm size in most industries, but that R&D spending by large firms generates less innovation per dollar than does spending by smaller firms.[94] And some have stated that the weight of economic theory and evidence shows that there is a non-linear, inverted-U-shaped relationship between concentration and innovation. In their view, low concentration may not be conducive to innovation, but "very high concentration has a positive effect only in rare cases, and more often it is apt to retard progress by restricting the number of independent sources of initiative and by dampening firms' incentive to gain market position through accelerated R&D."[95] Under this view, "[w]hat is needed for rapid technical progress is a subtle blend of competition and monopoly, with more emphasis in general on the former than the latter, and with the role of monopolistic elements diminishing when rich technological opportunities exist."[96]

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[89] *Id*.

[90] *Id*. at 29-30.

[91] *See, e.g., Id.* (summarizing these arguments).

[92] *See, e.g.,* F.M. SCHERER & DAVID ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 646 (3d ed. 1990). For a discussion of the possible implications of Schumpeterian theories for dynamic competition for monopoly, *see* Box 2-1.

[93] *See, e.g.,* Teece 2/26 at 195; SCHERER & ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 630, 652 (noting that growth of a venture capital industry in United States that can "channel[] investment into new high-technology firms shows that past monopoly profits are no *sine qua non* for supporting innovation").

[94] *See* Wesley Cohen *&* Steven Klepper*,* A *Reprise of Size and R&D*, 106 ECON. J. 925, 927-30 (summarizing prior research), 947 (suggesting that large firms may have greater incentives to undertake marginal research projects) (1996); *see also* Shelanski 2/25 at 25-36 (critiquing Schumpeter theory and noting lack of good empirical support).

[95] SCHERER & ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 660.

[96] *Id.*

Other panelists contended that the Schumpeterian hypothesis is true for some industries and markets but not true in others. For example, one panelist stated that industry conditions are so varied that it would be surprising to find a "simple Schumpeterian relationship" across all industries.[97] Likewise, another panelist stated that "result[s] vary a lot depending on the structure and nature of the industry."[98] Indeed, two studies that controlled for inter-industry differences found reason to question various facets of the Schumpeterian hypothesis.[99] In a similar vein, some have suggested that policymakers examine "the relationship between concentration, R&D activity, and innovation" in particular industries, because "industries probably vary too much for one theory to fit all."[100]

Statistical cross-section studies examining multiple industries have not identified any clear relationship between concentration and innovation.[101] To the contrary, many studies seem to suggest that the effect of concentration on innovation depends on many factors.[102] For example, some statistical evidence suggests that the existence of an inverted-U relationship between concentration and innovation depends on industry characteristics.[103] Some

[97] Nelson 2/20 at 132-36.

[98] Rubinfeld 2/25 at 20.

[99] *See* Wesley Cohen et al., *Firm Size and R&D Intensity: A Re-examination*, 35 J. INDUS. ECON. 543, 543-544 (1987) (questioning linkage between firm size and intensity of R&D); P.A. Geroski, *Innovation, Technological Opportunity, and Market Structure*, 42 OXFORD ECON. PAPERS 586, 586 (1990) (finding, based on data from the United Kingdom and a variety of measures of market structure, "fairly strong evidence against the hypothesis that increases in competitive rivalry decrease innovativeness").

[100] DENNIS W. CARLTON & ROBERT H. GERTNER, INTELLECTUAL PROPERTY, ANTITRUST AND STRATEGIC BEHAVIOR 14 (National Bureau of Econ. Research Working Paper No. 8976, 2002), *at* http://www.nber.org/papers/w8976.

[101] *See, e.g.,* Gilbert 2/25 at 12-14; SCHERER & ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 645-51 (noting that some statistical evidence points to a positive relationship between industry concentration and R&D/sales ratios, although that correlation may break down at high levels of concentration); Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569 (1995) (stating that firm- and industry-specific factors complicate the relationship between concentration and innovation); Richard Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 ANTITRUST L.J. 19 (1995) (citing the inconclusive economic literature on the relationship between concentration and innovation); Richard J. Gilbert & Steven C. Sunshine, *The Use of Innovation Markets: A Reply to Hay, Rapp, and Hoerner*, 64 ANTITRUST L.J. 75, 76-77 (1995) (suggesting that industry-specific factors obscure the statistical relationships); Shelanski 2/25 at 32 (stating that the "empirical data do not resolve any of the ambiguity in the relationship between competition and innovation," and that the "empirical evidence is really quite ambivalent").

[102] *See, e.g.,* Gilbert & Sunshine, 64 ANTITRUST L.J. at 76-77 (stating that "many factors influence the incentive to invest in the development of new products and processes").

[103] *See, e.g.,* SCHERER & ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 645-51 (noting that including variables such as R&D performed outside the industry, the pace of innovation, and the strength of appropriation mechanisms weakens the inverted-U relationship in some industries, which points to the importance of firm and industry effects in qualifying the relationship), Nelson 2/20 at 128 (noting potential data and statistical problems with at least some of the studies that have found inverted-U relationships). For a recent working paper finding inverted-U relationships in data involving United Kingdom firms, *see* PHILIPPE AGHION ET AL., COMPETITION AND INNOVATION: AN INVERTED U RELATIONSHIP (National Bureau of Econ. Research Working Paper No. 9269, 2002) (describing the inverted-U

Box 2-2. ***Additional Pricing Strategies.*** Panelists described a number of non-patent pricing strategies that firms may use to recoup fixed costs, including R&D spending.

Long-run average costs. One panelist noted that firms with declining average costs will not price at marginal cost because they must recover their substantial fixed costs. Ordover (stmt) 2. Another panelist echoed that a firm charging a flat price must set it higher than marginal cost if it has returns to scale. Varian 2/25 at 76. One panelist suggested that long-run average costs may be a useful analytical benchmark, but added that it is difficult to determine which of a firm's fixed costs correspond to individual products and that some temporary returns in excess of that benchmark may be necessary for adequate incentives to innovate. *See* Ordover (stmt) 3.

Price discrimination. Some maintain that, rather than use constant per-unit prices, firms have begun to adopt more "sophisticated" models of pricing – such as volume or loyalty discounts, bundling, and self-selective price discrimination – as a means of covering substantial up-front investments, such as R&D spending. *See* Varian 2/25 at 76-79.

industry case studies indicate that competition drives innovation in particular industries.[104]

4. Diversity of R&D Efforts

Several panelists discussed the importance of diverse research efforts in producing innovation. One panelist noted that when many firms devote R&D efforts to tackling the same problem, the public benefits.[105] Likewise, another panelist noted that "if you have fewer innovators [and] less diversity, you are likely to have less innovation or higher prices or lower quality products."[106] He illustrated his point by discussing a proposed merger that, he stated, might have stifled innovation in a market "where the strategy of innovation is highly unpredictable [and where] path-breaking innovations . . . are made by niche players and not by the leading incumbents."[107] Indeed, some commentators have observed that under certain conditions, rates of innovation are positively correlated with rates of entry.[108] Nevertheless, others suggested that the ability of diverse R&D efforts to affect innovation depends on a key industry

relationship), *at* http://nber.org/papers/w9269.pdf.

[104] *See, e.g.*, Lerner, 28 RAND J. ECON. at 244 (empirical study of the computer disk drive industry showing that "the greatest innovative activity is shown by firms that follow the leader"); Gilbert 2/25 at 12 (noting that the correlation between competition promoting innovation characterizes "almost any [sector of] the software industry," including operating systems and Internet browsers, as well as semiconductors); Gilbert & Sunshine 63 ANTITRUST L.J. at 580-81 (noting evidence and industry case studies that "support the stronger conclusion that protection from competition i[s] inimical to technological progress"); MICHAEL E. PORTER, THE COMPETITIVE ADVANTAGE OF NATIONS 143 (1990) ("[R]ivalry has a direct role in stimulating improvements and innovation").

[105] *See* Arrow 2/25 at 58-59 (stating that "diversity is good" with respect to "differing sources of R&D"); *see also* Thomas M. Jorde & David J. Teece, *Innovation and Cooperation: Implications for Competition and Antitrust*, 4 J. ECON. PERSPECTIVES 75, 81 (1990) (acknowledging that "horizontal cooperation" in research "may reduce diversity").

[106] Rubinfeld 2/25 at 19.

[107] Rubinfeld 2/25 at 22-23; *see also* Daniel Rubinfeld & John Hoven, *Innovation and Antitrust Enforcement*, *in* DYNAMIC COMPETITION AND PUBLIC POLICY 65, 87-88 (Jerry Ellig, ed. 2001) (noting need for diversity of innovation).

[108] *See* James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* (Public Comment) 13-15, *at* http://www.ftc.gov/os/comments/intelpropertycomments/jimbessenericmaskin.pdf (hereinafter Bessen & Maskin (stmt)).

characteristic: the predictability of subsequent R&D paths.[109]

B. Costs Of, and Limits To, Competition's Power to Spur Innovation

1. Appropriability Problems

As discussed above, however, panelists noted that competition cannot serve as the sole driver of innovation. Inventors sometimes cannot appropriate value from the invention without the grant of a patent, making patents an important incentive for innovation in such settings.[110]

2. Duplication of Effort

Some analysts have underscored one of the costs of competition to innovate: duplication of effort involved in parallel research efforts.[111] "Independent research activities often proceed down identical or near-identical technological paths," making a policy of encouraging diversity in R&D paths unhelpful, in their view.[112] They argue that excess efforts at innovation generate "wasteful patent race[s] to be the first successful inventor."[113]

Yet what some deem wasteful duplicative efforts is what others deem useful competition.[114] Firms compete via their R&D efforts, and such competition generates better consumer products and lower prices, benefits that may outstrip any social loss from the patent race, some observe.[115] Some have noted that the benefits accruing from diverse efforts at innovation may outweigh the waste involved in competitive innovation.[116] They argue that the potential wastefulness of parallel R&D efforts should not influence public policy decisions:

> [W]e do not normally consider the opening of a new gasoline station or grocery store near an existing one to be an example of waste, or at least not one with which public policy should be concerned, even though we believe that only one can survive and we know that some economic rent of location may accrue to the survivor. Rather, we consider the competition induced by the new entrant to lead to a better outcome

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[109] *See infra* Ch. 2(III)(A)(1).

[110] *See supra* Ch. 2(I)(A) (discussing patents' power to internalize externalities and protect against free riding). For a discussion of non-patent pricing strategies that firms may use to recover fixed research and development costs, *see* Box 2-2.

[111] *Cf.* William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J. LAW & ECON. 265, 267-68 (1987) (arguing that rent seeking is as wasteful as having many parties search for lost treasure).

[112] Jorde & Teece, 4 J. ECON. PERSPECTIVES at 81.

[113] Stoner 2/26 at 108-09; *see also* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation,* 78 VA. L. REV. 305, 308 (1992) (positing that competition to be the first to develop pioneer and follow-on innovations causes overinvestment that "dissipates," or eliminates, the benefit to society of the innovation or its improvement).

[114] *See, e.g.,* Dam, 23 J. LEGAL STUDIES at 263 (making this point).

[115] *See, e.g.,* Dam, 23 J. LEGAL STUDIES at 252, 263.

[116] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 873, 877 (1990).

than would accrue thorough legal protection of the exiting firm. So, too, we cannot have much confidence that some of the natural alternatives to competition in R&D would increase social welfare.[117]

III. PATENTS' EFFECTS ON FOLLOW-ON INNOVATION

Finally, it is appropriate to address the effects of patent grants on *follow-on* innovation. Innovation is often an ongoing, cumulative process, with each generation of innovations building on what came before.[118] For example, knowledge gained through basic research may serve as a foundation for subsequent applied activities; new products or services may go through multiple generations of improvements and extensions of use; initial research may produce tools – from laser technology through specialized software programs and isolated, purified genetic material – that follow-on research then applies to develop products and services for end-use consumers. In each case, the question arises whether policies and laws suitable for fostering a single generation of inventions also maximize welfare in the more dynamic, cumulative innovation settings actually observed. This section explores these issues.

First, this section identifies the relative strengths and weaknesses of follow-on innovation organized by the initial innovator versus that conducted by independent innovators. On the one hand, some argued that strong initial patent rights can facilitate follow-on innovation by, or under the management of, the initial innovator. For example, some have contended that broad initial patent grants can allow the original patentee to organize its licensees' research into the patent's prospects, avoiding wasteful patent races.[119] Others, however, disagreed, stating that subsequent researchers acting independently of the original inventor and competing against each other may foster greater innovation – and may have less market power in any resulting innovation.[120]

Second, this section considers the implications for independent follow-on innovation of a single, blocking, initial patent. Sometimes the follow-on innovator will seek to design around the initial patent, potentially generating new technologies, but also incurring R&D costs.[121] Other times the follow-on innovator will license the patented technology. This section examines the division of rewards between initial and follow-on innovators through such licensing and considers some of the impediments that might interfere with achieving licensing arrangements that adequately reward both generations of innovators.[122]

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[117] Dam, 23 J. LEGAL STUDIES at 263.

[118] *See, e.g.,* ABA (Economics stmt) 20, 24; Lemley 2/25 at 37; Scotchmer 2/26 at 128-29; Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

[119] *See infra* Ch. 2(III)(A)(1) (discussing follow-on innovation organized by the initial innovator).

[120] *See infra* Ch. 2(III)(A)(2) (discussing follow-on activities by independent follow-on innovators).

[121] *See infra* Ch.2(III)(B)(1) (discussing design-around innovation).

[122] *See infra* Ch.2(III)(B)(2)-(3) (discussing division of rewards and licensing).

Finally, this section considers implications for follow-on innovation in the face of multiple existing patents. Sometimes, the need to attain access to multiple existing patents in the hands of multiple patentees can pose difficulties for independent follow-on innovators. This problem may flow just from the transaction costs of negotiating multiple licenses.[123] Moreover, the necessary patents may be too numerous to identify and license; follow-on innovators may almost inevitably risk suit for infringement once they sink costs into their research or production efforts.[124] An additional problem may affect the level of the multiple royalties: the patentees, acting independently, may seek a higher total royalty than would a single patentee charging a package price.[125] Furthermore, some argue that oligopolists holding a collection of necessary patents can injure and block follow-on innovation by refusing to license, or charging high royalty rates, to entrants.[126] A patentee may use multiple patents on near substitutes for its original work to retard independent follow-on innovation and impede entry, some contend.[127] Finally, some suggest that, under certain conditions, the initial innovator's rivals might use multiple patents on trivial variants to constrain the initial innovator's future development efforts and force it to license away its technology.[128] Each point is discussed in turn below.

A. The Roles of Managed and Independent Follow-On Innovation

Panelists discussed follow-on innovation from the perspective of two general models. Under one model, follow-on innovation proceeds under the control and management of the initial innovator. That innovator might conduct follow-on activities itself. It also might effectively "hire" others to do some of the follow-on work, licensing them to use its technology for follow-on research and development. Both mechanisms are forms of "managed" follow-on innovation. Alternatively, follow-on activity may proceed independently of the initial innovator's coordination or control, with an array of outside researchers each seeking to build upon prior discoveries, a model that this Report terms "independent follow-on innovation." When a prior discovery is patented, an independent follow-on innovator may need a license, and the patentee may or may not wish to grant it.

1. Follow-On Innovation Organized by the Initial Innovator

In some instances, an initial innovator with a broad patent covering future development opportunities might pursue, or organize others to pursue, the follow-on innovations. Professor Edmund Kitch emphasized several advantages of such arrangements. Broad, initial patent

[123] *See infra* Ch.2(III)(C)(1) (discussing transaction costs).

[124] *See infra* Ch.2(III)(C)(2) (discussing hold up in the patent thicket).

[125] *See infra* Ch.2(III)(C)(3) (discussing royalty stacking and the Cournot complements problem).

[126] *See infra* Ch.2(III)(C)(4) (discussing oligopoly and group boycotts).

[127] *See infra* Ch.2(III)(C)(5) (discussing patent fences).

[128] *See infra* Ch.2(III)(C)(6) (discussing patent flooding).

rights can protect appropriability, not just for initial inventions but for the full range of follow-on activities needed to bring products to market. Broad initial patent rights enable the innovator to provide efficient, central management of the subsequent development efforts, avoiding unnecessary duplication of R&D activity and wasteful racing for follow-on patent rights. Broad initial patent rights permit innovators to disclose information without fear of free riding, thereby facilitating access to financing, complementary technology, and specialized supplies.[129]

These considerations are key elements of what has come to be known as the "prospect theory" of patent rights. The prospect theory focuses on exploration of technological opportunities, referred to as "prospects."[130] It emphasizes the effect of patents on commercialization, as opposed to a view that emphasizes the effect of patents on incentives to invent. Its perspective is forward looking, focusing on the efficient coordination of, and incentives for, follow-on activities.[131]

Several panelists identified potential shortcomings of this prospect theory. Some questioned whether initial innovators are likely to provide effective central management;[132] no one decision maker may have the range of knowledge necessary to choose the best follow-up opportunities or to select the ideal follow-up researchers.[133] Others noted that the theory depends on efficient licensing of follow-on opportunities, but that licensing negotiations may be lengthy and costly or break down due to differences in valuations.[134] Still others stressed that the efficiencies realized may be private, not social – arguing that follow-on patent races, although costly, may benefit consumers by yielding products sooner and with more certainty, and that coordination may eliminate desirable

[129] *See* Kitch 2/20 at 79-87; Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. LAW & ECON. 265 (1977). According to Professor Kitch, a broad patent places its owner in a position "to coordinate the search for technological and market enhancement of the patent's value so that duplicative investments are not made and so that information is exchanged among the searchers." *Id*. at 276. Broad patents also permit the owner "to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors." *Id*. at 276.

[130] *See* Kitch, 20 J. LAW & ECON. at 266.

[131] *See id*.; Scotchmer 2/26 at 129.

[132] *See, e.g.,* Lemley 2/25 at 37-38 (central management by initial innovator an unwise "gamble" when innovation is likely to be cumulative); Frederick M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348, 1362 (2002).

[133] *See, e.g*., Rubinfeld 2/25 at 20 ("very hard ex ante to know who is going to be successful"); *see also* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1048-52 (1997); Merges & Nelson, 90 COLUM. L. REV. at 873 ("[N]o one knows for sure what possible inventions are in the technological pool. . . . The only way to find out what works and what does not is to let a variety of minds try."); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1066-69 (1989) (arguing that central management by an initial innovator is least likely to be successful when follow-on research is likely to "lead[] down unexpected paths" and when it "depends on insights and creativity that may differ from one investigator to the next, " and concluding from this that the prospect theory may work better in contexts involving applied, rather than basic, research).

[134] *See, e.g.,* O'Rourke 2/20 at 98; Hall 2/26 at 182-83; Merges & Nelson, 90 COLUM. L. REV. at 874-75 (noting the "steep transaction costs of technology licensing"); *see also infra* Ch. 2(III)(B)(3). Professor Kitch acknowledged these concerns but argued that the fact that negotiation sometimes breaks down or proves costly does not reveal how well the process works as a whole. Kitch 2/20 at 109.

competition in the market for follow-on products.[135]

2. Follow-On Activities by Independent Follow-On Innovators

Follow-on innovation often proceeds through the activities of inventors independent of the initial innovator.[136] Independent follow-on innovation has all of the potential benefits identified *supra* in Ch. 2(II)(A), discussing the role of competition in spurring innovation. Competition may prod follow-on innovation efforts to proceed more quickly.[137] It may foster greater diversity of R&D activity, providing broader range for identifying research opportunities, designing and pursuing research paths, and recognizing and acting upon the implications of research results.[138] It may overcome biases in the initial innovator's choice of follow-on research projects attributable to its firm-specific skills or investments in complementary assets.[139] When research is complete and follow-on products enter the market, their derivation from independent lines of development may result in less market power than when the initial innovator controls follow-on innovation.[140]

Independent follow-on innovation, of course, might entail substantial duplication of effort.[141] Some scholars condemn this duplication as wasteful, rent-seeking activity. Professor Mark Grady, for example, explains that when an initial innovation signals opportunities for follow-on inventions, hopeful inventors may "redundantly waste efforts to find and capitalize on that method of improvement."[142] Others caution, however, that what to the firms involved is wasteful duplication of effort may have social benefit.[143] As Professor Suzanne Scotchmer explained, coordinating follow-on activities

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[135] *See* Scotchmer 2/26 at 136-39; Suzanne Scotchmer, *Competition Policy and Innovation: The Context of Cumulative Innovation* (2/26/02) (slides) at 7, *at* http://www.ftc.gov/opp/intellect/020226suzanneandersonscotchmer.pdf (hereinafter Scotchmer 2/26 Presentation); Bessen & Maskin (stmt) 4 ("increasing the number of firms in pursuit of a solution raises the probability that *someone* will succeed") (emphasis in original).

[136] Indeed, one analyst finds independent follow-on efforts the predominant pattern. *See* Scherer, 77 ACADEMIC MEDICINE at 1362 ("It is more the norm than the exception in the history of technology for the firms introducing significant derivatives of and improvements upon a basic discovery to be other than the original discoverer.").

[137] *See* Scotchmer 2/26 at 137-38.

[138] *See, e.g.,* Arrow 2/25 at 58-59; Barton 2/26 at 172-73.

[139] *See generally* Gilbert & Sunshine, 63 ANTITRUST L.J. at 577; Merges & Nelson, 90 COLUM. L. REV. at 873 ("Once a firm develops and becomes competent in one part of a 'prospect,' it may be very hard for it to give much attention to other parts, even though in the eyes of others, there may be great promise there.").

[140] Scotchmer 2/26 at 136-39 and Scotchmer 2/26 Presentation at 7.

[141] *See* Stoner 2/26 at 112-13; Kitch, 20 J. LAW & ECON. at 276. *See also supra* Ch. 2(II)(B)(2).

[142] Grady & Alexander, 78 VA. L. REV. at 308. The authors argue that many aspects of patent law can be explained as reflecting a desire to limit rent dissipation. *Id.* at 308-10. They note, though, that this effort may prove complex: a system that awards a broad initial patent to discourage wasteful follow-on races could unintentionally encourage duplicative efforts to win the initial patent. *Id.* at 308 ("The obvious compromise is to grant protection broad enough to prevent a race to improve . . . but not so broad as to create wasteful races for other patent goldmines.").

[143] *See supra* Ch. 2(II)(B)(2).

by eliminating patent races may increase the research firms' profits but harm consumers. "[T]ypically, the patent race will get us the product sooner, and may get us the product with higher probability," she stated.[144] Over all, the debate suggests that duplication may entail elements of both social benefit and undesirable waste.[145]

B. Follow-On Innovation in the Face of a Single Blocking, Initial Patent

The Hearings identified two distinct sets of issues that the patent system raises for independent follow-on innovation. First, initial innovation may give rise to individual patents that block certain follow-on activities. This section discusses two potential responses: (i) directing follow-on innovation around the blocking patent or (ii) negotiating with the initial patentee for a license to permit the follow-on activities to go forward. Second, in some settings, follow-on activities may require numerous, distinct pieces of patented technology to proceed; the special problems this may pose here are analyzed *infra* in Chapter 2(III)(C).

1. Design-Around Innovation

Several panelists stressed that a significant benefit of the patent system is its role in directing R&D away from imitation by forcing competitors to design around existing patents. In the long run, they argued, re-directing R&D toward more innovative goals encourages greater technological progress.[146] One panelist, for example, explained that patent protection of the ulcer-treating drug Tagamet forced design-around efforts that led to the development of another successful drug, Zantac;[147] others cited Xerox's photocopying technology, which developed out of an effort to design around Kodak's silver halide photography patents and which, in turn, gave impetus to design-around research that generated ink-jet technology.[148]

Other panelists pointed to the design-around theory's limits. In some settings design-around may be technically impossible.[149] In other settings, such as

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[144] Scotchmer 2/26 at 137 (terming this "a conflict between the private incentives to cut back on R&D and the social incentives").

[145] A focus on duplicative research efforts reveals both facets. On the one hand, Professor Rebecca Eisenberg finds merit in overlapping research, arguing that "different investigators are likely to make different observations and have different ideas for follow-up experiments, improving the chances for serendipitous discoveries" and that "[e]ven completely duplicative research efforts may serve a valuable function by confirming research results and enhancing the likelihood that a discovery will be noticed." *See* Eisenberg, 56 U. CHI. L. REV. at 1068-69. On the other hand, Professor Kitch finds unnecessary waste when initial research is kept secret and follow-on researchers must tread the same ground without knowing of or learning from the prior failed efforts. *See* Kitch, 20 J. LAW & ECON. at 276.

[146] *See, e.g.,* Myrick 3/19 at 20 and 10/30 at 40-42; Frankel 4/10 at 7; Banner 10/30 at 71; Frederick J. Telecky, *Statement of Frederick J. Telecky, Jr., Senior Vice President and General Patent Counsel, Texas Instruments: FTC/DOJ Hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy"* (2/28/02) 3, *at* http://www.ftc.gov/opp/intellect/020228telecky.pdf (hereinafter Telecky (stmt)).

[147] *See* Armitage 3/19 at 230.

[148] *See* Varian 2/25 at 94; Sobel 7/10 at 175.

[149] *See, e.g.,* Barr 10/30 at 90 (broad patents can prevent design-around); Detkin 2/28 at 668 ("unavoidable overlap of IP" in semiconductor technology); Richard Stallman, *The Danger of Software Patents Speech by Richard Stallman at Cambridge University, March 25 2002* (Public Comment) 4 ("no way around that patent. . . . nothing else you could do like that"), *at* http://www.ftc.gov/os/comments/intelpropertycomments/st

when the patented technology is needed to conform to a standard or consumers are otherwise locked in or when the infringing approach is already built into a competitor's product before the patent issues, design-around may be economically impossible.[150] In still other contexts the design-around may add little value, merely requiring that competitors "work harder to get to the same place."[151] Indeed, analysts emphasize that design-around is not costless, but rather consumes resources that, absent the initial patent, might be more fruitfully employed.[152] Without a clear basis for assessing the net value of design-around activity, general conclusions are difficult.

2. Division of Rewards

Rather than designing around an initial patent, an independent follow-on innovator may acquire a license to the patented technology and proceed with development of products or processes within the patent's coverage. In such cases, the division of rewards between the initial and follow-on innovators becomes crucial, because it determines the level of incentives for each generation of innovation. The initial innovation provides a benefit to the follow-on innovator, and the full social benefit of the initial innovation includes a portion of the follow-on benefits that it confers. Consequently, providing the initial innovator some share in the returns from the follow-on activity may be efficient.[153]

Optimal sharing arrangements, however, may prove elusive, for shifting rewards from one generation to another may reduce incentives at the disadvantaged generation. "The challenge is to reward early innovators for the technological foundation they provide to later innovators, but to reward later innovators adequately for their improvements and new products as well."[154]

Royalty payments from the follow-on innovator are a means for implementing the sharing arrangements. Standards of patentability, discussed in Chapter 4, shape the backdrop against which licensing

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[150] *See, e.g.,* Stallman 4/9 at 19, 88-89; Barr 10/30 at 79.

[151] *See* Stallman 4/9 at 38; *cf.* F. M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 446 (2d ed. 1980) (noting both "examples and counterexamples" of valuable and essentially duplicative design-around research).

[152] *See id.*; Kitch, 20 J. LAW & ECON. at 278-79. Stated differently, the design-around process may re-introduce some of the same duplications of effort *outside* the scope of an initial patent that are discouraged *within* the patent's coverage.

[153] *See* Scotchmer 2/26 at 128-29; Scotchmer, 5 J. ECON. PERSP. at 31 ("First innovators will have correct incentives to invest only if they receive some of the social surplus provided by second generation products."). Of course, as already noted, innovation may be continuous, so that the "follow-on" innovator at one stage in the cycle becomes the "initial" innovator at the next. *See* Scotchmer 2/26 at 170.

[154] Scotchmer, 5 J. ECON. PERSP. at 30. Substantial additional literature explores the economically optimal division of profit between initial and follow-on innovators. *See, e.g.*, HUGO A. HOPENHAYN & MATTHEW F. MITCHELL, INNOVATION FERTILITY AND PATENT DESIGN (National Bureau of Econ. Research Working Paper No. 7070, 1999), *at* http://www.nber.org/papers/w7070.pdf; Suzanne Scotchmer, *Protecting Early Innovators: Should Second-Generation Products be Patentable*, 27 RAND J. ECON. 322 (1996); Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND J. ECON. 20 (1995); Howard Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. ECON. 34 (1995).

negotiations occur. When the initial innovator obtains a narrow patent, so that the follow-on innovation does not infringe, the initial innovator will receive no royalty. It may still benefit if the follow-on innovation is a complement that increases the value of the initial innovation, but the initial innovator will suffer without compensation if the follow-on innovation is a substitute. If instead the initial innovator receives a broad patent, so that the follow-on innovation infringes, the initial innovator can force the follow-on innovator to take a license for the initial technology and share some of the follow-on benefits through the ensuing royalties.[155] If the follow-on innovator garners a patent on its improvement, it may have some negotiating leverage of its own; the patents are mutually blocking, and if the initial innovator wants access to the improvement, it will need to give as well as take.[156]

3. Licensing

The timing of negotiations affects whether licensing arrangements will adequately reward both initial and follow-on innovation. Results are most likely to be problematic when licensing occurs *ex post*, that is, after the follow-on innovator has incurred the sunk costs of its R&D efforts. At that point, the follow-on innovator is exposed: it must secure a license now, after its investments are sunk. Faced with opportunistic demands, the follow-on innovator may not receive rewards adequate for its contribution.[157] If this were the established pattern, socially efficient levels of independent follow-on innovation could not be sustained.[158]

Negotiation is more likely to divide rewards to support efficient follow-on activity if licensing occurs *ex ante,* that is, before the follow-on innovator makes its sunk investments.[159] Although incentives to enter *ex ante* licenses often may be present,[160] the Hearings and related scholarship suggested reasons that licensing may not occur *ex ante* in some circumstances.[161]

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[155] *See, e.g.*, Green & Scotchmer, 26 RAND J. ECON. at 21 ("Because the breadth of the first patent determines whether a product infringes, it thus determines the division of profit.").

[156] *See, e.g.,* O'Rourke 2/20 at 103-04 (describing the mutual infringement situation as the "blocking patent doctrine"); American Intellectual Property Law Association (AIPLA), *AIPLA Testimony* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/aipla.pdf.

[157] *See, e.g.,* Scotchmer 2/26 at 135; Rai 4/10 at 19; Green & Scotchmer, 26 RAND J. ECON. at 21, 23-24. Nevertheless, the initial innovator generally would not have an incentive to charge a royalty so high that the follow-on company would exit.

[158] Of course, follow-on innovation that is very valuable, and patent-protected, may still be profitable. *See* Green & Scotchmer, 26 RAND J. ECON. at 25. Thus, some panelists argued that when improvements are significant and adequate information is available, awarding a blocking position to the follow-on innovator may sufficiently protect that innovator even when licensing negotiations are conducted *ex post*. *See* Parkhurst 4/10 at 93-94; Kieff 4/10 at 163-64.

[159] *See* Stoner 2/26 at 118-19; Scotchmer 2/26 at 135.

[160] *See, e.g.,* Kieff 4/10 at 163 ("let's assume I have no idea where the big commercial utility is – I want to license everyone in the room in the hope that they find a commercial utility, because then I get a piece of that pie"); Blackburn 2/26 at 264-65 ("when you cannot predict ahead of time the incentive is there to broadly license").

[161] For full discussion of many of the possible licensing impediments, *see* Lemley, 75 TEX. L. REV. at 1050-61; Eisenberg, 56 U. CHI. L. REV. at 1073-74.

- Some analysts stress the potential licensee's exposure in bringing a follow-on idea to the initial innovator. In an *ex ante* context, *before* the follow-on innovator has made its R&D investment, the follow-on idea would not be patent-protected, and the initial innovator might misappropriate it. Contracts to protect against such conduct may prove inadequate.[162]

- Some analysts suggest that transaction costs of *ex ante* licensing may prove high.[163] The negotiations may be fraught with uncertainty because the subject matter entails research that has not yet been conducted.[164] There may also be substantial uncertainty regarding the validity and scope of the initial innovator's patent rights.[165]

- Divergent views regarding the relative value of initial and follow-on contributions may prevent reaching agreement.[166] One analyst highlights the potential for bargaining stalemates when the initial innovation involves basic research with little commercial value itself and the follow-on innovations require substantial investment.[167]

- In some circumstances, the initial innovator may not have a private incentive to license. Some panelists cautioned that firms may be reluctant to license others who may eventually prove to be competitors. When in-house development works to enhance or maintain market power, the initial innovator may serve its self-interest by forgoing socially beneficial licensing.[168]

Others responded that transaction costs and the effects of uncertainty usually can be overcome, that the holder of an upstream patent has the incentive to assure that downstream products reach the market,[169] and that if licensing to follow-on innovators

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[162] *See* Lemley, 75 TEX. L. REV. at 1051; Scotchmer, 5 J. ECON. PERSP. at 36 n.11; Eisenberg, 56 U. CHI. L. REV. at 1063, 1073. The argument is an illustration of the point that patents facilitate efficient transfers of information. *See infra* Ch. 2(I)(A)(2).

[163] *See, e.g,* O'Rourke 2/20 at 98; Lemley, 75 TEXAS L. REV. at 1053-55; Merges & Nelson, 90 COLUM. L. REV. at 874.

[164] *See, e.g.*, Lemley, 75 TEXAS L. REV. at 1053 ("if it is hard to value an invention that has already been made, it is well-nigh impossible to value one that might be made in the future"); Eisenberg, 56 U. CHI. L. REV. at 1073.

[165] *See, e.g.,* Teece 2/26 at 202-04, 210 (observing that unclear boundaries "foul up" the market for know-how, but concluding that solutions to licensing problems eventually emerge); *see infra* Ch. 5(I).

[166] *See, e.g.,* Rai 4/10 at 19. One mechanism for resolving uncertainties and divergent views regarding the likely value of follow-on research involves the use of licenses with reach-through royalties, that is, royalties measured as a percentage of the sales of the follow-on product or service. For discussion of the use of reach-through royalties in biotechnology contexts, *see infra* Ch. 3(III)(E)(1). For discussion of some of the legal and economic issues posed by reach-through royalties, *see* Second Report (forthcoming).

[167] *See e.g.,* Scherer 7/10 at 56 (noting the combination of technical and market uncertainty); Scherer, 77 ACADEMIC MEDICINE at 1362.

[168] *See, e.g.,* Rubinfeld 2/25 at 19-20 (discussing "in-house bias"); Cohen 10/30 at 151-52; Shapiro 11/6 at 164; McFalls 11/6 at 182-83.

[169] *See, e.g.,* Blackburn 2/26 at 264.

Box 2-3a. ***Patent Thickets.*** The potential economic problems associated with patent thickets are diverse. First, in a patent thicket where innovation depends on having access to existing patents held by many different owners, the transaction costs of access can rise substantially because of the costs of negotiating with each of many individual patentees. *See infra* Ch. 2(III)(C)(1). Second, in some situations, the transaction costs of learning about and individually licensing all existing relevant patents are high enough to significantly undermine the economic incentive to develop follow-on innovation and production. In other situations, uncertainty surrounding pending patents hampers reaching licensing agreements. Unless a firm can mitigate the problem, it may have to choose between the risk of being sued for infringement after it sinks costs into its invention or production, or dropping its innovative or productive efforts altogether. *See infra* Ch.2(III)(C)(2). Third, a follow-on innovator in a patent thicket generally needs to access multiple patentees' intellectual property to develop his invention. Following Cournot's prediction, each patentee will demand a higher royalty than its patent would command if it were licensed as part of a package. *See infra* Ch. 2(III)(C)(3). Finally, in patent thickets in which follow-on innovation depends on having access to many patents held by a group of oligopolists, the oligopolists may use the patents to prevent entry. *See infra* Ch. 2(III)(C)(4).

would be beneficial, it is likely to occur.[170] Prof. David Teece, for example, explained that although there may be "battles around patents" in the early days of an industry, "what tends to happen is that these problems get solved."[171] Anecdotal information and case studies point in both directions.[172]

C. Follow-On Innovation in the Face of Multiple Existing Patents

In some circumstances, the need for access to multiple existing patent-protected technologies may also hinder subsequent innovative work.[173]

Indeed, in some industries, there has been a proliferation of patents.[174] Commentators have noted five factors that contribute to patent proliferation. First, the technology developed in industries such as semiconductors, computer hardware, and software can contain a large number of

[170] *See, e.g.,* Teece 2/26 at 210-11; Kieff 4/10 at 159-60, 199-200; *cf.* Arora 2/25 at 88-89 (transaction costs generally are not large enough to prevent licensing provided that the proper incentives are present).

[171] Teece 2/26 at 210.

[172] For example, *compare* O'Rourke 2/20 at 98 and Rai 4/10 at 19 (both citing Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990), for its case studies of breakdowns in licensing opportunities) *with* Boulware 10/30 at 175-76 (citing two broad, basic biotech patents that have been widely licensed).

[173] *See infra* Ch. 3(III)(D)(4), (IV)(E)(2) and (V)(E)(2). For a summary of problems of the patent thicket and techniques for mitigating it, *see* Boxes 2-3a and 2-3b.

[174] *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001) (hereinafter *Navigating the Patent Thicket*); Mowery 2/27 at 427; Stallman 4/9 at 20; Burk 3/20 at 149; Greenhall 2/27 at 375-76; Detkin 2/28 at 667-68 and Peter N. Detkin, *A Semiconductor Patent Survey* (2/28/02) (slides) at 5, *at* http://www.ftc.gov/opp/intellect/020228peterndetkin.pdf. The introduction of patent maintenance payments may help somewhat to clear patent thickets because a significant number of patent holders do not maintain their patents for the full term. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1494, 1503-04 (2001) (50 percent of patents gone by twelfth year). Many of the patents so eliminated may never have had commercial significance, however. *See* Lemley, 95 Nw. U. L. REV. at 1503 ("Most of these [lapsed] patents aren't litigated or licensed during the short time they are in force.").

incremental innovations.[175] One panelist from the software industry noted that programs can contain millions of lines of code and include "potentially hundreds of thousands" of patentable inventions.[176] The complex nature of such technology creates a technology thicket over which a patent thicket develops.[177]

Box 2-3b. ***Mitigating the Patent Thicket.***

Techniques that companies use for handling the patent thicket include assuring mutual destruction, *see infra* Ch. 2(III)(C)(2)(b), patent pooling, cross-licensing, and package licensing, *see infra* Ch. 2(III)(C)(3).

Second, in their research, Hall and Ziedonis contend that a "pro-patent" shift in the U.S. legal environment in the 1980s was the stimulus for patent proliferation.[178] The authors believe that a series of congressional reforms in the early 1980s – including the creation of the Court of Appeals for the Federal Circuit, which "put in place a number of procedural and substantive rules that collectively strengthened the rights of US patent owners"[179] – produced this shift. Hall and Ziedonis also identified two events that arose out of the "pro-patent" shift and signaled the strength of the new patent regime: (i) Polaroid's patent infringement suit against Kodak, which resulted in almost $1 billion in damages and an injunction against Kodak's participation in the instant-film camera business,"[180] and (ii) higher royalty rates obtained by Texas Instruments from an aggressive licensing strategy, which demonstrated to other firms the revenue potential of mining a large patent portfolio.[181]

Third, in the semiconductor, computer hardware, and software industries, defensive patenting strategies can drive firms to patent even more. As more patents issue, the likelihood of "unintentional and sometimes unavoidable patent infringement" increases.[182] Some firms respond to this by "fil[ing] hundreds of patents each year" themselves, patents they can use defensively against firms threatening infringement actions.[183] The result of this, of course, is

[175] *See* Detkin 2/28 at 669-70, 710-11; Poppen 2/28 at 684, 712; Barr 2/28 at 713-14; Fox 2/28 at 714; Mowery 2/27 at 427; Armbrecht 3/19 at 54; Cohen 10/30 at 91.

[176] *See* Kohn 2/27 at 351-52; Pooley 2/27 at 382.

[177] *See* Teece 2/27 at 500 ("the right question to ask is not whether or not there's a patent thicket, but whether or not the patent thicket, if there is one, is undergirded by a technology thicket").

[178] Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995*, 32 RAND J. OF ECON. 101, 105 (2001). *See also* Jeffrey T. Macher, David C. Mowery & David A. Hodges, *Semiconductors, in* U.S. INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE 279-81 (1999), *at* http://www.nap.edu/books/0309061792/html/245.html.

[179] Rosemarie Ham Ziedonis & Bronwyn H. Hall, *The Effects of Strengthening Patent Rights on Firms Engaged in Cumulative Innovation: Insights from the Semiconductor Industry* 12 (June 2001), *at* http://emlab.berkeley.edu/users/bhhall/papers/HallZiedonis01%20libecap.pdf (draft version).

[180] Hall & Ziedonis, 32 RAND J. OF ECON. at 109.

[181] *Id*.

[182] Barr 2/28 at 677.

[183] *Id*.; *see also* Detkin 2/28 at 668 ("there's an unavoidable overlap of IP . . . people are tripping over each other's patents right and left"); Hart 4/9 at 42-42; Hall 2/28 at 661; Hall & Ziedonis, 32 RAND J. OF ECON. at 125.

yet more patenting.

Fourth, in some industries, increased patenting levels may reflect increases in R&D activity.[184] Finally, the issuance of unwarranted patents may be a contributing factor to patent proliferation.[185] One panelist cited interviews conducted with participants in the semiconductor industry in which the participants voiced concern regarding the patenting of "very trivial inventions."[186]

1. High Transaction Costs

a. Stemming From Number of Patents

When follow-on innovation depends on having access to patents held by many different owners, the transaction costs of access can rise substantially. In industries with incremental innovation, such as the software industry, innovation often depends on access to many patents.[187] There can be "potentially dozens or hundreds of patents covering individual components of a product" in such an industry.[188] One panelist's experience illustrates the concern: in searching the patent landscape surrounding a particular patent relevant to his business, he found 120 patents that appeared to overlap each other.[189] The cost of access rises in such situations because of the costs of negotiating with each of many individual patentees.[190]

b. Stemming from Lack of Benchmarks

Moreover, transaction costs may be greater where bargainers lack benchmarks for the deal they are trying to reach. In general, incomplete or asymmetrical information in bilateral bargaining situations raises transaction costs by lengthening negotiations.[191] Many licensing agreements are kept confidential, panelists noted,[192] and in any event, different transactions may involve unique elements that make comparisons difficult. As a result, when two parties wish to create a licensing agreement,

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[184] *See, e.g.,* Ziedonis 3/20 at 13-14 and Rosemarie Ziedonis, *The Role of Patents in Semiconductors: Insights from Two Recent Studies* (3/20/02) (slides) at 3, *at* http://www.ftc.gov/opp/intellect/020320rosemarieziedonis.pdf; Telecky 2/28 at 711 (increasing patents reflect increasing research budgets); Mossinghoff 2/6 at 82-83 (pharmaceutical R&D expenditures have increased at a greater rate than pharmaceutical patents).

[185] *See* Ziedonis 3/20 at 15-16.

[186] *See* Ziedonis 3/20 at 15-16.

[187] *See* Telecky (stmt) 3; Teece 2/27 at 500.

[188] Mowery 2/27 at 427.

[189] *See* Greenhall 2/27 at 375-76.

[190] Some have called this problem an aspect of the "tragedy of the anticommons." *See, e.g.,* Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998); Hall 2/26 at 182-83; *cf.* Dickinson 2/6 at 61-62 (referring to this transaction cost concern as "patent layering"). For a description of the tragedy of the anticommons and business panelists' perceptions of whether it actually occurs, *see infra* Ch. 3(III)(D)(4).

[191] *See, e.g.,* RICHARD A. POSNER, ECONOMIC ANALYSIS OF THE LAW 68-69 (5th ed. 1998) (using example of litigation settlement to demonstrate the transaction costs incurred by incomplete information, arguing that a potential litigant who does not know the price at which its counterpart would prefer litigation to settlement will find it expensive to determine the correct settlement terms, and will expend "much time and resources" trying to bargain once it has determined its counterpart's price "range"); Joseph Farrell, *Information and the Coase Theorem*, 1 J. ECON. PERSP. 113, 115 (1987) (sketching the difficulties that incomplete information raises for bilateral bargaining).

[192] *See, e.g.,* Pooley 2/27 at 436-37.

they may lack "a market-driven assessment of the value of the patent" in question, according to one panelist,[193] and that ignorance can raise transaction costs. Indeed, some would-be licensors feel the need to threaten litigation in order to have access to others' confidential licensing terms,[194] further heightening transaction costs.

2. Hold Up in the Patent Thicket

a. Hold Up

Sometimes, follow-on innovation and production depends on having access to patents that are economically infeasible to license because they are too numerous to license individually or even to learn about. In other situations, uncertainty surrounding pending patents hampers the reaching of licensing agreements. Unless downstream actors – whether innovators or manufacturers – can mitigate the problem, they may have to choose between the risk of being sued for infringement after they sink costs into invention or production, or dropping innovative or productive efforts altogether. Either option can injure economic welfare. Below is a discussion of the economic theories behind these concerns.

In some situations, the transaction costs of learning about and individually licensing all existing relevant patents are high enough to undermine significantly the economic incentive to develop follow-on innovation and production.[195] For example, one panelist noted that in industries such as semiconductors in which the ratio of patents to products is high, a firm cannot make a new product "without infringing hundreds if not thousands of patents."[196] Another commentator concurred: participants in the semiconductor industry receive "thousands of patents . . . each year and manufacturers can potentially infringe on hundreds of patents with a single product."[197] Another panelist observed that "the large number of issued patents in [the computer hardware industry] makes it virtually impossible to search all potentially relevant patents, review the claims, and evaluate the possibility of an infringement claim or the need for a license."[198]

In other situations, secrecy

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[193] Friedman 2/27 at 439 (noting that knowledge of others' licensing terms would be of limited use, since "markets with few people in it are extraordinarily inexact"); *see also* Pooley 2/27 at 437 (noting that if would-be licensees could review confidential terms of other licensing agreements, they could get an objective sense of the worth of the patent by evaluating not just the royalty rate but who the licensees were, how much "they are actually paying when weighed against other contributions that they're making or obligations they are taking," and the like).

[194] *See, e.g.,* Pooley 2/27 at 437-38 (suggesting that discovery in litigation could disclose such information).

[195] High transaction costs can render licensing from multiple intellectual-property holders economically infeasible. *See, e.g., Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.,* 441 U.S. 1 (1979) (determining that blanket license warranted review under the rule of reason). Some have called transaction costs *the* problem of the "patent thicket."

[196] *See* Lemley 2/25 at 37-39 (noting that in such industries, patents are awarded on "inventions [that] are small changes in process, they are small changes in product, they are circuit design innovations, they are little pieces of the innovation," and that in such industries with high ratios of patents to products, "hold-up problems are much greater than they are in other industries").

[197] Shapiro, *Navigating the Patent Thicket* at 125.

[198] Barr (stmt) 1; *see also* Barr 2/28 at 676-7.

surrounding a patent makes it very difficult for downstream actors to avoid it. Indeed, the holder of a yet-unpublished patent can (once it issues) use it to hold up follow-on innovators and producers who unknowingly infringed it.[199] One panelist stated that "the long delays in the patent office work to [some firms'] benefit by keeping the eventual coverage of their patents indefinite while others produce products."[200] Some noted that improving "information [available] at an earlier stage about patents likely to issue" could help ameliorate hold up,[201] but hold up may persist because of uncertainty about the scope of claims that eventually will issue.[202]

If an innovator or producer learns that it has infringed a patent only after it has committed sunk costs to its innovation and production – and thus locked in to the effort – the patentee may be in a position to demand supra-competitive royalty rates. If, before lock in, the downstream actor had known about the patent and could have designed its product or innovation around it, then the firm might have used the opportunity to adopt alternative designs as leverage for seeking a competitive royalty rate. But after lock in, the downstream actor no longer has that option. Redesigning a product after significant costs have been sunk may not be economically viable.[203] And the cost of being preliminarily enjoined is high: as one industry participant noted, losing a motion for a preliminary injunction in an infringement lawsuit "would be detrimental to a firm if it means shutting down a high-volume manufacturing facility [since the] loss of one week's production alone can cost millions of dollars."[204]

Hold up can injure innovation and competition. First, such a demand for payment after lock in can compel the downstream actor to pay the patentee a "far greater" royalty rate.[205] That higher rate, one scholar noted, can be passed along to consumers in the form of higher prices.[206] Second, the threat of hold up may reduce overall levels of innovation, because some companies will "refrain from introducing certain products for fear of holdup."[207]

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[199] *See* Barr 2/28 at 676.

[200] Barr (stmt) 2; *see also* Ch. 4(II)(C)(1) (discussing continuations).

[201] *See, e.g.,* Shapiro, *Navigating the Patent Thicket* at 126. For example, ninety percent of patent applications are now published within 18 months, pursuant to the requirements of the American Invention Protection Act; and a 1995 patent term change from 17 years after issuance to twenty years after filing may reduce incentives to prolong examinations. *See infra* Ch. 4(II)(C)(1). Some panelists believed that these developments can mitigate hold up; others pointed out that they would not completely cure the problem. *Id*.

[202] Barr 2/28 at 676; *see also infra* Ch. 4.

[203] *See, e.g.,* Shapiro, *Navigating the Patent Thicket* at 125; Barr (stmt) 2-3; Rosemarie Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* 8-9 (July 2002) (unpublished manuscript), *at* http://www.isnie.org/ISNIE02/Papers02/ziedonis.pdf.

[204] Hall & Ziedonis, 32 RAND J. OF ECON. at 109 (paraphrasing the statement of an industry participant whom they interviewed).

[205] Shapiro, *Navigating the Patent Thicket* at 125.

[206] *See id.* at 126; *see also* Poppen 2/28 at 690.

[207] Shapiro, *Navigating the Patent Thicket* at 126; *see also* Peter C. Grindley & David J. Teece, *Managing Intellectual Capital: Licensing and Cross-Licensing in Semiconductors and Electronics*, 39 CAL. MGMT. REV. 8, 20 (1997).

b. Strategies to Mitigate

(i). Mitigation Strategy of Amassing Patents and Assuring Mutual Destruction

To mitigate such hold up in the context of a patent thicket, some firms in certain industries have accumulated large patent portfolios.[208] Panelists noted that a firm with a large patent portfolio is in a better position to raise patent infringement counterclaims against a firm that tries to hold it up.[209] It is also better able to force others to license their patents (or perhaps portfolios of patents),[210] or to demand that other firms agree not to assert blocking patents against it (often called "non-assertion agreements").[211] The prospect of mutually assured destruction (or "MAD") ensures detente, and design freedom, for such firms.[212] Each firm takes into account that, if it tried to extract excessive royalties or impede the other's innovation efforts through threats of patent infringement litigation, the other firm could retaliate by suing it for patent infringement and enjoining its production. This leads the firms to reach licensing agreements with each other, often portfolio cross-licensing agreements.[213] Such agreements can give each firm the freedom to design and operate without fear of being sued by the other.[214]

(ii). Costs and Limits of MAD Mitigation Strategy

(A). Costly Arms Race

Amassing patent portfolios may mitigate hold up, but it also carries costs. It is, as one commentator noted, a "rather costly arms race."[215] It generates a "lot of resource waste," some panelists noted,[216] since firms spend "a significant amount on legal bills to apply for patents" to use in

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[208] *See, e.g.,* Hall & Ziedonis, 32 RAND J. OF ECON. at 104 (describing semiconductor industry); Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* at 4 (describing semiconductor industry); Barton 2/26 at 150 (predicting evolution of mutual-assured-destruction strategy in financial services industry and biotech industry, and noting that such strategies are "not going to be an uncommon situation").

[209] *See, e.g.,* COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 26-27 (stating that one of the most important uses of patents across all industries is to prevent infringement lawsuits); Hall 2/28 at 662 ("Basically we pile up a lot of patents because the other guy has a lot of patents and that, when we, if we, do get threatened, we can engage in a cross-licensing negotiation."); League for Programming Freedom, *Against Software Patents* (Public Comment) 6, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lpf.pdf.

[210] *See, e.g.,* COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 20-24 (stating that one reason firms in complex product industries obtain patents is to strengthen their position in cross-licensing negotiations).

[211] Non-assertion agreements are discussed in Second Report (forthcoming).

[212] *See* Hall 2/28 at 662; Hall & Ziedonis, 32 RAND J. OF ECON. at 109; Friedman 2/27 at 356 (describing one goal of amassing large patent portfolios as maintaining detente). MAD strategies apply only to firms that are vulnerable; those that are not are discussed below, *see infra* Ch. 2(III)(C)(2)(b)(ii)(B) (discussing undeterred NPEs).

[213] *See, e.g.*, Cohen 2/20 at 63-64.

[214] *See, e.g.*, *id*. *See also* Second Report (forthcoming) (discussing portfolio cross-licensing agreements).

[215] Cohen 2/20 at 33-34.

[216] Hall 2/26 at 178-79 (reporting semiconductor patent executives' views).

these MAD strategies.[217] One panelist issued a directive to his company's staff requiring that they "reallocate roughly 20 to 35 percent of [their] developer's resources and sign on two separate law firms to increase [their] patent portfolio."[218] The engineers' time dedicated to assisting in the filing of patents, which "have no . . . innovative value in and of themselves," could have been spent on developing new technologies, the panelist noted.[219]

(B). NPEs Undeterred

In addition to being expensive, MAD strategies are not always effective. Firms cannot use their patent portfolios defensively against companies referred to as non-practicing entities (NPEs).[220] NPEs are firms that are, for a variety of reasons, invulnerable to a countersuit for patent infringement. They may be design firms that patent their inventions but do not practice them or patent assertion firms that buy patents from other companies (particularly bankrupt ones) not to practice but to assert against others.[221] Since NPEs are not vulnerable to an infringement counter attack, MAD strategies threatening infringement actions do little to constrain their willingness to seek high royalty rates from locked-in downstream actors.[222] Thus, NPEs can threaten other firms with patent infringement actions, which, if successful, could inflict substantial losses, without fear of retaliation.[223] In short, MAD strategies do nothing to mitigate NPE hold up.[224]

One panelist hypothesized that NPEs' invulnerability may create a competitive problem if it prevents the type of cross-licensing that has evolved as a "safety valve" due to the prevalence of overlapping and cumulative patents.[225] Under this theory, a cross-licensing "safety valve" may be necessary for markets to work efficiently when there are large numbers of overlapping and cumulative patents. If the market-created safety valve relies on *all*

[217] Barton 2/26 at 177-78.

[218] Greenhall 2/27 at 376.

[219] *Id*. at 377, 420.

[220] Participants in the Hearings also used the terms "non-vertically integrated" intellectual property holders and "trolls" to refer to NPEs. For purposes of clarity, this Report uses the neutral term "NPE." *See* Poppen 2/28 at 685-88; Detkin 2/28 at 672; Carl Shapiro, *The FTC's Challenge to Intel's Cross-Licensing Practices,* Institute of Business and Economic Research Competition Policy Center Paper CPC02-029, at 7 (2002), *at* http://repositories.cdlib.org/cgi/viewcontent.cgi?article=1028&context=iber/cpc; *see also infra* Ch. 3(IV)(E) (noting view that NPEs are merely exercising legitimate patent rights).

[221] *See, e.g.,* Poppen 2/28 at 685-88; Detkin 2/28 at 672.

[222] *See, e.g*., Rhoden 2/28 at 723-24 ("There's nothing that they need that you have and so they're basically in the position where they have something perhaps that you need. Since there's no mutually assured destruction . . . they can come in and assert and shut your business down and you have no option against them."); McCurdy 3/20 at 72 (you cannot negotiate reasonable royalties from NPEs because "there is no counterassertion capacity."); *cf.* Ziedonis 3/20 at 71-72 ("The Lemelson Foundation, I think, has made a very successful business from setting licensing fees so that balancing payment, you set it low enough to where it's below the cost of actually going to court or the managerial time that it would take to basically fend off the lawsuit.").

[223] *See* Poppen 2/28 at 685-89; Detkin 2/28 at 671-72; Hall & Ziedonis, 32 RAND J. OF ECON. at 109.

[224] *See infra* Ch. 3(IV)(E)(2)(c) for a description of the recent rise in NPE activity.

[225] Farrell 11/6 at 174-75.

parties wishing to bring products to the market, then a patent holder that is not vulnerable to countersuit for infringement may "gum[] up the safety valve."[226]

3. Royalty Stacking and Cournot's Complements Problem

In addition, the so-called "complements problem" can raise costs for innovators who depend on access to multiple patents. First identified in 1838 by Antoine Cournot and echoed by subsequent observers, the complements problem refers to the welfare loss stemming from individual monopolists each selling complementary goods for a given use.[227] Profit maximizing behavior will lead each producer to extract a monopoly price for his good, resulting in cumulative monopoly rents proportional to the number of complements.[228] In contrast, if a single firm controlled the production of all complementary inputs, it would extract a single monopoly rent, and the price would be lower than the aggregate of individual monopoly prices.[229] This is because the firm would take into account the effect that the prices of complementary products have on each other's sales, and would set a package price that would maximize total profit.[230] Thus, if monopolistic producers of complementary products packaged their products and extracted a single monopoly rent, prices would fall, output would increase, and profits would rise.[231]

The complements problem is relevant to the problem of blocking patents, one panelist argued. A follow-on innovator frequently needs to access multiple patents to develop his invention. When acting alone, patent holders – like individual monopolists of complementary technology or information inputs – will demand higher aggregate royalties than they would if they acted as a group.[232] Such behavior imposes a financial burden on prospective licensees that might deter further innovation.[233]

Indeed, some have argued that over-generous granting of patent rights in the biomedical industry has resulted in follow-

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[226] *Id*. at 175.

[227] *See generally* ANTOINE COURNOT, RESEARCHES INTO THE MATHEMATICAL PRINCIPLES OF THE THEORY OF WEALTH (1838), tr. Nathaniel Bacon (1895); *cf.* Shapiro, *Navigating the Patent Thicket* at 145 n.6 (noting assumption that the complementary inputs are used in fixed quantities and cannot substitute for each other).

[228] *See* Shapiro, *Navigating the Patent Thicket* at 149 (applying economic theory to show that the aggregate monopoly "markup" of competing complement producers is equal to the number of producers multiplied by the markup for a single product).

[229] *See, e.g., id.* at 123 (observing that prices would be lower and profits higher if a single producer controlled all complements than if each were controlled by individual monopolists).

[230] *See* Carl Shapiro, *Theories of Oligopoly Behavior*, *in* 1 HANDBOOK OF INDUSTRIAL ORGANIZATION 339 (Richard L. Schmalensee & Robert D. Willig eds. 1989) (noting that competing monopolists of complementary goods would not take "negative externalities" into their pricing decisions).

[231] *See, e.g.*, Shapiro, *Navigating the Patent Thicket* at 123 (noting that "monopolist suppliers will find it in their joint interests to offer a package price that is less than the[] two components sold for when priced separately"); Nirvikar Singh & Xavier Vives, *Price and Competition in a Differentiated Duopoly*, 15 RAND J. OF ECON. 546, 547 (1984) (showing that rational firms supplying complementary goods will cooperate to offer a high enough quantity to "reinforce" one another's market).

[232] *See* Shapiro, *Navigating the Patent Thicket* at 123 (applying general Cournot theory of complements to blocking patents).

[233] *See id.* at 124.

on innovators' under-utilization of existing research. Biomedical researchers face a maze of overlapping patents in the hands of different owners, the critics state.[234] They argue that these conditions can raise to prohibitive levels the cost of licensing all of the relevant patents for a useful advance.[235] Perversely, it can also divert research to unpromising areas that are relatively barren of patents.[236] One commentator states that this situation provides an example of Cournot's complements problem: each biotechnology patent holder, acting in its own self-interest, holds royalty rates inefficiently high, raising the costs of further innovation.[237]

One panelist has suggested that an "impleading" mechanism could help cure the Cournot problem. Under a system similar to the one governing stakeholder lawsuits, a follow-on innovator could offer a "reasonable" royalty rate to all of the holders of relevant intellectual property.[238] Another commentator has suggested that patent pooling, cross-licensing, and package licensing can ameliorate the complements problem: when two or more patent holders predict that other firms might wish licenses to their patents, they can organize patent pools or package licenses to facilitate orderly transfer of intellectual property at lower combined royalty rates and higher combined profits.[239] Such mechanisms serve a similar function to the impleading proposal by allowing producers of complementary goods to set a mutually beneficial price. Such packages might also reduce the transaction costs faced by prospective follow-on innovators.[240]

4. Oligopoly/Group Boycott

When follow-on innovation depends on having access to many patents held by a group of oligopolists, the oligopolists can use the patents to prevent entry. Specifically, some argued that patentees can foster "MAD oligopolies" that deter entry. They noted that a group of patentees, each fearing an infringement counterclaim from the other, can tacitly agree not to sue each other for infringement.[241] The patentees could "give each other at least a tacit license [or an] explicit license with some kind of

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[234] *See* Heller & Eisenberg, 280 SCIENCE at 698 (discussing rising number of patents granted in biomedical research). The authors have deemed this an aspect of the "tragedy of the anticommons." *See id.* at 699. For a description of the tragedy of the anticommons, *see infra* Ch. 3(III).

[235] *See* Heller & Eisenberg, 280 SCIENCE at 698-99, 701 (describing the disincentive to follow-on innovation created by overlapping patents). The authors also noted that individual patent holders tend to overestimate the likelihood that their patent will be used in the final invention, which induces some to charge a higher royalty rate than their patent deserves, raising the direct costs of licensing for follow-on innovations. *See id.* at 701.

[236] *See id.* at 699 (describing distortionary effects of the anticommons problem).

[237] *See* Shapiro, *Navigating the Patent Thicket* at 124 (linking tragedy of the anticommons to the complements problem).

[238] *See* Pooley 2/27 at 415-16 (also noting industry consortia or government intervention as potential solutions to the problem).

[239] *See* Shapiro, *Navigating the Patent Thicket* at 123 (calling such solutions an "ideal outcome" under the right circumstances).

[240] *See supra* Ch. 2(III)(C)(1)(a).

[241] *See, e.g.,* Barton 2/26 at 151; *see also* Barton, 65 ANTITRUST L.J. at 464.

formal cross-license."[242] The group could deter entry either by refusing to license the new entrant or by charging the entrant high royalty rates.[243] For example, one panelist noted that "in Japan, . . . the leading firms in the industry . . . agglomerate[d] huge portfolios which they were swapping with each other, but which they were unwilling to trade with the outside players."[244]

On the other hand, what looks like a MAD oligopoly may really be a pro-competitive way of rewarding those who took the initial risks, some observed,[245] or of cutting through patent thickets.[246] Moreover, cross-licensing arrangements in the semiconductor industry appear not to have slowed innovation, one panelist argued.[247]

5. Patent Fences and Patent Extensions

Hearing discussion raised some of the potential strategic uses of multiple patents. One branch of the discussion focused on an initial innovator's efforts to accumulate patents to buttress a threatened position of market power. Thus, an initial innovator may seek to build a "fence" around its position by securing additional patents on near substitutes, thereby blocking follow-on innovators from designing around the initial patent or raising their R&D costs.[248] Under a pure "fence" strategy, the patentee would have no intention either to license the substitute patent technologies or to develop them on its own; the only goal would be to keep rivals out.[249] Some analysts suggest that preemptive patenting of this type is likely to be a useful strategy only in exceptional circumstances, given the costs and the potential for multiple routes to entry.[250] Nonetheless, some recent survey evidence suggests that "fence" strategies may be frequently employed in "discrete products" industries – which entail relatively few patents per commercial product – in which individual patents fail to prevent

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[242] Barton 2/26 at 151.

[243] *Id*. at 152 (noting that patentee group could charge outsiders royalty rates "that were not simply enough to cover a reasonable share of the research costs and so forth, but [were] so big as to knock everybody else out of the industry").

[244] Ordover 11/6 at 105.

[245] *See, e.g.,* Teece 2/26 at 176-77 (arguing that often, patentees cross-license "as a way to extract a fee. So the latecomers who didn't . . . incur a lot of those early expenses end up . . . having to pay something, and you seem to me that you've solved the classic sort of free-rider problem").

[246] *See, e.g.,* Barton 2/26 at 152 (noting that some cross-licensing agreements are "appropriate because we have zillions of mutually-blocking patents"); Shapiro 11/6 at 111. *See generally supra* Ch. 2(III)(C)(2)(b) (discussing MAD strategies).

[247] *See* Teece 2/26 at 177.

[248] *See* Cohen 2/20 at 31; COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 22, 25; Richard J. Gilbert, *Patents, Sleeping Patents and Entry Deterrence*, *printed in* STRATEGY, PREDATION, AND ANTITRUST ANALYSIS 223-25 (S. Salop ed. 1981); SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 451 (1980).

[249] *See* Cohen 2/20 at 32; COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 22, 25.

[250] *See* Gilbert & Newbery, 72 AMER. ECON. REV. at 514-15; Gilbert, *Patents, Sleeping Patents and Entry Deterrence* at 227 (observing that if there are many patentable alternatives at comparable development costs, then "the use of preemptive patenting to fence in a monopoly is about as effective as holding back a flood with a sieve"), 268-69.

imitation or substitution.[251]

Panelists did not suggest that patent fences developed by a firm's own research are, or should be, antitrust violations.[252] Some scholarship, however, raises concerns regarding the effects of patent fences on follow-on innovation and efficiency. Some commentators suggest that using patents to build fences departs from traditional patent goals; rather than securing a defined reward for beneficial innovation, it expands that initial reward by broadening the zone of exclusivity – and the possible impact on entry and independent follow-on innovation – without conferring additional social benefits through new products or processes.[253] Other analysts have contended that socially wasteful expenditures of resources flow from fencing activities.[254]

A related strategy, which might be designated "patent extensions," involves efforts to extend patent protection beyond the life of an initial patent by accumulating patents on improvements. During the Hearings, Professor F.M. Scherer argued that Xerox's strategy for photocopying illustrated this approach, stating that "by amassing this continuing portfolio of improvement patents, Xerox was going to monopolize the industry, not for 17 years, but forever."[255] For the strategy to be effective however, there must be some reason to expect that, following expiration of the initial patent, competitors offering the no-longer-patent-protected core product would not adequately constrain pricing of the improved version.[256]

6. Patent Flooding

Efforts to build a sufficient patent portfolio to induce others to share their technology through cross licenses may shade into more aggressive strategies. When rivals obtain patents on trivial variants of an initial innovation, "patent flooding" becomes possible. Under this strategy, "[t]he flooder 'surrounds' a competitor's patent or technology . . . so that over time, the competitor finds itself 'unable to maneuver.'"[257] Lacking the breathing room

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[251] *See* Cohen 2/20 at 32 and Cohen Presentation at 14 and 15; COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 22-25 (treating as indicative of a fence strategy survey responses that reported blocking, but not negotiating or licensing, as among the motives for patenting and finding such responses 44-45% of the time in discrete product industries).

[252] Building a fence through acquisitions of patents, however, could raise issues under Section 7 of the Clayton Act, 15 U.S.C. § 18. *See, e.g.,* McFalls 11/6 at 183-84.

[253] *See* COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS at 28; *cf.* SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 451-52 (1980) (patent fencing a way "to extend and pyramid . . . monopoly power").

[254] *See* HOPENHAYN & MITCHELL, INNOVATION FERTILITY & PATENT DESIGN at 4.

[255] Scherer 7/10 at 180. Professor Scherer's textbook cites a similar prolongation of control through a series of improvement patents on the electric light bulb. *See* SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE at 451-52 (1980).

[256] *See* Sheila F. Anthony, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Before the American Bar Association Program on "Antitrust and Intellectual Property: The Crossroads" (June 1, 2000) (analyzing analogous issues raised by Eli Lilly's acquisition of an exclusive license from Sepracor), *at* http://www.ftc.gov/speeches/anthony/sfip000601.htm.

[257] Sri Krishna Sankaran, *Patent Flooding in the United States and Japan*, 40 IDEA 393, 394 (2000), *quoting* Dan Rosen & Chikako Usui, *The Social Structure*

to develop improvements or to find new uses for its invention, the initial innovator eventually must accede to demands that it share its technology through a cross license with the flooder.[258] Critics of patent flooding argue that these cross licenses are one-sided, extracting valuable intellectual property from the targets and undermining initial innovators' incentives to innovate without contributing significant follow-on benefits.[259] Typically they point to examples in Japan, where the patent system appears more conducive to flooding strategies than in the United States.[260] The hearing record does not suggest that patent flooding is currently a widespread practice in this country.[261]

Conclusion. Competition policy and patent policy enhance economic welfare in complementary ways. Yet neither competition nor patent policy can, alone, promote innovation fully. Competition alone is not a perfect tool for fostering innovation. For example, the award of patents is often necessary to remedy free riding on others' innovations. But patent policy alone also is not a perfect tool for fostering innovation. Indeed, patent rights can in some circumstances hinder follow-on innovation and competition. Rather, the two means of promoting innovation must work in tandem with each other.

The balance of this Report explores how they can best do so. Chapter 3 provides extensive real-world illustrations of the economic phenomena as voiced by business representatives from the pharmaceutical, biotechnology, computer hardware, and software/Internet industries. Chapters 4 and 5 translate the core economic concerns into a detailed examination of patent system standards and procedures.

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of Japanese Intellectual Property Law, 13 UCLA PAC. BASIN L. J. 32, 44 (1994); Jeffrey A. Wolfson, *Patent Flooding in the Japanese Patent Office: Methods for Reducing Patent Flooding and Obtaining Effective Patent Protection*, 27 GEO. WASH. J. INT'L L. & ECON. 531 (1994).

[258] *See, e.g.,* Wolfson, 27 GEO. WASH. J. INT'L L. & ECON. at 533 (describing cross-licensing as the flooder's typical goal).

[259] *See, e.g., id.* at 533, 554-55.

[260] *See, e.g.,* Sankaran, 40 IDEA at 399-404 (emphasizing that patent applicants in Japan may defer examination for up to seven years, allowing them to assert the claimed rights coercively for a prolonged period without ever having to demonstrate patentability). Several analysts note the perception of a proclivity in Japan to issue narrow patents to initial innovators and to grant patents on relatively minor variations on prior inventions; they argue that this would increase the potential for flooding. *See, e.g.,* John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Rights*, 84 J. PAT. & TRADEMARK OFFICE SOC'Y 83, 110-11 (2002); Sankaran, 40 IDEA at 395; Wolfson, 27 GEO. WASH. J. L & ECON. at 539-41; Ordover, 5 J. ECON. PERSP. at 48.

[261] *See* Kunin 7/11 at 181-83 (describing patent flooding as a product of the Japanese patent system). Even an analyst who argues that patent flooding may have occurred in the United States identifies at most a handful of instances in which it has been alleged. *See* Sankaran, 40 IDEA at 411-17. As discussed below, the patent law's obviousness doctrine, which deals with the size of inventive step necessary for obtaining a follow-on patent, affects opportunities to employ flooding strategies. *See infra* Ch. 4(II)(A)(1). In the United States, some aspects of this doctrine work against flooding. *Cf.* Merges 2/26 at 162-64 (explaining that the double patenting doctrine in the United States gives initial innovators greater ability than improvers to patent what would otherwise be obvious variations).

CHAPTER 3 BUSINESS TESTIMONY: CURRENT INNOVATION LANDSCAPE IN SELECTED INDUSTRIES

CHAPTER 3 BUSINESS TESTIMONY: CURRENT INNOVATION LANDSCAPE IN SELECTED INDUSTRIES

I. SUMMARY

Over six days of Hearings, business representatives from four high-tech industries discussed the drivers of innovation in their industries. Representatives from the pharmaceutical, biotechnology, Internet, and computer hardware and software industries described their real-world experience with how patents and competition affect incentives to innovate. Their discussions confirmed many of the principles summarized in Chapter 2 and sometimes shed additional light and offered new perspectives on the topics. They highlighted both the benefits and costs of current patent and antitrust policies applied in their industries. This chapter discusses the diverse views presented by the panelists, and also incorporates the results of business surveys and other industry-specific scholarship.

The panelists identified various attributes that characterized innovation in the different industries. Panelists discussed whether innovation in their industries tends to be discrete or cumulative, building incrementally on prior discoveries. Panelists also addressed sources and amounts of capital required for entry, barriers to entry, the extent to which industries are vertically integrated, and difficulties in commercializing new products. They raised issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation, adding business insights and practical experience to the analysis of Chapter 2. According to both panelists and academics, factors such as these shape the role of competition and patents in spurring or discouraging innovation in their industries.

Pharmaceutical and biotechnology representatives testified that strong patent protection is essential to innovation in their industries. Business representatives characterized innovation in these industries as costly and unpredictable, requiring significant amounts of pioneering research to discover and test new drug products. By preventing rival firms from free riding on discoveries, patents allow pharmaceutical firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products. Biotech representatives emphasized that patent protection is critical to attract the capital necessary to fund this high-risk investment. Indeed, firms believed that the biotech industry would not exist but for patents. One concern involved patents on the research tools used to assist in the discovery of new drug products. Biotech representatives expressed concern that such patents could obstruct the commercialization of new products, thereby hindering follow-on innovation. To date, however, evidence suggests that such problems have not emerged.

Pharmaceutical and biotech representatives testified that they use patent information disclosures required by the patent statutes to direct their research and development (R&D) into areas not claimed by the patents. Representatives from generic pharmaceutical firms discussed how patent disclosures guide their efforts to "design-around" patents, so that they can develop

non-infringing generic versions of brand-name drug products.

By contrast, computer hardware and software industry representatives generally emphasized competition to develop more advanced technologies as a driver of innovation in these rapidly changing industries. These representatives, particularly those from the software industry, described an innovation process that is generally significantly less costly than in the pharmaceutical and biotech industries, and they spoke of a product life cycle that is generally much shorter. Some software representatives observed that copyrights or open source code policies facilitate the incremental and dynamic nature of software innovation. They discounted the value of patent disclosures, because they do not require the disclosure of a software product's underlying source code.

Computer hardware manufacturers noted that they often use trade secrets, rather than patents, to protect their inventions, because it is difficult to discover whether a rival firm has infringed a patented manufacturing invention. Computer hardware manufacturers generally would rather keep the invention secret than publicly disclose it and risk third party misappropriation of patent rights that they will be unable to discover. By contrast, computer hardware firms that specialize solely in hardware design and have no manufacturing responsibilities valued patent protection as a way to raise venture capital.

Representatives from both the computer hardware and software industries observed that firms in their industries are obtaining patents for defensive purposes at rapidly increasing rates. They explained that the increased likelihood of firms holding overlapping intellectual property rights creates a "patent thicket" that they must clear away to commercialize new technology. They discussed how patent thickets divert funds away from R&D, make it difficult to commercialize new products, and raise uncertainty and investment risks. Some computer hardware and software representatives highlighted their growing concern that companies operating in a patent thicket are increasingly vulnerable to threats to enjoin their production from non-practicing entities that hold patents necessary to make the manufacturer's product.

A global concern that representatives from each of the four industries described was that poor patent quality (*e.g.,* a patent for which there is invalidating prior art, or a patent broader than was enabled) can blunt incentives to innovate. They described the costly nature of litigation to invalidate these patents, both in terms of dollars and resources diverted from R&D. They also discussed how a timely, less costly mechanism to review poor quality patents would enhance innovation in their industries.

These representatives also described how each industry has developed licensing practices to extract value from their patents or, in some cases, to obviate some of the problems raised by patent thickets. They raised concerns that uncertainty about the parameters of antitrust enforcement may be hindering the use of certain methods to extract patent value. For example, biotech

representatives noted that antitrust concerns have contributed to uncertainty about the propriety of using reach-through royalty provisions in research tool licenses.

Firms in the computer hardware and software industries indicated that antitrust concerns may be inhibiting joint discussions of licensing terms during the standard-setting process. They noted that antitrust has traditionally been suspicious of joint discussions of licensing terms arising prior to the adoption of a standard. Some panelists suggested, however, that such conduct is necessary for the efficient establishment of new standards because some companies are using patents strategically.

Box 3-1. ***Independent Inventors and the FTC's Invention Promotion Cases***

One cross-industry concern raised by a specific sub-group was the vulnerability of independent inventors to fraudulent practices as they seek patents and offer licenses on those patents. This problem has been, and continues to be, a matter of FTC concern. Two panelists representing the independent invention community mentioned the defrauding of inventors by invention promotion firms. *See* Udell 2/28 at 568-69 ("the FTC has done a magnificent job of not only educating inventors, but also getting the scam organizations that have been bleeding inventors for decades out of the pockets of the poor inventors in America."); Hayes-Rines 3/19 at 61-62 (urging enhanced FTC enforcement efforts).

In 1997, the FTC launched a consumer education program and a law-enforcement sweep entitled "Project Mousetrap" because a "number of firms in the invention promotion industry are perpetrating a massive fraud" against independent inventors. As a result of this sweep and other enforcement actions, the Commission brought eight cases against invention promoters during the 1990s. The complaints have named 41 defendants, consisting of 21 companies and 20 individuals. In some cases, the Commission alleged that the defendants represented that they would obtain patents for their customers' inventions without clarifying that these would be design patents, which typically have less commercial value than utility patents. The Commission generally alleged that the defendants represented that their research and marketing services were likely to secure profitable licenses for their customers' inventions. The Commission further alleged that, in fact, the defendants were rarely successful at securing licensing agreements, and that the few licenses that the defendants did secure seldom resulted in appreciable income for the inventors.

In six cases, the Commission obtained consent orders that required the defendants to pay consumer redress and to make affirmative disclosures to prospective customers about the promoters' past success rates. One case is still in litigation and the eighth case was dismissed after the U.S. Attorney's office filed criminal charges. More recently, the Commission has expanded its consumer education program, in cooperation with the PTO, to include rights available to inventors under the American Inventors Protection Act of 1999. Further details on the Commission's consumer education efforts and enforcement actions are *available at* http://www.ftc.gov/bcp/conline/edcams/invention/ and http://www.ftc.gov/opa/1997/07/mouse.htm.

II. THE PHARMACEUTICAL INDUSTRY

A. Introduction

Representatives from the pharmaceutical industry stated that patent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities. The sunk cost of engaging in research projects aimed toward the development of these drugs is extremely high. By preventing rival firms from free riding on the innovating firms' discoveries, patents can enable pharmaceutical firms to cover their fixed costs and regain the capital they invest in R&D efforts. Moreover, the patenting process requires disclosure of the underlying invention covered by the patent, potentially encouraging further innovation. Generic drug companies report they use disclosed patents as a basis on which to "invent-around" patented, brand-name products in order to develop generic variations.

The panelists who represented pharmaceutical firms or organizations at the Hearings were Robert A. Armitage, representing Eli Lilly and Company; Monte R. Browder, representing Ivax Corporation; David Coffin-Beach, representing Torpharm, Inc.; Gregory J. Glover, Counsel to Pharmaceutical Research and Manufacturers of America; Nancy J. Linck, representing Guilford Pharmaceuticals; and Ross Oehler, representing Aventis Pharmaceuticals Inc. One scholar, Edward A. Snyder, from the University of Chicago, and one attorney, Rochelle K. Seide, from Baker Botts, LLP, also participated in a business perspective panel on the pharmaceutical industry.

B. Industry Description

R&D in the pharmaceutical industry generally produces two main types of innovation: (1) discrete innovation, which means, in general terms, that the invention might be improved, but does not point the way to wide-ranging, subsequent discoveries of new chemical entities (NCEs);[1] and (2) incremental innovation, which describes the development of improvements to existing drug products, often referred to as product line-extensions.[2] Obviously, innovation can occur at many points along the continuum, from discrete to incremental, but these categories are useful in identifying certain characteristics associated with innovation in the pharmaceutical industry.

1. Discrete Research and Development for NCEs

Discrete R&D in the pharmaceutical industry focuses on the discovery and development of new chemical or molecular

[1] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 880 (1990) (discussing types of innovation); *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Mark Lemley Testimony Feb. 25, 2002*, at page 37 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)); Richard C. Levin, *Testimony of Richard C. Levin, President, Yale University* (2/6/02), at http://www.ftc.gov/os/comments/intelpropertycomments/levinrichardc.htm (hereinafter R. Levin (stmt)). *But cf.* Browder 3/19 at 174 (noting the potential need for progression from generic compound to specific compound to unique formulation).

[2] For an overview of the different types of pharmaceutical patents, *see* Box 3-2.

entities to make small molecule drug products.[3] The discovery of a chemical molecule that is both efficacious and safe for human usage can result in a totally new drug product. Such discoveries typically require significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high. Brand-name companies spend a substantial amount in development costs over the course of 10 to 15 years to bring a product involving an NCE to market from the initial research stage.[4] The brand-name companies' trade association reports that most newly marketed drugs do not cover their average development costs.[5] Brand-name companies typically rely on a small number of "blockbuster" drugs to recoup their overall investment in innovation, including R&D costs for failed products.[6]

Box 3-2. *Pharmaceutical Patents*

Pharmaceutical patents are issued for four different categories: drug substance, method of use, formulation, and process. Drug substance patents cover the compound or active ingredient in the drug product, such as fluoxetine hydrochloride, which is the active ingredient in Prozac. Method of use patents cover the use of the product to treat certain health problems, such as depression or asthma. Formulation patents cover the physical composition or delivery mechanism of the drug product, such as an extended release tablet or capsule. Process patents generally cover the procedure used to make the active ingredient. For further details on pharmaceutical patents, *see* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (hereinafter, FTC, *Generic Drug Study*), *at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Relatively few patents are required to protect a product with an NCE.[7] One panelist noted that an actual drug product can be based on between four and 15 patents.[8] The low number of patents contained in a pharmaceutical product

[3] This contrasts with the biotechnology industry, which focuses instead on cells and large biological molecules (such as DNA and proteins). *See* Beier 2/26 at 248.

[4] *See* Gregory J. Glover, *Competition in the Pharmaceutical Marketplace* (3/19/02) 3 (stating that the average cost to develop a new drug is $802 million), *at* http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf (hereinafter Glover (stmt)); Armitage 3/19 at 127-28; s*ee also* Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999) (discussing development risk), *available at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf (hereinafter BE Staff Report, *The Pharmaceutical Industry*); Arthur D. Little, *Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/littlearthurd2.pdf).

[5] *See* Pharmaceutical Research and Manufacturers of America, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights* (Public Comment) 9, *at* http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf (hereinafter PhRMA (stmt)); *see also* Glover (stmt) 4; Armitage 3/19 at 129; BE Staff Report, *The Pharmaceutical Industry* (discussing market risk).

[6] *See* The National Institute for Health Care Management, *Changing Patterns Of Pharmaceutical Innovation* 4 (2002), *at* http://www.nihcm.org/innovations.pdf (hereinafter *NIHCM Innovation Report*); IMS Health, *IMS HEALTH Data Reveal Dramatic Growth in Megabrands*, *at* http://secure.imshealth.com/public/structure/dispcontent/1,2779,1362-1362-143992,00.html; PhRMA (stmt) 11.

[7] One panelist defined discrete product industries as those that require relatively few patents to protect a product, and complex product industries as those that require a relatively large number. *See* Cohen 2/20 at 30 and Wesley M. Cohen, *Patents: Their Effectiveness and Role* (2/20/02) (slides) at 13, *at* http://www.ftc.gov/opp/intellect/cohen.pdf.

[8] *See* Browder 3/19 at 174.

means that, as panelists noted, the development of patent thickets is generally not a concern.[9] Although brand-name companies may compete with each other in the same therapeutic class, such as anti-depressants or blood-pressure-lowering drugs, and may seek to obtain a number of patents in a particular area to ensure freedom to operate, such behavior has not given rise to so many overlapping sets of patent rights as to hinder the commercialization of new technologies.[10] From 1989 to 2000, the Food and Drug Administration (FDA) approved 1,035 New Drug Applications (NDAs), 361 of which were for NCEs.[11] The remaining 674 NDAs that FDA approved during this period were incrementally modified drugs (IMDs).[12]

2. The Demanding Nature of the NCE Development Process

Panelists provided an overview of the two-stage process to determine whether an NCE is safe and efficacious to market – a process that is time-consuming, uncertain, and expensive.[13] The first stage involves the identification of chemical compounds that might treat an indication or disease.[14] In general, the brand-name companies' trade association reported, "only 20 in 5,000 compounds that are screened enter preclinical testing," which involves laboratory and animal testing.[15]

The second stage begins when the company sponsoring the drug submits an NDA to the FDA. Three phases of clinical testing then follow, which the drug-sponsoring company undertakes and the FDA's Center for Drug Evaluation and Research oversees. Brand-name companies conduct Phase I clinical studies on healthy human beings to determine side effects and gather preliminary evidence of effectiveness. Phase II studies "are designed to obtain data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition."[16] Phase III studies are expanded controlled and uncontrolled trials and can involve thousands of patients. These clinical trials are often very resource and time-intensive.[17]

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[9] *See* Glover (stmt) 8.

A patent thicket is a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001) (hereinafter *Navigating the Patent Thicket*).

[10] *See* Glover (stmt) 6, 8; Armitage 3/19 at 230.

[11] *See NIHCM Innovation Report* at 3.

[12] *See NIHCM Innovation Report* at 3. IMDs are drugs which rely on an active ingredient present in a drug already approved for the U.S. market, or a closely related chemical derivative of such an ingredient, that has been modified by the manufacturer. *Id.* at 5.

[13] *See* Armitage 3/19 at 127-28.

[14] *See id.* "Indication" means disease, illness, or disorder.

[15] *See* Glover (stmt) 3; Armitage 3/19 at 127.

[16] Tufts Center for the Study of Drug Development, *How New Drugs Move through the Development and Approval Process* (2001), *at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4.

[17] *See* Glover (stmt) 3.

3. The Implications of Clinical Trials for Effective Patent Term of NCEs

The time-consuming nature of clinical trials to evaluate a drug product's safety and efficacy may limit the length of effective patent term that brand-name companies can realize. Panelists testified that brand-name companies seek to obtain patents early in the R&D process – usually before clinical trials have commenced.[18] One panelist stated that the initial patent(s) to be issued for a totally new drug product are on the drug substance (*i.e.*, the NCE or molecule).[19] This panelist contended that drug substance patents are typically the most valuable for the brand-name company, because they are much more difficult for potential competitors (including generic companies) to design around than formulation or method of use patents.[20]

In the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, Congress provided for restoration of a portion of the patent term that elapses while clinical trials and FDA review are under way.[21] The Hatch-Waxman Amendments can restore patent term up to a maximum of five years, depending on how long clinical trials and FDA review take. Total effective patent term may not exceed more than 14 years from the date of FDA approval.[22] Pharmaceutical companies report, however, that by the time clinical trials are complete and a drug product is ready to market, the effective patent life for a drug patent – even with patent term restoration – is typically about 11 years,[23] substantially shorter than the 20-year statutory patent term.[24] Congress also has provided other market exclusivity periods for brand-name

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[18] *See* Glover 3/19 at 172-74; Armitage 3/19 at 176-77.

[19] *See* Armitage 3/19 at 178.

[20] *See id.*; McCurdy 3/20 at 36-37.

[21] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[22] 35 U.S.C. § 156 (c)(3). Another approach to restoring the patent term that elapses during FDA review would be to reduce FDA approval time. One study has found that reductions in regulatory approval times are somewhat more effective in increasing cash flow for a brand-name company, because such reductions add years to the less heavily discounted beginning of the product life cycle, rather than the end. *See* James W. Hughes et al., *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare* (Public Comment) 8-9, *at* http://www.ftc.gov/os/comments/intelpropertycomments/snydermoorehughes.pdf.

[23] *See* PhRMA (stmt) 9-10 (stating that "the [average] effective patent life for drugs introduced from 1984-1995 that received patent term restoration, including such restoration, was only about 11 years" and *citing* Sheila R. Shulman et al., *Patent Term Restoration The Impact of the Waxman-Hatch Act on New Drugs and Biologics Approved 1984-1995*, 2 J. BIOLAW AND BUS. 63, 66 (1999)); *see also* Linck 4/9 at 97; Browder 3/19 at 174-75; Seide 3/19 at 176; Armitage 3/19 at 176-77. *But see* NIHCM Foundation Issue Brief, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation* 1, 3 (Aug. 2000) (arguing that the effective patent term has increased by at least 50% since the passage of the Hatch-Waxman Amendments), *at* http://www.nihcm.org/prescription.pdf.

[24] A patent's term is 20 years from the date of *filing* the application. Due to the time-consuming nature of the patent examination process, *most* patents are unlikely to have an effective patent term of 19 or 20 years. *See* 35 U.S.C. § 154(a)(2), *as amended* by the Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, which changed patent term from 17 years measured from date of a patent's issuance to 20 years measured from date of filing the patent application.

companies.[25]

Box 3-3. ***Generic Drug Entry Prior to Patent Expiration: An FTC Study***

In light of the questions its various generic drug investigations raised, the Commission began an industry-wide study of generic drug competition in October 2000. The Generic Drug Study focused solely on the procedures used to facilitate generic drug entry *prior to* expiration of the patent(s) that protect the brand-name drug product. The Commission issued nearly 80 special orders - pursuant to Section 6(b) of the FTC Act - to brand-name companies and to generic drug manufacturers, seeking information about certain practices. The Commission staff compiled the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. Based on this data, the Commission made two primary recommendations concerning the 30-month stay provision and the 180-day exclusivity to mitigate the possibility of abuse that deters more generic drugs from becoming available. The Generic Drug Study is *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

4. Incremental Innovation for the Development of IMDs

The other main type of innovation in the pharmaceutical industry consists of enhancing known chemical entities by formulating new dosage forms or additional methods of use for existing chemical entities. This type of innovation is generally described as "incremental," which, in general terms, means that "today's advances build on and interact with many other features of existing technology."[26] In the pharmaceutical industry, incremental innovation generally falls into one of three categories. The modified product may use a new formulation, such as a transdermal patch instead of a pill, may combine two previously approved active ingredients, or may use a new salt or esther, which is a more purified form of the original chemical entity.[27] Several panelists suggested that brand-name companies have responded to effective patent term reduction and the increasing cost of discovering and developing NCEs by implementing product life-cycle management, including the use of IMDs.[28] Some have noted that IMDs "provide a high return on investment."[29]

Participants in the Hearings expressed differing views about the benefits of these modified drugs. Some testified that IMDs benefit consumers by providing more convenient dosing or "superior therapeutic

[25] For example, the safety and efficacy data for a product may not be relied upon by another company for five years if the product contains an NCE and for three years if the product involves a new use of an existing compound. 21 U.S.C. § 355(c)(3)(D)(ii). A drug product also can obtain an additional six months of market exclusivity if it conducts studies showing the product is safe and effective for children. 21 U.S.C. § 355a.

[26] *See* Merges & Nelson, 90 COLUM. L. REV. at 881.

[27] *See NIHCM Innovation Report* at 5; Armitage 3/19 at 217.

[28] *See* Linck 4/9 at 97-98; Aventis Pharmaceuticals Inc., *Comments of Dr. Nahed Ahmed, Vice President, Productivity, Portfolio & Project Management Drug Innovation & Approval Aventis Pharmaceuticals Inc.* (Public Comment) 3-4 (contending that there are strong economic incentives for brand-name companies to implement IMDs, because they are "safer, faster, and more cost effective for the development as an incremental improvement rather than an original product."), *at* http://www.ftc.gov/os/comments/intelpropertycomments/aventis.pdf (hereinafter Aventis (stmt)); Armitage 3/19 at 216-218; Snyder 3/19 at 224; *NIHCM Innovation Report* at 3.

[29] *NIHCM Innovation Report* at 4; *see also* Aventis (stmt) 4.

properties than the original formulation,"[30] or by serving certain patient populations better than the original product.[31] The brand-name companies' trade association stated that if physicians and consumers choose IMDs in preference to generic alternatives of the original brand-name product, the modified drug is warranted.[32] In contrast, a generic drug manufacturer suggested that IMDs might be a tactic employed by brand-name companies "to extend patent monopolies beyond the patent expiry of the new chemical entity . . . by a matter of years, not days or weeks or months."[33] This panelist also argued that the PTO issues too many questionable patents, which create a gridlock of patent litigation in the district court system and thereby delay generic entry.[34] The FTC's Generic Drug Study found that over time, for blockbuster products, brand name companies are suing for infringement on more patents, and those suits take longer on average than suits involving a single patent.[35] Others have reported that "the FDA view[s] the vast majority of IMDs as providing no significant clinical improvement."[36]

C. The Role of Patents In Spurring Pharmaceutical Innovation

Panelists reported that patent protection promotes innovation in the pharmaceutical industry by creating incentives for brand-name companies to innovate, and by disclosing inventions, thereby encouraging generic companies to innovate by designing around brand-name company patents.

Participants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of NCEs.[37] One panelist noted that patents are particularly important in the pharmaceutical industry, because the Hatch-Waxman Amendments permit generic applicants to rely on the brand-name company's proprietary data demonstrating the safety and efficacy of the brand-name drug product.[38]

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[30] Glover (stmt) 7.

[31] *See* Snyder 3/19 at 224.

[32] *See* PhRMA (stmt) 29-30; *see also* Glover (stmt) 7.

[33] Coffin-Beach 3/19 at 201-05, 212-213 (suggesting that brand-name companies time their incremental modifications to maximize their product's franchise, for example, by waiting 10 years to develop a sustained-release version of an NCE).

[34] Coffin-Beach 3/19 at 204-205.

[35] *See* FTC, *Generic Drug Study* at 47-48.

[36] *NIHCM Innovation Report* at 7; *see also* Coffin-Beach 3/19 at 201-05 (stating that IMDs may have "questionable therapeutic merit.").

[37] *See* PhRMA (stmt) 10-13; Glover (stmt) 2, 4 (describing the cost of new drug development and generic entry); Linck 4/9 at 48-49; Armitage 3/19 at 165; *see supra* Ch. 2(B)(1)(b) (discussing economic studies on the role of patents in protecting against free riding in different industries).

[38] *See* Armitage 3/19 at 133, 165. The FDA considered retesting of generic drugs to be wasteful if the underlying drug is safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be

Patent law requires applicants to disclose the inventions for which they seek patents. The purpose of the disclosure obligation is to foster further innovation by enabling a person skilled in the particular art to learn from another's invention.[39] This disclosure obligation is a trade-off for obtaining the right to exclude others from making, using, offering for sale or selling an invention.[40] Several panelists observed that the disclosure requirement fosters innovation in the pharmaceutical industry by enabling both brand-name and generic companies to discern the development plans and scientific development of rival companies.[41] One panelist reported that patent literature is an important source of information on technological advances for the pharmaceutical industry, whereas scientific literature, much of which is enabled by patents, is more important in the biotechnology industry.[42]

One way in which a generic company can compete with a particular brand-name product prior to the expiration of the patents that cover the drug product is to design around those patents.[43] Representatives of generic companies observed that the process of designing around brand-name patents can give rise to innovation.[44] In some circumstances a generic company may obtain a patent for its design-around innovations.[45]

D. The Role of Competition in Spurring Pharmaceutical Innovation

Panelists described competition among brand-name companies and the role of the Hatch-Waxman Amendments in fostering competition and innovation in the pharmaceutical industry. One panelist observed that the granting of a pharmaceutical patent does not necessarily confer a "monopoly on the treatment of any specific disease;" brand-name companies may compete with each other in the same therapeutic class, such as drugs that reduce cholesterol.[46] Moreover, according to the brand-name companies' trade association, competition among brand-name companies is increasing, because the period of market exclusivity between the introduction of breakthrough medicine and competing innovators has been consistently shrinking

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effective. *See* H.R. REP. No. 98-857, Part I at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649. The ability of other companies to rely on that data and develop bioequivalent generic versions of NCEs at much lower costs significantly reduces the profits for the branded product. One panelist stated that once a certain drug has a generic counterpart, the result is a "more rapid decline in the pioneer share of the market" because pharmacy benefit managers and formulary managers require that physicians and patients use generic drugs, as opposed to the more expensive branded drugs. *See* Glover 3/19 at 171.

[39] *See supra* Ch. 2(I)(A)(3).

[40] Rogan 2/6 at 21.

[41] *See* Coffin-Beach 3/19 at 212; Glover 3/19 at 224-25; Seide 3/19 at 226; Browder 3/19 at 238; Oehler 2/26 at 319.

[42] *See* Blackburn 2/26 at 319-20.

[43] For further details, *see* FTC, *Generic Drug Study*. For discussion of design-around innovation by brand-name companies, *see* Armitage 3/19 at 230.

[44] *See, e.g.,* Browder 3/19 at 228.

[45] *See* Coffin-Beach 3/19 at 225.

[46] *See* Glover (stmt) 6. *But see NIHCM Innovation Report* at 3 (suggesting that price competition among several new drugs products in a therapeutic class is limited.).

since 1965.[47] None of the panelists believed, however, that competition alone could generate sufficient innovation in the pharmaceutical industry.[48]

One of the unique aspects of the pharmaceutical industry is how the regulatory structure governing the approval of new brand-name and generic drug products has spurred additional competition and innovation. In this case, the Hatch-Waxman Amendments sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. The streamlined approval process gives generic drug applicants the opportunity to obtain FDA approval of their generic drug products prior to patent expiration.[49] By removing obstacles to generic competition, the Hatch-Waxman Amendments "stimulated the development of a generic pharmaceutical industry in the United States. Since the law's passage, the generic industry's share of the prescription drug market has jumped from less than 20 percent to almost 50 percent today."[50] The Hatch-Waxman Amendments have fostered significant price competition in those markets with generic entry.[51] The generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams.[52] Brand-name companies often have introduced IMDs for which they can seek patent protection to lessen the impact of this generic competition.[53]

Congress also encouraged generic

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[47] *See* Glover (stmt) 7; PhRMA (stmt) 28. *But see* Sal Ricciardi, *Comments Re: Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy Public Hearings, Spring and Summer, 2002* (Public Comment) 10 (discussing restraints on secondary market competition), *at* http://www.ftc.gov/os/comments/intelpropertycomments/pda.pdf.

[48] Panelists disagreed on the extent to which innovation would occur in the pharmaceutical industry absent patent protection, although all believed that it would decline markedly. Professor Snyder, who has conducted research into this particular issue, cited findings indicating that in the absence of patent protection for pharmaceuticals, innovation would decrease by approximately 60%. Armitage disagreed with Snyder, asserting that the absence of patents would eliminate innovation in the pharmaceutical industry. *Compare* Snyder 3/19 at 170 *with* Armitage 3/19 at 180.

[49] Brand-name companies must provide the FDA with information regarding patents that cover their drug products, which the FDA then lists in a publication commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A) and FTC, *Generic Drug Study* at Ch. 3. Generic drug companies who seek FDA approval prior to patent expiration must give notice to brand-name companies stating that the listed patents are invalid or not infringed by the generic product.

[50] *See* Glover (stmt) 7; *see also* Ashoke Bhattacharjya, *FTC Health Care Workshop: Panel on Branded and Generic Pharmaceuticals* 5 (stmt presented at the FTC's Healthcare Workshop Sept. 10, 2002), *at* http://www.ftc.gov/ogc/healthcare/bhatta.pdf; FTC, *Generic Drug Study* at (i) (identifying these figures as shares of prescriptions filled).

[51] Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand and rapidly secures as much as a two-thirds market share. *See, e.g.,* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (July 1998), *at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0; DAVID REIFFEN & MICHAEL R. WARD, GENERIC DRUG INDUSTRY DYNAMICS (Federal Trade Commission Bureau of Econ. Working Paper No. 248, 2002), *at* http://www.ftc.gov/be/econwork.htm; *see also* BE Staff Report, *The Pharmaceutical Industry*.

[52] *See, e.g.*, Glover 3/19 at 146 (noting that "even major companies must develop a blockbuster every two to three years or face massive financial contraction").

[53] Browder 3/9 at 227-28.

entry by granting 180 days of marketing exclusivity to the first generic applicant to file an application for a generic drug product that does not infringe the brand-name product or that challenges the validity of the brand-name company's patents.[54] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher price until more generic products enter). Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs.[55] Indeed, one generic panelist reported that competition among generic companies for the 180 days of exclusivity has become "acute."[56]

Once a brand-name company is notified of the filing of such a generic application, it has a 45-day window in which to sue the generic applicant for patent infringement. The initiation of the patent infringement suit triggers a 30-month stay of FDA approval of the generic drug application. According to the legislative history, the stay allows for the commencement of a lawsuit and takes into account the patent owner's rights while still encouraging generic entry.[57]

[54] For a fuller discussion of the effect of the 180-day marketing exclusivity provision on competition, *see* FTC, *Generic Drug Study* at Ch. 3.

[55] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[56] Coffin-Beach 3/19 at 239.

[57] H. REP. NO. 98-857, at 27 (1984).

E. The FTC's Pharmaceutical Industry Enforcement Actions and Generic Drug Study

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers when it had reason to believe that a company abused its patent rights in violation of the antitrust laws. The Commission has addressed conduct that it alleged would have the effect of delaying generic entry, including certain patent settlement agreements between brand-name companies and generic applicants,[58] a brand-name company's acquisition of an exclusive license to a particular patent,[59] the purported

[58] *Abbott Laboratories,* No. C-3945 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. *Geneva Pharmaceuticals,* No. C-3946 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3946.do.htm. *Hoechst/Andrx,* No. 9293 (FTC May 8, 2001) (consent order), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm. In another matter, *Schering-Plough,* the Commission resolved all claims against one of three respondents, American Home Products (AHP), by issuing a final consent order. *Schering-Plough Corp.*, No. 9297 (FTC Apr. 2, 2002) (consent order as to AHP), *available at* http://www.ftc.gov/os/2002/04/scheringplough_do.htm.

The case against the other two respondents is in litigation before the Commission. *See Schering-Plough Corp.*, No. 9297 (FTC July 2, 2002) (Initial Decision), *available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf.

[59] *Biovail Corp.*, No. C-4060 (FTC Oct. 2, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf.

use of sham litigation,[60] and an agreement between generic drug manufacturers.[61] It also has addressed conduct that the Commission contended would eliminate a potential competitor for an NCE in the merger context.[62]

Over the past few years the Commission also has observed through its investigations, law enforcement actions, and Generic Drug Study that some brand-name and generic drug manufacturers may have "gamed" the 180-day marketing exclusivity and the 30-month stay provisions, attempting to restrict competition beyond what the Hatch-Waxman Amendments intended.[63] The Commission has undertaken two main types of enforcement activities in this area. It has addressed patent settlement agreements between brand-name companies and generic applicants that the Commission alleged had delayed the entry of one or more generic applicants through manipulation of the 180-day exclusivity period.[64] It also has addressed allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings[65] that trigger the Hatch-Waxman provision prohibiting the FDA from approving a generic applicant for 30 months.[66]

Brand-name companies previously could obtain additional 30-month stays by obtaining additional patents that claimed their brand-name products. There were opportunities for "gaming" the 30-month stay because the FDA does not oversee whether these additional patents meet the requirements for listing with the FDA, and there is no private right of action for a court to make such a determination. Not surprisingly, given the amount of revenue at stake, the FTC found in its Generic Drug Study that some brand-name companies have "gamed" the 30-month stay provision, and that it had the potential to be "gamed" in the future, absent reform.[67] The FDA changed its rule to prevent brand-name companies from obtaining additional 30-month stays. This rule change was based

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[60] *Bristol-Myers Squibb*, No. C-4076 (FTC Mar. 7, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[61] *Biovail Corp. and Elan Corp. PLC*, No. C-4057 (FTC Aug. 20, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/06/biovailelando.pdf.

[62] *In the Matter of Glaxo Wellcome plc, and SmtihKline Beecham PLC*, No. C-3990 (FTC Jan. 31, 2001) (consent order) (requiring divestiture of certain intellectual property rights on NCEs), *available at* http://www.ftc.gov/os/2001/01/glaxosmithklinedo.pdf.

[63] For further details on the Generic Drug Study *see* Box 3-3.

[64] *Abbott Laboratories,* No. C-3945 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. *Geneva Pharmaceuticals,* No. C-3946 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3946.do.htm.

[65] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co.,* No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Brief of Amicus Curiae Federal Trade Commission, *Am. Bioscience, Inc. v. Bristol Myers Squibb Co.*, 2000 U.S. Dist. LEXIS 21067 (No. CV-00-08577), *available at* http://www.ftc.gov/os/2000/09/amicusbrief.pdf.

[66] *Biovail Corp*., No. C-4060 (FTC Oct. 2, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf; *Bristol-Myers Squibb*, No. C-4076 (FTC Mar. 7, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[67] *See* FTC, *Generic Drug Study at* (ii)-(iv) and Ch. 3.

largely on the FTC's recommendation.[68]

F. Conclusion

Representatives from the pharmaceutical industry emphasized that patents are critical for promoting pharmaceutical innovation of NCEs. Brand-name companies depend on patents to recoup their substantial investment in the discrete innovation that leads to the development of new drug products. Also, brand-name companies make and patent incremental improvements to their products to manage them on a life-cycle basis. Panelists differed as to the extent to which such IMDs benefit consumers.

Competition in the pharmaceutical industry occurs in two primary ways: between brand-name companies that have products in the same therapeutic class and between brand-name and generic companies. Competition between and among brand-name companies and generics can foster innovation, as well as other benefits of competition. Patent disclosure requirements can enable brand-name and generic competitors to design around some patents covering brand-name drug products in order to bring competing products to market. The Commission has brought enforcement actions in the pharmaceutical industry to protect competition, including incentives to innovate.

The innovation that the patent system spurs for the discovery and commercialization of NCEs in the pharmaceutical industry in many ways showcases the patent system's benefits. Such innovation entails the high fixed research costs, relative ease of imitation, and free riding problems that patent protection effectively manages. Fewer patent thicket issues arise in the pharmaceutical context than in industries where innovation is less discrete and individual products are covered by many patents. Subsequent sections examine how the roles of patents and competition vary in industries that exhibit different characteristics.

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[68] *See* Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 68 Fed. Reg. 36,675 (2003) (to be codified at 21 C.F.R. § 314).

III. THE BIOTECHNOLOGY INDUSTRY

A. Introduction

The biotechnology industry also relies primarily on patents to provide incentives to invest in innovation. Biotechnology companies seek patent protection to appropriate the value of their inventions, to attract investment from capital markets, which funds their costly research, and to facilitate inter-firm relationships necessary for commercial development of their inventions. Patent disclosures can assist biotechnology firms in focusing their R&D efforts on areas not covered by patents. Competition also encourages innovation, for example, as firms race to develop new technologies.

Although panelists generally agreed on the benefits of patents in the biotechnology industry, many panelists also stated that the issuance of questionable patents is harming innovation in the industry, and that the mechanisms for challenging such patents, including litigation, are inadequate. Some also expressed concern that the need for multiple, patented research tools has the potential to create difficulties for follow-on innovation. Others discussed how licensing practices, such as reach-through license agreements and patent pools, can be used to surmount some of these difficulties by facilitating access to research tools that promote further innovation.

The panelists who represented biotechnology firms or organizations at the Hearings were David W. Beier, Counsel to the Biotechnology Industry Organization; Lee Bendekgey, representing Incyte Genomics; Robert Blackburn, representing Chiron Corp.; Monte R. Browder, representing Ivax Corporation; Barbara Caulfield, representing Affymetrix, Inc.; David Coffin-Beach, representing Torpharm, Inc.; David J. Earp, representing Geron Corp.; Michael K. Kirschner, representing Immunex Corp.; and Ross Oehler representing Aventis Corp. Rochelle K. Seide, from Baker Botts, LLP, also participated in a business perspective panel on the biotechnology industry.

B. Industry Description

The biotechnology industry uses cellular and molecular (*i.e.*, biological) processes to address problems or make products. R&D in the biotechnology industry focuses on cells and large biological molecules (such as DNA and proteins) rather than the chemical compounds that the pharmaceutical industry uses to make small molecule drug products.[69]

Cells are the basic building blocks of all living things. Plants, animals, and humans are incredibly diverse, yet there are remarkable similarities among the species that are invisible to the naked eye. All living things use essentially the same cellular processes and speak the same genetic language.[70] This unity at the cell level of different species provides the foundation for biotechnology research.

Participants asserted that R&D

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[69] *See* Beier 2/26 at 248.

[70] *See* Biotechnology Industry Organization, *Biotechnology: A Collection of Technologies*, *at* http://www.bio.org/er/technology_collection.asp.

spending in the biotechnology industry "is more than double the average of the pharmaceutical industry (both on a per employee basis and as a percentage of sales), and the pharmaceutical industry is several times more R&D intensive than any other industry."[71] R&D is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries.[72] Panelists also noted that the commercialization of biotechnology research is particularly difficult, due to three factors. First, as discussed above in relation to the pharmaceutical industry, the drug development process is time-consuming, uncertain, and expensive. One panelist noted that his company took 10 years to bring its first product to market, and another 6 years before it brought its second product to market.[73] Second, much biotechnology research is basic, at least a step removed from the more applied research that is directly susceptible to commercialization.[74] Biotechnology thus highlights the issues that lie at the core of the prospect theory regarding incentives for, and efficiencies in, bridging the gap between basic research and ultimate commercial sales.[75] Third, most biotechnology industry participants are small, particularly relative to the pharmaceutical industry, and lack internal financial resources sufficient for undertaking extensive drug development.[76]

Although innovation in the biotech industry has many facets, it generally results in two classes of inventions.[77] One class relates to newly discovered and isolated genes or proteins or to pharmaceutical inventions based on those genes or proteins. Although one cannot patent a naturally-occurring gene or protein as it exists in a plant, animal, or human, one can patent a gene or protein that has been isolated from the body and is useful in that form as a pharmaceutical drug or other application.[78] The other class of biotechnology inventions relates to methods of treating patients with a given disease through the use of a particular gene or protein. Even if someone has a patent on a gene or protein, a researcher who discovers a new method of use for that gene or protein can patent the new method of use.[79]

The biotechnology industry is closely related to the pharmaceutical industry. One panelist observed that both industries try to

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[71] Biotechnology Industry Organization, *Testimony* (2/26/02) 2, *at* http://www.ftc.gov/opp/intellect/020226davidwbeier.pdf (hereinafter BIO (stmt)); Kirschner 2/26 at 240.

[72] *See* Beier 2/26 at 248-49; Kirschner 2/26 at 240.

[73] *See* Kirschner 2/26 at 239.

[74] *See* Earp 2/26 at 252; Seide 3/19 at 167.

[75] *See* Rai 4/10 at 21 (citing bio-pharmaceuticals as a context in which "patents serve not only the traditional incentive function but also serve the function of incentivizing further commercialization and development"); *see generally supra* Ch. 2(III)(A)(1) (discussing Professor Kitch's prospect theory).

[76] *See* Earp 2/26 at 252.

[77] *See generally* Biotechnology Industry Organization, *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine*, *at* http://www.bio.org/genomics/primer.html (hereinafter BIO, *Primer*).

[78] *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 2105 (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (hereinafter MPEP); Seide 3/19 at 167-68.

[79] *See* BIO, *Primer* at 6.

discover end-use products.[80] Indeed, small molecule-type research, the aim of which is to produce a traditional pharmaceutical drug product, has become much more efficient through the use of biotechnology tools such as proteins and genomic sequences.[81] Also, many biotechnology companies conduct basic research to identify promising products, and then partner with a pharmaceutical company to test and commercialize the product.[82] Patents facilitate this process; there is a tremendous amount of licensing, as well as acquisition activity, between the two industries searching for synergies to bring products to market.[83]

C. The Role of Competition in Spurring Biotechnology Innovation

Several panelists discussed the role of competition in spurring biotechnology innovation.[84] One panelist commented that "one thing that competition does is, it sure makes you hurry up."[85] Drawing on his experience in the biotech industry, he observed that companies typically found their initial success by introducing a product with no comparable or rival product.[86] After this success, much bigger and better funded competitors entered the market, thus adding competitive pressure to keep innovating.[87] In general, however, although panelists found competitive forces important, they placed emphasis on the role of patents as drivers of innovation in the biotech industry.

D. The Implications of Patent Protection for Innovation

1. The Role of Patents in Spurring Innovation in the Biotechnology Industry

a. Patentability Encourages Investment in R&D

In 1980, the Supreme Court in *Diamond v. Chakrabarty*[88] decided that living organisms produced by human intervention are patentable. Participants stated that the biotechnology industry would not have emerged "but for the existence of predictable patents,"[89] and that *Chakrabarty* spurred significant growth in the biotechnology industry.[90] Their discussion describes the role of patents in an industry with a very costly, high-risk R&D process and a structure consisting significantly of

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[80] *See* Blackburn 2/26 at 250-51.

[81] *See* Seide 3/19 at 188-89, 244-45 (discussing "rational drug design"); Blackburn 2/26 at 250, 261-62.

[82] *See, e.g.,* Blackburn 2/26 at 251; Earp 2/26 at 252.

[83] *See* Bendekgey 2/26 at 257-59; Oehler 2/26 at 254.

[84] *See, e.g.,* Caulfield 3/19 at 242-43.

[85] *See* Bendekgey 2/26 at 286. Patent races may lead to excessive R&D in a particular area, although distinguishing beneficial from wasteful overlapping efforts may prove difficult. *See supra* Ch. 2(III).

[86] *See* Bendekgey 2/26 at 285-86.

[87] *See id.*

[88] *Diamond v. Chakrabarty*, 447 US 303 (1980).

[89] *See* Kirschner 2/26 at 240-41, 328.

[90] BIO (stmt) 4.

small, not-yet-profitable firms.[91]

A biotechnology trade association highlighted one particular role of patents in this setting: patentability of biotech inventions enables the biotechnology industry "to attract venture capital."[92] Biotechnology companies overwhelmingly underscored the importance of patents for attracting venture capital.[93] As one of these panelists stated, "patents are indeed the key asset for us. They enable us to have access to the capital markets and to continue our innovation and development."[94] The venture capital accessed through patents thus enables not-yet-profitable companies to "sustain . . . innovation through massive investments in research and development."[95]

b. The Role of Patent Disclosures in Fostering Biotechnology Innovation

The panelists differed on the extent to which required patent disclosures encourage the dissemination of information and, therefore, foster follow-on innovation in biotech.[96] One panelist stated that the patent literature "has not been a significant source of ideas" for the company's research.[97] By contrast, a panelist from a pharmaceutical firm with a biotechnology affiliate noted that "there is value to be found in patents as literature."[98] Another panelist noted that "the information transfer happens in the scientific literature [rather than] the patent literature," but added that "quite a bit of the scientific literature is enabled by the fact that there's been a patent filed on it."[99] This panelist observed that patent literature is a more important source of information in the pharmaceutical industry than the biotechnology industry.[100]

c. Patenting of Biotechnology Research Tools

A research tool is a technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product or properties of a potential drug product.[101] As such, it serves as a springboard for follow-on innovation. Examples of these types of enabling tools include high-throughput screening technologies, micro-array-type technologies, genomic databases, and

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[91] *See id.* at 2, 4; Beier 2/26 at 265-66; Blackburn 2/26 at 275-76.

[92] BIO (stmt) 4.

[93] *See* Earp 2/26 at 237; Bendekgey 2/26 at 256; Blackburn 2/26 at 263.

[94] *See* Earp 2/26 at 326.

[95] BIO (stmt) 4.

[96] *See* Kirschner 2/26 at 318; Blackburn 2/26 at 319; Oehler 2/26 at 319.

[97] Kirschner 2/26 at 318.

[98] Oehler 2/26 at 319.

[99] *See* Blackburn 2/26 at 319.

[100] *See id.* at 320.

[101] *See* Blackburn 2/26 at 250, 260 (noting that there are likely to be slightly varying definitions of research tools); Bendekgey 2/26 at 267-68, Cohen 10/30 at 150, McGarey 11/6 at 160.

Box 3-4. ***Effects of Research Tool Patents and Licensing on Biomedical Innovation***
John P. Walsh, Ashish Arora & Wesley M. Cohen *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://books.nap.edu/books/0309086361/html/285.html#pagetop.

John P. Walsh, Ashish Arora, and Wesley M. Cohen conducted an empirical study of the implications for innovation of patenting and licensing practices in the pharmaceutical and biotech industries. The authors conducted "70 interviews with IP attorneys, business managers and scientists from 10 pharmaceutical firms and 15 biotech firms, as well as university researchers and technology transfer officers from 6 universities, patent lawyers and government and trade association personnel."

The authors found that patents on research tools have increased, but have not significantly hindered drug discovery. The increased complexity of the patent landscape, they concluded, has not resulted in a tragedy of the anticommons. (*See* Box 3-5 for further explanation of this theory.) They noted that some university research has been delayed by restrictions on the use of patented genetic diagnostics, and that there have been some delays or access restrictions to research tools or other foundational discoveries. In some instances, research was re-directed to areas where there were fewer patents. Overall, however, the researchers found that no valuable research projects were halted as a result of limited access to a research tool. The authors cautioned, however, that the potential exists and ongoing scrutiny is warranted. *See infra* Ch. 3(III)(D)(4).

The authors also concluded that firms and universities use a range of strategies to avoid breakdown and restricted access to research tools, including taking licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools and challenging patents in court. New PTO guidelines, active intervention by the NIH, and overall shifts in the courts' attitudes towards research tool patents also have lessened these potential threats, they found. A new Federal Circuit case that stated a narrow scope of the research exemption available to universities led the authors to question the extent to which some of these findings will remain applicable. The relevant Federal Circuit case, *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert denied*, 123 S. Ct. 2639 (2003), is discussed *infra* Ch. 4(II)(D).

modeling programs. Research tools are generally patentable. Researchers require a license to use patented research tools to identify and develop inventions, but typically do not require a license from the research tool patent holder to practice the ensuing inventions.[102]

Several commentators discussed the benefits to innovation derived from using and patenting research tools.[103] For example, one panelist explained that with gene chip array technology "what used to take a post-doc[toral student] in the laboratory approximately six months with proper front-end research can now be done in 20 minutes."[104] Another panelist suggested that research tools have led to a considerable reduction in the cost and time required for the targeting of therapeutic antibodies during the initial stages of new drug research. He mentioned "a very small pre-IPO firm that has moved into a phase two product in three years based on research tool technology" and went on to state that this would have been "inconceivable to have

[102] *See* Blackburn 2/26 at 260.

[103] *See id.* at 262; Bendekgey 2/26 at 258-59 and 267-68; Seide 3/19 at 167. For discussion of issues raised by research tool patents, *see* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://books.nap.edu/books/0309086361/html/285.html#pagetop (hereinafter *Research Tool*) and Box 3-4.

[104] *See* Caulfield 3/19 at 135.

happened 20 years ago, before the invention of research tools."[105]

Two panelists stressed the importance of patenting research tools.[106] One of them asserted, for example, that "if there's anything you want to protect and incent with patents, it's the research tool technology."[107] He argued that patent protection will be critical in encouraging investment in the next generation of research tools, which might reduce the costs and time required for the clinical trial phases, which are the most "expensive part" of the drug development process.[108]

2. The Quality of Biotechnology Patents

Panelists discussed concerns with the quality of biotechnology patents. Many of the panelists observed that poor quality patents can hinder innovation and competition.[109] A number of panelists stated that poor quality patents can harm innovation and competition by deterring a rival firm from entering or continuing with a particular area of research.[110] Two panelists observed that questionable patents create a "significant drag" on competition, and another panelist stated that questionable patents have a "chilling effect on both public and private sector research."[111]

One panelist stated his personal view that "the PTO's ability to provide a meaningful examination of biotechnology patents right now is in a cris[i]s."[112] Acknowledging the dedication and quality of the PTO's examiners, this panelist noted that the examiners are under such time constraints that they may be unable to conduct a meaningful patent examination.[113] According to this panelist, the PTO should

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[105] Blackburn 2/26 at 261, 262 (discussing the screening of small molecules); Oehler 2/26 at 277-78 (noting that research tools offer "great promise," but as yet have only reduced the time required for the early phases of research).

[106] *See* Blackburn 2/26 at 262; Bendekgey 2/26 at 258-59, 267-68.

[107] *See* Blackburn 2/26 at 262.

[108] *See id.* at 262-63. *See supra* Ch. 3(II)(B) (discussing the phases of pharmaceutical drug development).

[109] *See* Bendekgey 2/26 at 230; Earp 2/26 at 238; Kirschner 2/26 at 241; Oehler 2/26 at 292; Blackburn 2/26 at 294.

[110] *See* Earp 2/26 at 238, 290-91; Caulfield 3/19 at 159; Blackburn 2/26 at 296.

[111] Caulfield 3/19 at 159; Barbara A. Caulfield, *Business Perspectives on Patents: Biotech and Pharmaceuticals, Federal Trade Commission/Department of Justice Hearings* (3/19/02) (slides) at 6, *at* http://www.ftc.gov/opp/intellect/020319barbaracaufield.pdf (hereinafter Caulfield Presentation); Blackburn 2/26 at 296, Kirschner 2/26 at 328.

[112] *See* Kirschner 2/26 at 242. Mr. Kirschner voiced concerns with patents issued to wrong parties or to multiple parties on the same invention; patents that "contain overly-broad claims in view of the prior art or the scope of what was enabled or the scope of what was described" *id* at 242; and patents for which "the best prior art was not cited to the patent office, was not discovered by the patent office, or was cited to the patent office and clearly the examiner did not appreciate it." *Id*. at 241-42, 289.

[113] *See* Kirschner 2/26 at 241-44, 288-90. Similarly, a panelist commented that "examiners have an incentive to move cases along and dispose of them." *See* Bendekgey 2/26 at 231 ("I've certainly had comments repeated to me to the effect that . . . examiners have an incentive to move cases along and dispose of them, and sometimes they think there's something novel here, they're not sure what, and so they're just going to allow it and let things get sorted out in litigation. And I can tell you, when you're at the receiving end of litigation like that it has a decidedly chilling effect on competition.").

"focus on improving quality, at least within [the biotechnology patent examination group]," because patent quality is more important than pendency in the biotechnology industry.[114] Another panelist observed, "of the issues that people raise . . . in many cases [it] just come[s] down to the quality of the examination."[115]

Although panelists agreed that poor patent quality can adversely affect innovation, disagreement existed whether patent quality in the biotechnology area was any different from that in other industries. One panelist reported that patent quality is not a field-specific problem.[116] In fact, he observed that biotechnology patents may be of a higher quality than those in other industries, because of "the concentration of the Patent Office on guidelines and resources in the biotech field" in the last 10 years.[117] The representative of a biotechnology trade association similarly noted that the PTO has responded affirmatively to public controversies in relation to biotechnology patents as they have arisen and thus has headed off any lasting adverse impacts of questionable biotechnology patents.[118]

[114] *See* Kirschner 2/26 at 243, 329. *But cf.* Armitage 3/19 at 134 (raising concerns with pendency periods for biotechnology patent applications).

[115] *See* Bendekgey 2/26 at 230.

[116] *See* Oehler 2/26 at 292.

[117] *See id.*

[118] *See* Beier 2/26 at 296 (noting that "the patent system has been remarkably self-correcting."); *see also* Kirschner 2/26 at 329 (noting the PTO's responsiveness to concerns raised by the industry).

3. The Mechanisms Available for Challenging Questionable Patents

Firms in the biotechnology industry reported that they avoid infringing even questionable patents and therefore refrain from entering or continuing with a particular field of research.[119] Most panelists observed that the two existing mechanisms for challenging a questionable patent are generally inadequate.[120]

a. Challenging Questionable Patents Through Litigation

Panelists considered litigation to be an inadequate means of challenging a patent for three main reasons. First, the pace of innovation in the biotechnology industry is so rapid that by the time a court determines the question of patent validity, the research or product opportunity has passed. As one panelist observed, "six months can be a tremendous amount of time" in biotechnology research, while a biotechnology patent case "takes two to three years" to litigate.[121] Moreover, other

[119] *See, e.g.,* Earp 2/26 at 290-91, 238; Blackburn 2/26 at 296; Caulfield 3/19 at 161; s*ee also* Alik Widge, *Comments Regarding Competition and Intellectual Property* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/widgealik.htm.

[120] *See* Bendekgey 2/26 at 231; Earp 2/26 at 238, 291, 327; Kirschner 2/26 at 244, 328; Blackburn 2/26 at 294; Caulfield 3/19 at 160. One panelist noted that a third option exists that permits the public to submit comments to the PTO about patent applications published because they have been pending before the PTO for longer than 18 months. He also acknowledged this approach was not as "perfect and as targeted as an opposition proceeding, as in Europe." Oehler 2/26 at 294.

[121] Caulfield 3/19 at 160; *see also* Barton 2/26 at 220-21.

panelists suggested that just because a patent is not challenged through litigation does not mean that the patent is not problematic.[122]

Second, the cost of litigation is prohibitively expensive for many firms in the biotechnology industry. One panelist reported that a biotechnology patent case costs between five and seven million dollars to litigate.[123] Such expenditure, this panelist observed, on an area that may not end up producing revenue is beyond the means of most firms in the biotechnology industry.[124] According to panelists, most firms tend to be small and generally have to obtain funding from the capital markets or venture capitalists because of the difficulties in commercializing products.[125]

Finally, current standing requirements prevent a potentially infringing party from determining in advance the merits of a questionable patent.[126] A potentially infringing party can seek a declaratory judgment to invalidate a patent only after that party has been threatened with litigation by the patent owner. Patent owners in the biotechnology industry are careful to avoid such a situation.[127] This means the potentially infringing party has to choose whether to forge ahead with the research, and risk being sued after significant costs have been sunk, or avoid the area of research.[128] Panelists stated their companies usually will choose to avoid the area of research altogether rather than risk possible infringement later in the R&D process.[129] One panelist observed that the inability of a company to challenge the validity of a patent unless that company itself has been threatened with litigation by the patent owner results in harm to competition, because "bad patents [are able to] . . . sit out there . . . [where] you can't touch them."[130]

b. Challenging Questionable Patents Through Reexamination Procedures

Any person at any time may file a request for reexamination, and if the request raises a substantial new question of patentability affecting any claim of the patent, reexamination is commenced. Reexamination is available on an *ex parte* and *inter partes* basis.[131] The panelists unanimously considered the reexamination procedures as they existed at the time of the hearing inadequate for a third party to challenge the validity of another party's patent.[132] Participants articulated three

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[122] *See* Blackburn 2/26 at 309; Kirschner 2/26 at 308.

[123] *See* Caulfield 3/19 at 160.

[124] *See id.*

[125] *See* Kirschner 2/26 at 239; Earp 2/26 at 252; Armitage 3/19 at 166; Seide 3/19 at 167.

[126] *See* Blackburn 2/26 at 294.

[127] *See id.*

[128] *See id.* at 295.

[129] *See* Earp 2/26 at 238, 290-291; Caulfield 3/19 at 159; Caulfield Presentation at 6; Blackburn 2/26 at 296.

[130] Blackburn 2/26 at 294-6.

[131] For further discussion of reexamination, opposition, and review, *see infra* Ch. 5(III).

[132] *See*, *e.g.*, Earp 2/26 at 301, Bendekgey 2/26 at 303, Beier 2/26 at 301, Blackburn 2/26 at 294-96. One panelist wryly observed that as of the time of the hearing the *inter partes* reexamination procedures had been invoked in only four out of 160,000 cases. *See* Beier 2/26

problems with the reexamination system, two of which Congress has addressed by legislation since the Hearings.[133] The remaining problem panelists cited was that participation in an *inter partes* reexamination proceeding estops a third party participant from raising a broad spectrum of issues in subsequent court litigation.[134]

c. Challenging Questionable Patents Through a New Opposition System

Three of the panelists suggested that the United States should implement an opposition system for challenging questionable patents.[135] These panelists recommended that such an opposition system draw on the best features of other patent opposition proceedings, particularly the European system.[136] One panelist suggested that the best features of the existing United States reexamination system should also be incorporated into any opposition system.[137]

Another panelist stated that an opposition system should be implemented regardless of whether the problems discussed above in relation to reexamination proceedings were addressed by statute.[138] In fact, he noted that even if the reexamination proceedings were improved, it "probably wouldn't convince a whole lot more people to go forward with it."[139] This view was not challenged among the panelists.

4. The Potential for Patents to Impede Innovation in the Biotechnology Industry

Unlike the pharmaceuticals industry, in which major aspects of the innovation process are relatively discrete, biotechnology innovations typically form the basis of, or provide the tools for, independent follow-on R&D. Commentators discuss two ways in which patents have the potential to harm follow-on innovation in biotechnology: (1) through the development of an anticommons;[140] and (2) through the withholding of access to technologies

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at 301.

[133] These two problems were: a third-party who invoked the reexamination procedures was precluded from appealing the PTO's decision to the federal courts (*see* BIO (stmt) 24; Beier 2/26 at 301; Earp 2/26 at 301; Bendekgey 2/26 at 303); and prior art of record during the patent application process could not be the basis for a reexamination (*see* Earp 2/26 at 302). Amendments to the patent statute enacted in November 2002 conferred appeal rights on third party requesters in *inter partes* patent reexamination proceedings, overruled the decision in *In re Portola Packaging Inc.*, 110 F.3d 786 (Fed. Cir. 1997) (holding that reexamination could not be used if the basis is the same prior art references that the examiner considered, since such references do not raise a substantial new question of patentability), and clarified that patent reexamination on the basis of previously cited prior art "is not precluded." Patent and Trademark Office Authorization Act of 2002 § 5-6, 35 U.S.C. § 303(a), 312 (a) 134, and 141-44.

[134] *See, e.g.,* Beier 2/26 at 301.

[135] *See* Bendekgey 2/26 at 231; Earp 2/26 at 238, 291, 327; Kirschner 2/26 at 244, 329.

[136] *See* Earp 2/26 at 238, 291, 327; Bendekgey 2/26 at 231.

[137] *See* Kirschner 2/26 at 244.

[138] *See* Earp 2/26 at 327.

[139] *See id.*

[140] For further explanation of this theory, *see* Box 3-5.

needed for follow-on innovation.[141]

a. The Development of an Anticommons

Scholars have argued that innovation can be harmed by the development of an anticommons, which can arise when multiple property right owners have claims to separate inputs needed for some product or line of research.[142] Some panelists believe that an anticommons threatens innovation in the biotechnology industry.[143] One panelist stated, for example, that the need "to have access to a wide range of technologies to discover, create, manufacture and market a human therapeutic product" means the biotechnology industry is "highly vulnerable to . . . the tragedy of the anticommons";[144] he found "the risk of" an anticommons problem.[145] He cited the example of Enbrel, which at one time was subject to royalties paid to seven companies.[146] The panelist later noted that the royalty stacking that took place in relation to Enbrel was prior to the advent of research tool patents and reach-through royalties, which, he indicated, have increased the likelihood of anticommons problems.[147]

In their business survey of the biotechnology industry, Professors Walsh, Arora, and Cohen examined whether the existence of multiple research tool patents associated with a new product or process poses anticommons concerns.[148] They concluded that such concerns have "not been especially problematic," because mechanisms are being used, such as relying on a research exemption, obtaining a license, or inventing around patents, to prevent harm

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[141] One potential limit on such harm may spring from an experimental use defense. Although there is some debate about its scope, the industry panelists generally accepted that an experimental use defense exists at common law offering some shelter from infringement litigation to non-commercial research. *See* Armitage 3/19 at 186-87; Polk 3/19 at 190; *cf.* Thomas 2/8 (Patent Session) at 30; Sung 2/8 (Patent Session) at 136-38; Caulfied 3/19 at 163. For further discussion of the research exemption, *see infra* Ch. 4(II)(D). In their study of the biotechnology industry, Walsh, Arora, and Cohen noted that informal reliance on this defense by members of the research community has helped to prevent an anticommons or lack of access to existing patents from stifling follow-on innovation. *See* Walsh et al., *Research Tool* at 333-34.

The Federal Circuit has stated a narrow scope of this exemption in an opinion in October 2002: *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert denied*, 123 S. Ct. 2639 (2003). Some believe that this decision will chill university research, because researchers will no longer be able to rely on the exemption to overcome anticommons or access issues. *See* Cohen 10/30 at 149-52, 161-62.

[142] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE MAG., May 1, 1998, *available at* http://www.sciencemag.org/cgi/content/full/280/5364/698 and Box 3-5. For further discussion of anticommons and related issues deriving from the presence of multiple patents, *see supra* Ch. 2(III)(C).

[143] *See* Kirschner 2/26 at 241, 310-11; Caulfield 3/19 at 163-64; McGarey 11/6 at 153-54. *See also* Tom Horton, *Patenting Our Lives and Our Genes: Where Does Congress Stand in the Coming Clash?* 7-8 (noting the development of practical problems from the proliferation of biotechnology patents but finding the effect on research "uncertain"), *at* http://www.ftc.gov/os/comments/intelpropertycomments/hortonthomasjarticle.pdf.

[144] *See* Kirschner 2/26 at 241.

[145] *See id.* at 310-11.

[146] *See id.* at 241. He went on to note that one of those companies no longer receives royalties because its patent expired.

[147] *See id.* at 310. Reach-through royalties are discussed below.

[148] *See* Walsh et al., *Research Tool* at 286-89.

Box 3-5. ***Can Patents Deter Innovation? The Anticommons in Biomedical Research***
Michael A. Heller and Rebecca S. Eisenberg, Science 1998 May 1; 280: 698-701.

The tragedy of the anticommons refers to a problem that might arise when multiple owners each have a right to exclude others from a scarce resource, and no one has an effective privilege of use. There are two mechanisms by which a government might inadvertently create an anticommons:
(1) by creating too many concurrent fragments of intellectual property rights in potential future products;
(2) by permitting too many existing patent owners to stack licenses on top of the future discoveries of users.

The authors theorize that patenting of gene fragments and of receptors useful for screening potential pharmaceutical products are two situations in which too many concurrent fragments may result in an anticommons. If a tragedy of the anticommons were to emerge, it might endure because of the transaction costs of rearranging entitlements, heterogeneous interests of owners, and cognitive biases among researchers, the authors suggest.

The authors suggest that policy-makers should seek to ensure coherent boundaries of existing patents and to minimize restrictive licensing practices that interfere with product development. Otherwise, they conclude that more patent rights may lead paradoxically to fewer useful products for improving human health.

to innovation from occurring.[149] Another factor that mitigated anticommons concerns, the authors noted, is the very high number of technological opportunities in the biotechnology industry, which enables firms to redirect their research efforts to areas less encumbered by patent claims to avoid possible infringement issues.[150]

Some panelists expressed views similar to these findings.[151] One panelist commented, for example, that licensors tend to be "fairly sensitive" to the implications of royalty-stacking for product commercialization.[152] "If the licensor . . . is about to propose a royalty that's going to kill the product, [the licensor] is not going to make any money. And most of the players in this field are sophisticated enough to understand that," he argued.[153]

b. Access to Existing Technologies Needed for Follow-On Innovation

There is a debate among scholars as to the optimal balance of incentives to innovate between parties engaged in initial research and parties engaged in follow-on research. Some contend that broad patents maximize innovation by enabling the initial inventor to coordinate future follow-on R&D.[154] Others contend that restricted access to patents - especially broad patents - on discoveries such as research tools can

[149] *See id.* at 331, 333-34 (Although these mechanisms may prevent projects from being stopped, these scholars cautioned that they impose social costs, such as time delays and distraction from research.).

[150] *Id*. at 304, 331-32.

[151] *See* Blackburn 2/26 at 314-15; Beier 2/26 at 312-13; Seide 3/19 at 189; Dreyfuss 7/10 at 62

[152] *See* Blackburn 2/26 at 315.

[153] *Id*. But *cf*. Janice M. Mueller, *No "Dilettante Affair:" Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 7, 57 (2001) (arguing that "[t]he royalty stacking problem in biotechnology . . . has escalated in severity").

[154] *See, e.g.,* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977).

harm follow-on innovation.[155]

In their business survey of the biotechnology industry, Professors Walsh, Arora, and Cohen evaluated whether the later possibility has arisen. They concluded that there is no evidence that biotechnology research has been significantly impeded. Nevertheless, "the prospect exists and ongoing scrutiny is warranted."[156] They noted that access restrictions that harm innovation are most likely to occur when a research tool will be used primarily to develop innovations that will compete with one another in the marketplace, and the research tool is potentially key to progress in one or more therapeutic areas.[157] In such circumstances, the patent holder may seek either to develop the technology itself or exclusively license it to another.[158] Given that multiple technologies may require the use of such a research tool to foster further innovation, the authors saw such a development as likely to retard innovation.[159] These scholars also observed that mechanisms to mitigate such harm to innovation exist, such as "invoking a 'research exemption' that is broader than the existing legal exemption," inventing around patents, using the technology offshore, or seeking to invalidate the patent, but cautioned that many of these mechanisms can impose social costs.[160]

E. Licensing Practices for Biotechnology Research Tools

The panelists discussed two licensing arrangements that have been used in the biotechnology industry to provide firms with access to research tools: reach-through license agreements and patent pools. They also offered some observations on the merits of exclusive licensing of research tools.

1. Reach-Through License Agreements

Reach-through license agreements (RTLAs) are a form of licensing agreement used by patent owners that hold rights on a biotechnology research tool, or other upstream areas of research, to share in the value of the discoveries by licensees. Typically, RTLAs establish royalty obligations measured as a percentage of sales of the licensee's product. Usually, however, the licensee of the research tool does not need access to the research tool to make or sell its product. Rather, the licensee uses the research tool only to identify and develop the product.[161] By letting eventual market results determine the amount of royalties paid, RTLAs potentially are a means to overcome some of the uncertainties and valuation disputes that may

[155] *See, e.g.,* Merges & Nelson, 90 COLUM. L. REV. 839; Frederick M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348 (2002). For further discussion of these issues, *see supra* Ch. 2(III).

[156] Walsh et al., *Research Tool* at 331.

[157] *Id.* at 333. The authors cite stem cell technology as an example of a technology to which a patent holder might prefer to restrict access. *Id. See also* Cohen 10/30 at 94-95 (discussing Geron's incentives to limit access to embryonic stem cell technology).

[158] Walsh et al., *Research Tool* at 333.

[159] *Id.* at 290-91, 333 (arguing that "no one firm can even conceive of all the different ways that the discovery might be exploited. . . .").

[160] *Id*. at 324, 334-35.

[161] *See supra* Ch. 3(III)(D)(1)(c).

impede efficient licensing, as discussed *supra* in Chapter 2. [162]

One panelist identified two ways in which reach-through license agreements for research tools can promote competition and innovation. First, they can facilitate access to a wide range of research tools by reducing the up-front licensing costs.[163] This access is particularly important in the context of the biotechnology industry, which includes many small and yet-to-be-profitable firms.[164] Second, RTLAs may facilitate risk-sharing between the tool owner and the licensee.[165] One panelist suggested that RTLAs might place too much risk on the licensor, because the research tool may prove useful in the initial stages of R&D, but the potential product ultimately might fail in the clinical trial phase, thereby denying the tool owner licensing fees.[166] Such risk-allocation issues, however, might be resolved through adjustments to the pricing levels in RTLAs.[167]

Other panelists identified potential ways in which RTLAs might harm competition and innovation, and noted uncertainty surrounding the antitrust analysis of these agreements. One panelist contended that RTLAs present a "severe risk" of creating an anticommons by fostering royalty stacking.[168] Another panelist expressed concern that, by "demanding royalties on the sale of a product that is not covered by their patent," a licensing company could be violating the patent misuse and antitrust laws.[169] This panelist stated that it is unclear how antitrust would weigh the competitive effects of these types of arrangements and suggested that additional guidance by the Agencies may be necessary to provide certainty surrounding the use of RTLAs.[170]

2. Patent Pools

Patent pools involve "patents [from multiple patentees being] licensed in a package, either by one of the patent holders or by a new entity established for this purpose, usually to anyone willing to pay the associated royalties."[171] A biotechnology trade association stated that voluntary patent pools are "one of the important potential solutions to concerns regarding overlapping patents."[172] Indeed, this participant noted approvingly the paper released by the PTO entitled "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?," which discusses the use of patent pools as a means of fostering access to

[162] According to one panelist, RTLAs tend to be used "in more unique tool technology" rather than "fungible research tools." *See* Blackburn 2/26 at 315.

[163] *See id.* at 275.

[164] *See* Beier 2/26 at 265; Blackburn 2/26 at 275-76; BIO (stmt) 2.

[165] *See* Blackburn 2/26 at 275.

[166] *See* Oehler 2/26 at 278.

[167] *See* Blackburn 2/26 at 279.

[168] *See* Kirschner 2/26 at 311.

[169] Earp 2/26 at 270.

[170] *See id.* at 272-73, 327-28. For further discussion of RTLAs under the antitrust laws, *see* Second Report (forthcoming).

[171] Shapiro, *Navigating the Patent Thicket* at 127. For antitrust treatment of patent pools, *see* Second Report (forthcoming).

[172] BIO (stmt) 12.

patented research tools.[173]

The OECD, however, has questioned whether industry participants can solve the transaction cost problems that arise in markets for genetic inventions by forming patent pools.[174] It noted that these technologies are fundamentally different from the electronics sector, in which patent pools are used more frequently because of the importance of standards and interoperability.

3. Non-Exclusive Licensing of Patented Research Tools

Two of the panelists observed that owners of patented research tools generally have the incentive to grant non-exclusive, rather than exclusive, licenses. One panelist explained that firms prefer to grant non-exclusive licenses on their research tools, because it is impossible to know in advance whether any particular licensee will succeed in bringing a product to market.[175] He suggested that when the patentee can profit from the exploitation of a research tool, the incentives exist to drive the broad dissemination of the particular tool.[176] He did, however, note that there "are probably examples of tools that maybe are appropriately exclusively licensed" and suggested that the market for potential genomic cancer targets might be such a market.[177]

Another panelist cited an example to demonstrate the potentially adverse implications for a business of exclusive licensing: in a market with two competitors over the provision of genomic database information, one of the companies gave an exclusive license to its database to a large pharmaceutical company. The direct consequence of this exclusive license was to force the other large pharmaceutical companies to seek nonexclusive access to the rival firm's database.[178] This panelist noted that the economics of licensing databases or research tools dictate that companies license on a nonexclusive basis, because it is not possible to build a business

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[173] United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* 3 (2000), *at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

[174] Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* 67 (2002) ("It is true that there is a growing interdependence among patents, that the claims of many patents are narrower, and that patents are held by multiple owners. Licensing transaction costs are burdensome and freedom of operation is restricted, thus increasing the potential for conflict among researchers. However, the pharmaceutical biotechnology industry may be fundamentally different from the electronics sector. It is not an industry in which defining standards is important, and assuring interoperability of technologies is not very important, especially not in the development of therapeutics. A company's worth is tightly tied to its intellectual property and fosters a 'bunker mentality.' There are likely to be disagreements among partners over the value of the different patents in a pool, and dominant players may not have a strong incentive to join the pool. If a limited field of application and essential patents can be defined, the patent pool model is worthy of consideration in biotechnology (Marks et al., 2001). The suitability of the patent pool for biotechnology patents certainly requires further study, as does the role of government in promoting them."), *at* http://www.oecd.org/dataoecd/42/21/2491084.pdf.

[175] *See* Blackburn 2/26 at 264.

[176] *See id.* at 265.

[177] *See id.* at 264 (noting that his company has identified so many potential genomic cancer targets that supply exceeds demand, and licensees can insist on exclusive licenses).

[178] *See* Bendekgey 2/26 at 268-69.

around a single customer.[179]

F. Conclusion

Biotechnology innovation is heavily dependent on the patent rights that have been available for biotechnology inventions since 1980. Patents help firms to recover high, fixed R&D costs and are particularly useful in enabling biotechnology companies, which are generally small in size, to attract capital investment and to contract with other firms for commercial development of their inventions. This capital is critical for ongoing R&D, because product commercialization in the biotechnology industry is particularly time-consuming and expensive. Patent disclosures assist the innovation process by encouraging information dissemination and enabling the publication of discoveries in the scientific literature. Competition also encourages innovation, although panelists typically gave greater stress to the role of patents.

Poor quality biotechnology patents also have the potential to harm innovation by causing companies to avoid the field of inquiry covered by such patents, rather than to seek to invalidate them. Panelists stated that litigation is too expensive and time-consuming for small biotechnology companies. Views varied on whether patent quality in the biotechnology field differed from that in other industries.

Biotechnology, with its heavy investment in basic research and research tools, poses more issues of cumulative innovation than pharmaceutical drugs, for which much of the innovation process was discrete. Biotechnology patents might harm follow-on innovation through the creation of an anticommons and by restricting access to inventions. A few panelists suggested that these problems can be mitigated by mechanisms such as reach-through royalty agreements, cross-licensing, and patent pools. It is also possible that recent uncertainty about the scope of the research exemption may hinder non-commercial research.

[179] *See id.* at 269.

IV. THE COMPUTER HARDWARE INDUSTRIES, INCLUDING SEMICONDUCTORS

A. Introduction

In the computer hardware industries, panelists reported that firms' attitudes toward the role of competition and patent protection in furthering innovation depends on the nature of the firm. Panelists stressed the importance of competition and trade secrecy as drivers of innovation for integrated design and manufacturing firms and foundries; for specialized design firms, panelists gave greater emphasis to patents. Discussion frequently highlighted the special issues that arise in industries characterized by incremental, cumulative innovation and by products requiring a great many, separately held patents. Commentators, for example, extensively discussed the problems that patent thickets pose for innovation and the licensing arrangements that firms use to maneuver through such thickets to achieve product commercialization. Commentators also expressed concern that patents may deter innovation in the computer hardware industries as a result of hold-up strategies by firms unconstrained by litigation concerns.

The panelists who represented computer hardware firms at the Hearings were Robert Barr representing Cisco Systems, Inc; George B. Brunt representing Alcatel USA; Peter N. Detkin representing Intel Corporation; Stephen P. Fox representing Hewlett-Packard Company; Les Hart representing Harris Corporation; Julie Mar-Spinola representing Atmel Corporation; Daniel McCurdy representing ThinkFire; Joel Poppen representing Micron Technology, Inc; Desi Rhoden representing Advanced Memory International, Inc.; Frederick J. Telecky, Jr. representing Texas Instruments; Richard L. Thurston representing Taiwan Semiconductor Manufacturing Company, Ltd.; Harry Wolin representing Advanced Micro Devices, Inc.; and Gary Zanfagna representing Honeywell International. Two scholars, Bronwyn H. Hall, from the University of California, Berkeley, and Rosemarie Ham Ziedonis, from the University of Pennsylvania, also participated in business perspective panels on the computer hardware industry.

B. Industry Description

In general terms, the computer hardware industries produce the physical components for computers, telecommunications, and other information technology devices, such as the computer itself, monitors, servers, routers, and scanners.[180] The semiconductor industry produces one particular type of hardware: the integrated circuits and discrete devices that process binary data through the control of electrical signals. Integrated circuits are more commonly referred to as 'chips' or 'processors.'

The panelists discussed various types of firms that drive innovation in these industries: specialized design firms, integrated firms, and semiconductor foundries.[181] Both specialized design firms and integrated firms engage in R&D, but

[180] "Hardware" is a general term that distinguishes the physical aspects of computers and related devices from "software," which is the intangible aspect that controls hardware through programs.

[181] *See* Ziedonis 3/20 at 11, 16.

they differ in terms of the ownership of manufacturing facilities. Specialized design firms, which emerged in the 1980s,[182] contract with semiconductor foundries[183] to have their products manufactured; integrated firms own their manufacturing facilities.[184] One panelist observed that the emergence of independent semiconductor foundries (or "contract manufacturers") "enabled the creation and proliferation of a new generation of semiconductor companies - the fabless semiconductor company."[185] Panelists reported that manufacturing facilities cost at least two billion dollars to construct, and the construction of the most advanced facilities can cost in excess of four billion dollars. They also stated that more advanced manufacturing facilities can become obsolete in less than five years, and that less advanced facilities become obsolete even more quickly.[186]

C. The Role of Competition in Spurring Computer Hardware Innovation

Panelists representing integrated firms, foundries, and hardware companies observed that competition drives innovation.[187] Similarly, the business survey of Cohen, Nelson, and Walsh shows that obtaining lead-time over rivals, which is a function of the competitive process, is one of the two key mechanisms for ensuring appropriability of returns on R&D investments in the semiconductor industry. The other mechanism is trade secret protection.[188]

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[182] *See* Jeffrey T. Macher et al., *Semiconductors, in* U.S. INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE 247 (1999), *at* http://www.nap.edu/books/0309061792/html/245.html. Hall and Ziedonis, in their business survey of the effects of strengthening patent rights on firms in the semiconductor industry, attribute the emergence of specialized design firms to the strengthening of patent rights in the 1980s. Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry*, *1979-1995*, 32 RAND J. ECON. 101,104 (2001) and Box 3-6. A similar version of this study is available in draft under the name *The Effects of Strengthening Patent Rights on Firms Engaged in Cumulative Innovation: Insights from the Semiconductor Industry*, June 2001, *at* http://emlab.berkeley.edu/users/bhhall/papers/HallZiedonis01%20libecap.pdf.

[183] Foundries are referred to as wafer fabrication facilities, or "fabs" for short, in the semiconductor industry.

[184] *See* Ziedonis 3/20 at 17.

[185] Richard L. Thurston, *Opening Statement of Dr. Richard L. Thurston, Vice President and General Counsel, Taiwan Semiconductor Manufacturing Company* (3/20/02) 3, *at* http://www.ftc.gov/opp/intellect/020320richardthurstonstatement.pdf (hereinafter Thurston (stmt)); *see also* Thurston 3/20 at 10 (noting that Taiwan Semiconductor Manufacturing Company has contracted with over 175 fabless companies).

[186] *See* Poppen 2/28 at 683; Thurston 3/20 at 29; Ziedonis 3/20 at 16, 83; Hall & Ziedonis, 32 RAND J. ECON. at 110.

[187] *See* Detkin 2/28 at 751 (stating that "the clear driving force behind innovation is competition"); Poppen 2/28 at 750; Fox 2/28 at 757; Barr 2/28 at 674-77; Brunt 3/20 at 91; Thurston (stmt) 9. For discussion of the changing nature of competition in the semiconductor industry, *see* Peter C. Grindley & David J. Teece, *Managing Intellectual Capital: Licensing and Cross-Licensing in Semiconductors and Electronics*, 39 CAL. MGMT. REV. 8, 27-29 (1997).

[188] *See* W. M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Econ. Research Working Paper No. 7552, 2000), *at* http://papersdev.nber.org/papers/w7552 (hereinafter COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS); Rosemarie Ziedonis, *The Role of Patents in Semiconductors: Insights from Two Recent Studies* (3/20/02) (slides) at 2, *at* http://www.ftc.gov/opp/intellect/020320rosemarieziedonis.pdf. Trade secrecy is discussed below. Patents were considered relatively unimportant for securing returns to innovation in the hardware industry.

The representative of one hardware company stated that between 1984 and 1993, the first 10 years of the company's existence, it filed only one patent, which issued in 1992.[189] Yet by 1994, "the company had grown to over a billion dollars in annual revenue. This growth was obviously not fueled by patents, it was fueled by competition and by open, nonproprietary interfaces."[190] Another panelist stated that "competition is what drives . . . innovation; patents have almost nothing to do with innovation."[191] Similarly, a third panelist noted that "innovation is driven by competition in all of our markets."[192]

D. Alternative Means of Fostering Innovation

The panelists representing integrated firms and foundries identified trade secrecy as an important mechanism for protecting a company's investment in innovation.[193] Some panelists expressed the view that trade secret protection is a supplement to patent protection in the sense that the two are used in different factual contexts, rather than as substitutes to be used in the same contexts.[194] One panelist suggested, for example, that trade secrecy is useful in the early stages of innovation.[195]

Other panelists discussed how they choose between the use of trade secret protection and patents as means to protect their inventions. They stated that firms consider whether they could detect patent infringement.[196] Disclosure of an invention due to patent requirements may simply enable rival firms to copy the invention without the patentee being able to detect and sue for patent infringement.[197] Because manufacturing processes cannot easily be observed by rivals, trade secrecy is particularly important for foundries and the manufacturing facilities of integrated firms.[198] Panelists observed that holders of trade secrets risk losing access to their technologies, however. Should a rival company obtain a patent on an invention for which a company had used trade secret protection, the patentee could successfully sue the company that used trade secret protection for patent infringement, despite its having discovered the invention earlier.[199]

One panelist noted that reliance on trade secrecy could harm competition and innovation by stifling the flow of

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[189] This panelist represented Cisco Systems.

[190] Barr 2/28 at 673-74.

[191] Rhoden 2/28 at 754.

[192] Zanfagna 3/20 at 90.

[193] *See* Thurston 3/20 at 29-30, 47-8; Wolin 3/20 at 51; Ziedonis 3/20 at 52; McCurdy 3/20 at 53; Brunt 3/20 at 26, 46-47; Detkin 2/28 at 666; Barr 2/28 at 756 and 10/30 at 79-80.

[194] *See* Ziedonis 3/20 at 52; McCurdy 3/20 at 53; Brunt 3/20 at 47.

[195] *See* Brunt 3/20 at 47.

[196] *See, e.g.,* McCurdy 3/20 at 49-50, 53; Thurston 3/20 at 30, 47-48; Detkin 2/28 at 665.

[197] *See* McCurdy 3/20 at 49-50.

[198] *See* Thurston 3/20 at 30, 47-48.

[199] *See id.* at 47; McCurdy 3/20 at 49; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 463 (explaining that trade secrets do not serve as prior art).

information to the public domain.[200] Another panelist, however, questioned whether patents yield significantly better results, asserting that the disclosure of information through patents is seldom sufficient for a rival to replicate the innovation.[201] That panelist viewed the frequent inclusion of trade secret information in modern patent licenses to facilitate the licensee's harnessing of the technology as evidence of the uninformative nature of patent disclosures.[202]

E. The Implications of Patent Protection for Innovation

The panelists differed on how patents affect innovation; differences depended on whether patents fulfilled offensive or defensive purposes.[203] Although the terms do not have a precise definition, "offensive patenting" generally means obtaining patents to appropriate returns in R&D; it can require the patent to be enforced through litigation.[204] In this sense, the term is synonymous with the traditional economic justification for the patent system. "Defensive patenting" is primarily motivated by a desire to ensure freedom to operate and includes the use of patents as bargaining chips in cross-licensing negotiations.[205] It thereby reflects the strategy identified by economic analysts of using the prospect of mutually assured destruction to achieve detente, as discussed *supra* in Chapter 2.

1. The Role of Patents in Spurring Innovation

A number of representatives of integrated firms, foundries, and hardware companies testified that patents are necessary for innovation, and thus they obtain patents for offensive reasons.[206] One panelist stated, for example, that the prevention of free riding is their primary motivation for obtaining patents; three other reasons are to negotiate cross-licenses, to obtain freedom to operate, and to generate revenue through licensing.[207] Another panelist contended that, although patents are necessary to prevent free riding, the number of patents in the semiconductor industry far exceeds any requirement for that purpose.[208] He pointed to the pharmaceutical industry as an example of one in which only a few patents cover each product, yet he considered free riding to be successfully

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[200] *See* Brunt 3/20 at 46.

[201] *See* McCurdy 3/20 at 53; *see also* Barr 2/28 at 755-56 ("it's been my experience in my practice, not just with Cisco, that I've actually never met an engineer that learned anything from a patent"). *But see* Telecky 2/28 at 754 (finding patent disclosures "a source of ideas").

[202] *See* McCurdy 3/20 at 38, 53.

[203] *See e.g.* Detkin 2/28 at 751.

[204] *See* Teece 2/27 at 507; David J. Teece, *IP, Competition Policy, and Enforcement Issues* (2/27/02) (slides) at 8, *at* http://www.ftc.gov/opp/intellect/020227davidjteece.pdf.

[205] Cross-licensing is discussed below in the context of patent thickets. Obtaining freedom to operate and patent mining are discussed below in the context of hold-up.

[206] *See* Thurston (stmt) 5; Fox 2/28 at 753; Barr 2/28 at 678, 755; Brunt 3/20 at 23-24.

[207] *See* Fox 2/28 at 753.

[208] *See* Barr 2/28 at 678 (stating that, in an ideal world, to prevent copying in the semiconductor industry "we'd need probably one or two or three for each product on the key features, and that's what I think you'll find in [the pharmaceutical and medical devices] industries.").

prevented.[209]

Specialized design firms typically obtain patents for offensive purposes. According to Professor Ziedonis, patents are critical business assets for design firms, and are used in a manner consistent with how the patent system was intended to operate.[210] Such firms seek "very strong, solid patent protection" for two reasons: to raise venture capital and to stake out proprietary positions primarily against other niche market rivals, but also against integrated firms.[211]

Professor Ziedonis noted two differences about the patenting behavior of specialized design firms when compared to that of integrated firms, foundries, and hardware companies. First, the rate at which specialized design firms are enforcing their patent rights is high. Four out of every hundred patents issued to specialized design firms are enforced through a court action, which is a "very, very high number relative to other industries and within the semiconductor industry."[212] Second, as the revenue of specialized design firms increases and the companies mature, attitudes toward patenting shift, so that such firms begin to patent more defensively and to increase their patent portfolio size, she noted.[213]

[209] *See* Barr 2/28 at 678.

[210] *See* Ziedonis 3/20 at 19.

[211] *Id*. at 17-18.

[212] *Id*. at 18 (observing, however, that specialized biotechnology firms exhibit a similar high rate of patent enforcement).

[213] *See id.*

2. The Potential for Patents to Impede Innovation

a. Patent Thickets in the Computer Hardware Industries

None of the panelists disputed the existence of densely overlapping patent rights (*i.e.*, a patent thicket) in the computer hardware industries. One panelist stated that more than "90,000 patents generally related to microprocessors are held by more than 10,000 parties."[214] Likewise, he reported, there are approximately 420,000 semiconductor and systems patents held by more than 40,000 parties.[215] This panelist observed that the number of patents on semiconductor-related inventions has increased to the point where there is an "unavoidable overlap" of intellectual property.[216]

Panelists discussed three reasons for the emergence of patent thickets in the computer hardware industries: (1) incremental innovation due to the nature of

[214] Detkin 2/28 at 667-68 and Peter N. Detkin, *A Semiconductor Patent Survey* (2/28/02) (slides) at 5, *at* http://www.ftc.gov/opp/intellect/020228peterndetkin.pdf (hereinafter Detkin Presentation).

[215] Detkin 2/28 at 667-68 and Detkin Presentation at 5.

[216] Detkin 2/28 at 668 ("there's an unavoidable overlap of IP. . . people are tripping over each other's patents right and left"); s*ee also* Barr 2/28 at 677; Macher et al., *Semiconductors* at 281. Commentators have described the computer hardware industries as prime examples of "complex product industries," in which relatively numerous patents protect individual commercializable products. *See, e.g.,* Cohen 2/20 at 30.

Box 3-6. ***The Patent Paradox Revisited: An Empirical Study of Patenting in the US Semiconductor Industry, 1979-1995***

Bronwyn H. Hall and Rosemarie Ham Ziedonis, RAND Journal of Economics, Vol. 32, No. 1, Spring 2001, pp 101-128.

Bronwyn H. Hall and Rosemarie Ham Ziedonis conducted an empirical study of patenting practices in the semiconductor industry in order to explain a paradox in the economic literature: the patenting rate per R&D dollar doubled in the semiconductor industry since the mid-1980s, while other economic studies indicated that industry participants did not regard patents as an important means for recouping investments in innovation.

The study was based on a combination of qualitative and quantitative research methods. The qualitative analysis involved the authors conducting interviews with intellectual property managers and executives from several U.S. semiconductor firms. The quantitative analysis involved the authors compiling a database of the patent portfolios of 100 publicly traded U.S. semiconductor firms whose R&D expenditures were primarily focused on semiconductor-related areas from 1975 to 1998. They matched these data with financial and other variables to formulate estimates of the patent propensities of individual firms during the period of the study.

The authors concluded that the significant increase in patenting per R&D dollar was attributable to the strengthening of patent rights in the United States, which spurred "patent portfolio races" among capital-intensive firms. Firms were engaged in these races to reduce concerns about "being held up by external patent owners and at negotiating access to external technologies on more favorable terms."

the underlying technology; (2) the rise of defensive patenting; and (3) the ease of obtaining patents at the PTO.

(i). Incremental Innovation and the Nature of Hardware and Semiconductor Technology

Four industry representatives testified that the technology developed by the hardware and semiconductor industries is susceptible to the creation of patent thickets, because hardware and semiconductors contain an incredibly large number of incremental innovations.[217] The complex nature of computer hardware technology is one factor that contributes to the existence of a technology thicket over which a patent thicket has developed.[218]

(ii). The Rise of Defensive Patenting

As discussed above, firms in the computer hardware industries have been obtaining patents at rapidly increasing rates largely for defensive purposes. The likelihood of firms holding overlapping intellectual property increases as more patents issue over semiconductor and hardware innovations. In this way, the problem is self-perpetuating. As one panelist acknowledged, "the only practical response to this problem of unintentional and sometimes unavoidable patent infringement is to file hundreds of patents each year ourselves."[219]

In their research, Professors Hall and

[217] *See* Detkin 2/28 at 669-70, 710-11; Poppen 2/28 at 684, 712; Barr 2/28 at 713-14; Fox 2/28 at 714. Their testimony offered confirmation of similar observations by academic panelists. *See, e.g.,* R. Levin (stmt); Lemley 2/25 at 37 (noting the cumulative nature of semiconductor innovation).

[218] *See* Teece 2/27 at 500.

[219] Barr 2/28 at 677; *see also* Hart 4/9 at 42-42.

Ziedonis identified a "pro-patent" shift in the US legal environment in the 1980s as the stimulus for the rise of defensive patenting.[220] The authors believe that this shift resulted from a series of congressional reforms in the early 1980s, including the creation of the Court of Appeals for the Federal Circuit, which "put in place a number of procedural and substantive rules that collectively strengthened the rights of US patent owners."[221]

Professors Hall and Ziedonis also identified two events that arose out of the "pro-patent" shift and signaled the importance of the new patent regime to firms in the semiconductor industry. First, Polaroid's successful patent infringement suits against Kodak resulted in Polaroid being "awarded almost $1 billion in damages and Kodak . . . [being] barred from competing in the instant-film camera business."[222] This case created a fear among firms that owned manufacturing facilities that the "courts were willing to take an aggressive stance against infringement by halting – either temporarily or permanently – production utilizing infringed technologies."[223] Second, the revenue obtained by Texas Instruments from mining its patents – that is, seeking patent royalties from firms that operate outside the range of Texas Instruments' business – prompted other firms also to commence patent mining programs.[224]

(iii). Ease of Obtaining Patents

Professor Ziedonis contended that the ease of obtaining patents at the PTO, although not the sole cause of the thicket, is a contributing factor.[225] She cited interviews conducted with participants in the semiconductor industry in which the participants stated that the standard for obviousness should be increased so as to prevent "very trivial inventions" being patented by the PTO.[226]

b. The Potential for Patent Thickets to Harm Innovation

The panelists discussed several ways in which patent thickets can harm innovation.[227] First, the need of integrated firms and hardware companies to develop extensive patent portfolios for defensive purposes diverts funding from R&D into the obtaining of patents. As one panelist

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[220] Hall & Ziedonis, 32 RAND J. ECON. at 105.

[221] Hall & Ziedonis, *The Effects of Strengthening Patent Rights on Firms Engaged in Cumulative Innovation: Insights from the Semiconductor Industry* at 12.

[222] Hall & Ziedonis, 32 RAND J. ECON. at 109.

[223] *Id*. A number of panelists discussed the threat of an injunction. *See, e.g.,* Poppen 2/28 at 686, 691, 725; Detkin 2/28 at 722-23; Barr 2/28 at 723.

[224] Hall & Ziedonis, 32 RAND J. ECON. at 109. Panelists reported that some companies have sought to license their patents to companies that operate outside the market of the patent holder, because a higher royalty can be extracted due to an imbalance in bargaining positions. *See* Brunt 3/20 at 25; Poppen 2/28 at 684; Thurston 3/20 at 34. In this situation, one panelist contended, the management of a company treats patents as an asset that must generate a return, instead of as a means to exclude parties from a particular invention. *See* Wolin 3/20 at 81. *See also infra* Ch. 3(IV)(E)(2)(c)(i).

[225] *See* Ziedonis 3/20 at 15-16.

[226] *Id.*

[227] Another potential harm, resulting from the strategic use of patents in licensing negotiations, is addressed in the next section.

observed, "the time and money we spend on patent filings, prosecution, maintenance, litigation and licensing could . . . be much better spent on product development and research leading to more innovation."[228]

Patent thickets can reduce follow-on innovation by requiring an innovator to seek licenses from multiple patentees.[229] In these industries, one panelist reported, "hundreds, thousands of patents cover a single product."[230] As discussed *supra* in Chapter 2, the transaction costs and potential for royalty stacking involved in obtaining multiple licenses from numerous patent holders may pose obstacles to the development of follow-on technologies.[231]

Patent thickets also can harm innovation by creating uncertainty, which affects investment decisions. One panelist stated that the proliferation of patents and patent-related litigation has created "pervasive uncertainty about legal rights . . . [that] heightens risks surrounding innovation investment decisions . . . [and] is without doubt a serious drag on the technological and scientific progress that the patent system was designed to promote."[232]

[228] Barr 2/28 at 677-78. Similarly, another panelist contended that "patents are assets that suck money out of the system." Brunt 3/20 at 25.

[229] *See* Shapiro, *Navigating the Patent Thicket* at 120-121.

[230] Poppen 2/28 at 684.

[231] *See* Detkin 2/28 at 764 (noting the presence of "half a million patents owned by 40,000 parties . . . and we have to worry about how we're going to negotiate with them"); Poppen 2/28 at 690 (raising royalty stacking concerns).

[232] Fox 2/28 at 696; s*ee also* Barr 2/28 at 675-76.

c. The Strategic Use of Patents in Licensing Negotiations

Panelists discussed the strategic use of patents in licensing negotiations, and in particular one type of strategic use, generally known as "hold-up."[233] They discussed hold-up as enabled by sunk costs that a firm already has invested in product development or manufacturing, before learning of the patent, which in turn enable the patentee to demand royalties higher than it could have sought before the firm sunk its costs; with so very many patents at issue, panelists suggested, infringing *someone's* patent may be inevitable, but there may be no economically feasible way, prior to making sunk investments, to identify and obtain rights to all the relevant patented technologies.[234] Some commentators argue that hold-up in this sense harms competition and innovation.[235] Others suggest that such behavior constitutes a legitimate exercise of a patentee's right to exclude.[236]

[233] For discussion of hold-up for antitrust enforcement purposes, *see* Timothy J. Muris, *The FTC and the Law of Monopolization*, 67 ANTITRUST L.J. 693, 704 (2000); Benjamin Klein, *Market Power in Franchise Cases in the Wake of Kodak: Applying Post-Contract Hold-Up Analysis to Vertical Relationships*, 67 ANTITRUST L.J. 283 (1999).

[234] *See, e.g.,* Barr 2/28 at 677; Detkin 2/28 at 764.

[235] *See* Shapiro, *Navigating the Patent Thicket* at 124-26; *see also supra* Ch. 2(III)(C)(2) and *infra* Ch. 3(IV)(E)(2)(c)(iii).

[236] *See generally* Frederick J. Telecky, *Statement of Frederick J. Telecky, Jr., Senior Vice President and General Patent Counsel, Texas Instruments: FTC/DOJ Hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy"* (2/28/02) 5 ("refusal to license is at the heart of the patent system"), at http://www.ftc.gov/opp/intellect/020228telecky.pdf (hereinafter Telecky (stmt)).

In their business survey, Professors Hall and Ziedonis concluded that semiconductor firms with large sunk costs in complex manufacturing facilities started to patent defensively in the 1980s to reduce, among other things, "concerns about being held up by external patent owners."[237] These concerns stemmed in part from Polaroid's successful patent infringement suit against Kodak.[238] One industry participant interviewed by Professors Ziedonis and Hall stated, "a preliminary injunction would be detrimental to a firm if it means shutting down a high-volume manufacturing facility; loss of one week's production alone can cost millions of dollars."[239] Firms in the computer hardware industries responded to the possibility of having their production enjoined by accumulating large patent portfolios. If a rival company sought to employ a hold-up strategy against them, they would draw on their portfolio to assert patent infringement counterclaims against that rival, resulting in what panelists described as "mutually assured destruction" or "MAD."[240]

(i). The Rise of Non-Practicing Entities

The potential for hold-up to result in mutually assured destruction means firms actively participating in the industry – patent practicing entities (PPEs) – are unlikely to employ this strategy against each other.[241] Panelists, however, identified firms referred to as non-practicing entities (NPEs) that can successfully employ a hold-up strategy without fear of retaliation.[242] NPEs obtain and enforce patents against other firms, but either have no product or do not create or sell a product that is vulnerable to infringement countersuit by the company against which the patent is being enforced. As discussed *supra* in Chapter 2, MAD strategies to mitigate hold-up will not work against NPEs, who are not susceptible to the threat of a countersuit shutting down their production.[243] In contrast, NPEs can threaten PPEs with patent infringement and an injunction, which, if granted, could inflict substantial losses.[244]

Panelists identified three types of NPEs in the computer hardware industry: (1) non-practicing design firms, which patent their inventions but do not make or sell patented products to consumers; (2)

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[237] Hall & Ziedonis, 32 RAND J. ECON. at 104; *see also* Box 3-6; Rosemarie Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* 4 (July 2002) *in draft at* http://www.isnie.org/ISNIE02/Papers02/ziedonis.pdf.

[238] *See* Hall & Ziedonis, 32 RAND J. ECON. at 109.

[239] *Id.*; *see generally* John R. Boyce & Aidan Hollis, *Innovation, Imitation & Preliminary Injunctions in Patents* (Public Comment), at http://www.ftc.gov/os/comments/intelpropertycomments/0205xxhollis.pdf.

[240] *See* Hall 2/28 at 662; Detkin 2/28 at 669; Poppen 2/28 at 684-85; Barr 2/28 at 713; *see also* Hall & Ziedonis, 32 RAND J. ECON. at 109.

[241] *See* Poppen 2/28 at 684-86.

[242] *See* Rhoden 2/28 at 723-24; Carl Shapiro, *Technology Cross-Licensing Practices: FTC v. Intel (1999), in* 4 THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION AND POLICY 350, 356 (John E Kwoka, Jr. & Lawrence J. White eds. 2004).

[243] *See* Poppen 2/28 at 685-89; Detkin 2/28 at 671-72.

[244] *See* Poppen 2/28 at 685-89; Detkin 2/28 at 671-72; Hall & Ziedonis, 32 RAND J. ECON. at 109. For additional discussion of issues raised by NPE conduct, *see supra* Ch. 2(III)(C)(2) and Second Report (forthcoming).

"professional" patent assertion companies that buy patents from other companies, particularly those that are bankrupt, and then assert them against practicing entities; and (3) "patent miners," which are companies that assert their patent portfolios against firms outside of their business.[245]

Professor Ziedonis noted that the number of cases filed by NPEs has increased since the mid-1980s, and that the sale of patents by failing companies has increased since the 1990s.[246] One third of the patent lawsuits filed by a group of 136 companies, for example, involved patents not invented by the company.[247] Two panelists confirmed that an increasing number of companies are seeking to buy and sell the patent portfolios of failing companies to assert against other firms.[248] In their business analysis of licensing practices in the semiconductor and electronics industry, Professors Grindley and Teece observe that "occasionally, firms can purchase a portfolio of patents with which to establish cross-licensing relationships; but quality patents often are not available in this fashion."[249]

(ii). Hold-Up and Patent Thickets

In industries such as the computer hardware industries, where innovation is cumulative, panelists noted that hold-up is more likely to occur, because the presence of a patent thicket makes patent infringement very difficult to avoid.[250] As Professor Shapiro observed, participants in the semiconductor industry receive "thousands of patents . . . each year and manufacturers can potentially infringe on hundreds of patents with a single product."[251] Another panelist stated that "the large number of

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[245] *See* Poppen 2/28 at 685-88; Detkin 2/28 at 672.

The panelists discussed two reasons for the emergence of "patent mining" by companies. First, the need to patent defensively has forced many firms to develop extensive patent portfolios, at considerable cost. One business representative stated that it costs about $200,000 to maintain a patent worldwide over a period of 20 years. *See* Brunt 3/20 at 25. Panelists reported that some companies have sought to offset these costs by seeking to license their patents to other companies, particularly companies that operate outside the market of the patent holder, because a higher royalty can be extracted due to an imbalance in bargaining positions. *See id.*; Poppen 2/28 at 684; Thurston 3/20 at 34.

Second, panelists contended that business attitudes towards patents have changed since the 1980s. The management of some companies, some asserted, have begun to treat patents as an asset that must generate a return, instead of as a means to exclude parties from a particular invention. *See* Wolin 3/20 at 81. Panelists cited two examples to support this change in attitude. First, a number of panelists mentioned Texas Instruments, which successfully instigated a patent mining program in the late 1980s to save the company from bankruptcy, and thereby became an example to other companies of how to mine their patents. *See* Thurston 3/20 at 28-29; Wolin 3/20 at 81; Ziedonis 3/20 at 83; Telecky 2/28 at 653; Macher et al., *Semiconductors* at 281; Grindley & Teece, 39 CAL. MGMT. REV. at 20. Second, a widely read book in business circles entitled *Rembrandts in the Attic* encourages managers to generate revenue from their patents by mining them. *See* Hughes 2/28 at 614; KEVIN G. RIVETTE & DAVID KLINE, REMBRANDTS IN THE ATTIC: UNLOCKING THE HIDDEN VALUE OF PATENTS (Harvard Business School Press 1999).

[246] *See* Ziedonis 3/20 at 71, 73-74.

[247] *See* Ziedonis 3/20 at 73-74.

[248] *See* Thurston 3/20 at 75; Wolin 3/20 at 76.

[249] Grindley and Teece, 39 CAL. MGMT. REV. at 31; *see also* Shapiro 11/6 at 176 (observing that "I've even seen a situation where a portfolio was split up and some patents split off to a third party who had no other commercial interests, so they could assert it most aggressively against other industry players.").

[250] *See* Barr 2/28 at 676; Hall & Ziedonis, 32 RAND J. ECON. at 110.

[251] *See* Shapiro, *Navigating the Patent Thicket* at 125.

issued patents in our field makes it virtually impossible to search all potentially relevant patents, review the claims, and evaluate the possibility of an infringement claim or the need for a license."[252] This problem of unavoidable patent infringement is heightened, commentators stated, by the risk of patent applications still pending and unpublished by the PTO after a company has sunk significant costs in a new product.[253]

Commentators have also observed that companies seeking to hold up rivals can set the licensing fees below the cost of litigation, including the managerial distraction, so as to make the taking of a license the only economically sensible alternative, regardless of the strength of the patent.[254] Professor Shapiro contends that the lack of effective mechanisms to challenge questionable patents, the presumption of validity, and "a patent office that is generous to patent applicants" also facilitate the use of hold-up strategies by NPEs.[255] Several panelists asserted that companies can use a continuation on their own patent application deliberately to delay patent issuance by the PTO.[256] This enables such companies, one panelist asserted, to tailor their patent claims to cover a rival's product using insights gained from reverse-engineering that product.[257]

(iii). The Potential for Hold-Up to Harm Consumers

Commentators identified four ways that hold-up can harm competition and innovation. First, obtaining a license after costs have been sunk will result in a higher royalty to the NPE than if a license were negotiated prior to the sinking of costs.[258] One reason for this higher royalty is that PPEs obtaining a license under threat of hold-up typically do not have the option of designing around the patent the NPE asserted, because redesigning a product after significant costs have been sunk is usually not economically viable.[259] According to Professor Shapiro, the higher royalty paid by companies subject to a hold-up strategy may result in higher prices to consumers, inefficiently low use of the affected

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[252] Robert Barr, *Statement* (2/28/02) 1, *at* http://www.ftc.gov/opp/intellect/barrrobert.doc (hereinafter Barr (stmt)).

[253] *See* Barr 2/28 at 676; Shapiro, *Navigating the Patent Thicket* at 125-26. *See supra* Ch. 2(III)(C) and *infra* Chs. 4(II)(C)(1) and 5(II)(C)(4).

[254] *See* Ziedonis 3/20 at 71-72; Barr 2/28 at 680 and (stmt) 2; Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L.REV. 1495, 1517 (2001) (noting that "patent owners might try to game the system by seeking to license even clearly bad patents for royalty payments small enough that licensees decide that it is not worth going to court").

[255] Shapiro, *Technology Cross-Licensing Practices: FTC v. Intel (1999)* at 355.

[256] *See* Poppen 2/28 at 687-88; McCurdy 3/20 at 37; Mar-Spinola 2/28 at 715-16; Barr 10/30 at 146-47; *see also infra* Ch. 4(II)(C)(1).

[257] *See* Poppen 2/28 at 688.

[258] *See* Shapiro, *Navigating the Patent Thicket* at 125.

[259] *See* Shapiro, *Navigating the Patent Thicket* at 125; Barr (stmt) 2-3; Rosemarie Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* at 8. Just as an NPE may wish to set the royalty fee it seeks at just below what it would cost the "held up" firm to litigate the validity or infringement of the NPE's patent, so an NPE may wish to set its requested royalty fee at just below what it would cost the firm to redesign around the patent.

products, and deadweight loss.[260] The cumulative effect of many such licenses may exacerbate these effects.[261] Second, innovation may suffer because some companies will "refrain from introducing certain products for fear of hold-up."[262]

Third, by seeking royalties below the cost of challenging a patent's validity, NPEs can obtain royalties on improperly granted patents. Royalties on improperly granted patents cause an inefficient allocation of society's resources and a transfer that "encourages patenting and discourages competition to a greater extent than is socially optimal."[263] One panelist observed that NPEs can use this same strategy to induce PPEs to obtain licenses for patents that are likely not infringed by the PPE's product.[264] Finally, a number of panelists representing manufacturing firms contended that hold-up causes a wealth transfer from firms engaged in innovation that results in benefits to firms that are simply exploiting the patent system without benefitting consumers.[265] One panelist, however, responded that "we're not sure that in every instance where there's a patentee with no product, that they haven't legitimately contributed something to the fund of human knowledge."[266]

F. Tools to Navigate the Patent Thicket

The panelists discussed three licensing strategies that firms can use to navigate patent thickets: (1) cross-licensing; (2) patent pooling; and (3) standard setting. The panelists generally agreed that each strategy, despite involving certain transaction costs, has been effective in clearing the patent thicket.[267]

1. Cross-Licensing

Cross-licensing is one of the mechanisms used by integrated firms and hardware companies in particular to obtain design freedom when a patent thicket exists.[268] The main variables are: (1) the number of patents at issue; and (2) the use of balancing payments (*i.e.*, monetary payments to even out the value of the portfolios being cross-licensed).[269] The

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[260] *See* Shapiro, *Navigating the Patent Thicket* at 125; Poppen 2/28 at 690.

[261] *See* Shapiro, *Navigating the Patent Thicket* at 126.

[262] *Id.*; *see also* Grindley & Teece, 39 CAL. MGMT. REV. at 20.

[263] Lemley, 95 NW. L. REV. at 1517.

[264] Barr (stmt) 2-3.

[265] *See* Poppen 2/28 at 689-90; Barr 2/28 at 679 and (stmt) 1-3 (the exploitation of the patent system as a revenue-generating tool in its own right has hindered true innovation and outweighed the benefits); Detkin 2/28 at 673 and 728-30. Another concern expressed was that hold-up may force innovative firms to move their manufacturing and sales operations offshore to minimize their exposure to such strategies.

[266] Telecky 2/28 at 703.

[267] *See* Grindley & Teece, 39 CAL. MGMT. REV. at 16; Detkin 2/28 at 711 (stating that hold-up is the problem, not thickets).

[268] *See* McCurdy 3/20 at 67 (noting the greater prevalence of cross-licensing in semiconductors and information technology industries than in pharmaceuticals). For a discussion of the antitrust treatment of cross-licensing, *see* Second Report (forthcoming). For an historical overview of licensing practices at Texas Instruments, *see* E. Thompson 11/6 at 9-11.

[269] *See* McCurdy 3/20 at 67-69.

number of patents that are cross-licensed can vary from two to a complete patent portfolio, which might include thousands of patents. Balancing payments are often negotiated by the parties and are used to address a relative imbalance in patent portfolio size or quality.[270]

One panelist outlined three factors his company considers when deciding whether to license: (1) potential patent infringement claims the prospective licensee might have against his company; (2) potential patent infringement claims his company has against the prospective licensee; and (3) the relative interest of the parties in reaching a cross-licensing arrangement.[271] According to another panelist, integrated firms and hardware companies usually settle cross-licensing negotiations without filing lawsuits.[272]

2. Patent Pools

The centralized management that patent pools entail may help in avoiding the royalty stacking/complements problems that economists have suggested may develop when multiple patents are needed for follow-on activities, and each patentee independently determines its own royalty rates.[273] One panelist stated that "patent pools have become critically important mechanisms for enabling widespread use of new technologies that require access to a multitude of patents dispersed among a multitude of parties."[274]

That panelist expressed two concerns, however, about the use of patent pools. First, he stated that some patent holders with critical patents avoid *ex ante* negotiations by asserting that the antitrust laws prevent them from negotiating royalties prior to selection of the specific patents in the pool.[275] He argued that the negotiation of the royalty in advance of the selection of specific patents in the pool was preferable.[276] Second, he contended that applicants should be able to choose which patents they license from a patent pool, rather than be forced to take a license for the totality of patents, which is the most commonly used approach.[277]

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[270] *See id.* at 69, 72.

[271] *See* Detkin 2/28 at 669-70 (stating that Intel considers three things when deciding whether to license: "What have they got on us, what do we have on them, and who cares?").

[272] *See* McCurdy 3/20 at 69. For a discussion of some of the antitrust issues raised by cross-licensing, *see* Second Report (forthcoming).

[273] *See* Barr 2/28 at 733 (finding patent pools useful for consolidating administration and limiting royalty stacking problems). *See generally supra* Ch. 2(III)(C)(3) (discussing royalty stacking and Cournot's complements problem).

[274] Fox 2/28 at 700.

[275] *See id.* at 732; *see also* Second Report (forthcoming).

[276] *See* Fox 2/28 at 737, 732 (suggesting that lower royalties or better terms might be negotiated in return for accepting the patent into the pool). For analysis of analogous issues raised by *ex ante* negotiations involving standard-setting bodies, *see* Second Report (forthcoming).

[277] *See* Fox 2/28 at 699. For analysis of the relevant antitrust considerations, *see* Second Report (forthcoming).

3. Standard-Setting

By establishing rules governing access to the intellectual property embodied in their standards, standard-settings organizations (SSOs) can clear patent thickets that otherwise might stand in the way of follow-on innovation. Professor Lemley, who recently conducted a study of SSOs, found them most active "in industries in which it looks like patent hold-up is the biggest problem [such as] in computers, in semiconductors . . . [but not in] pharmaceuticals, in biotechnology, and so forth."[278] Without a way to "clear[]" intellectual property rights held by "dozens or hundreds of different parties," he warned, "nobody's going to be able to make a product that works with a particular technical standard."[279] Professor Lemley found that 17 of the 21 SSOs studied in fact required "some form of licensing . . . [m]ost commonly . . . on 'reasonable and non-discriminatory terms.'"[280]

G. Conclusion

Panelists in the hardware and semiconductor industries emphasized competition as a driver of innovation. Trade secret protection also contributes to innovation in these industries. Testimony regarding the role of patents was mixed. The record generally corresponded with the results obtained by Professors Cohen, Nelson, and Walsh in their business survey of appropriability mechanisms for firms in the United States: the semiconductor industry was among the least reliant on patents to appropriate returns on investment in R&D.[281] Panelists, however, also identified an exception to these results: patents are a driver of innovation for design firms.

The hearing record highlighted many of the issues that economists suggested might arise in contexts that involve cumulative innovation and a multiplicity of patents. Specifically, the participants from these industries confirmed a trend toward defensive patenting and stated that patents can deter innovation: (1) by contributing to patent thickets, and (2) through their use by NPEs to hold up PPEs. Panelists also observed that various patent licensing arrangements – cross-licensing, patent pools, and the licensing requirements of standard setting organizations – have helped to mitigate the potential harm to innovation caused by patent thickets.

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[278] Lemley 4/18 at 35-37. Of course, other factors, such as considerations of achieving compatibility and network effects, also might explain this result.

[279] *Id*. at 20.

[280] *Id*. at 23. Certain of the antitrust issues raised by SSO activities are discussed in Second Report (forthcoming).

[281] *See* COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS.

V. THE SOFTWARE AND INTERNET INDUSTRIES

A. Introduction

In the software and Internet industries, innovation generally occurs on an incremental basis, with participation possible at the design level by individual programmers and small firms. Panelists consistently emphasized that competition is an important driver of innovation in these industries. Although some panelists stated that software and business method patents foster innovation, many disagreed, asserting that such patents are often questionable and are actually stifling innovation by increasing entry barriers and creating pervasive uncertainty. Some panelists questioned whether it was necessary to have patent protection on software, given the availability of copyrights. Others reported that defensive patenting has accelerated the development of a patent thicket, which, in turn, has increased the likelihood of patentees holding up their rivals. Panelists generally agreed that too many questionable patents are issued; they attributed this to the difficulty patent examiners can have in considering all the relevant prior art in the field and staying informed about the rapid advance of computer science.

The software and Internet industry panelists who participated in the Hearings were: Dean Alderucci, representing Walker Digital; Edward J. Black, representing the Computer & Communications Industry Association; Yar R. Chaikovsky, General Counsel, Zaplet, Inc.; Bradford L. Friedman, Director of Intellectual Property, Cadence Design Systems, Inc.; R. Jordan Greenhall, representing Divx Networks; Joshua Kaplan, representing Intouch Group, Inc.; Robert H. Kohn, Vice Chairman, Borland Software Corp.; Paul Misener, representing Amazon.com; Mary U. Musacchia, representing SAS Institute; Scott Sander, representing SightSound Technologies; Richard Stallman, representing Free Software Foundation; Mark Webbink, representing Red Hat, Inc.; and Robert Young, Chairman, Center for Public Domain and Chairman, Red Hat, Inc. Two scholars, Dan L. Burk, from the University of Minnesota Law School, and David C. Mowery, from the University of California, Berkeley, participated in business perspective panels on the software and Internet industries. Also, three attorneys, Timothy D. Casey, from Fried, Frank, Harris, Shriver & Jacobson, R. Lewis Gable, from Cowan, Liebowitz & Latman, P.C., and James Pooley, from Milbank, Tweed, Hadley & McCloy, participated in business perspective panels on the software and Internet industries, and Dan Crouse, Deputy General Counsel of Microsoft Corporation, submitted a statement.

B. Industry Description

The software and Internet industries create programs, sometimes consisting of millions of lines of code, that direct the functions of a computer, or a group of several computers, and provide a range of services through electronic commerce. Commentators identified five factors that characterize the software and Internet industries. First, innovation occurs cumulatively.[282] As one panelist noted in a

[282] Microsoft, *Statement of Dan Crouse, Deputy General Counsel, Microsoft Corporation* (Public Comment) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/m

paper he co-authored, "[i]nnovation in software is a cumulative activity, and individual software products frequently build on components from other products."[283] Another participant similarly noted, "The path of innovation is often incremental, with new ideas added, and products developed and commercialized, using earlier work as the foundation and building blocks."[284]

Second, innovation in the software and Internet industries generally requires considerably less capital than innovation in other high-tech industries.[285] Companies or individuals can develop and distribute software without the high up-front research costs, clinical trials, or factories required in the pharmaceutical, biotechnology, hardware, and semiconductor industries. The growth of the Internet has further enhanced the market significance of programs developed with limited financial backing by creating "new channels for low-cost distribution and marketing."[286]

Third, the rate of technological change in the software and Internet industries is rapid.[287] Imitation may occur quickly,[288] and entire product life cycles sometimes pass before patents can be issued.[289] Fourth, alternative means of fostering innovation exist: software can be protected by copyright protection and can be developed using open source software strategies. Finally, the software and Internet industries have experienced a regime change in terms of the availability of patent protection.[290] The formal recognition of the

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sc.pdf (hereinafter Microsoft (stmt)); *see also* Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2346 (1994).

[283] Stuart J. H. Graham & David C. Mowery, *Intellectual Property Protection in the U.S. Software Industry, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 225 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://faculty.haas.berkeley.edu/graham/unix/swconf.pdf.

[284] Microsoft (stmt) 2.

[285] *See* Young 4/11 at 31 ("we started [Red Hat] on our credit card balances"); Mowery 2/27 at 427 ("the cost of entry [in the software industry] . . . is relatively low"); Mark Webbink et al., *Red Hat's Comments to the Joint FTC/DOJ Hearing on Competition and Intellectual Property Law* (Public Comment) 3, *at* http://www.ftc.gov/opp/intellect/020320webbink.pdf (hereinafter Webbink (stmt)); s*ee also* League for Programming Freedom, *Against Software Patents* (Public Comment) 3-4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lpf.pdf (hereinafter League for Programming Freedom (stmt)). *But cf.* Microsoft (stmt) 2 (discussing large investments made by Microsoft in connection with some products).

[286] Graham & Mowery, *Intellectual Property Protection in the U.S. Software Industry* at 223.

[287] *See* Webbink (stmt) 3; Rusty Lee, *Comments regarding Competition & Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lerusty.htm (hereinafter Lee (stmt)); Microsoft (stmt) 4; Samuelson et al., 94 COLUM. L. REV. at 2345, n. 134; Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 46 (2001).

[288] *See* Brunt 3/20 at 26 (innovations "walk out the door far before the patent is available to help us"); Jeremiah T. Moree, *IP Law* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/moreejeremiaht.htm.

[289] *See, e.g.,* Burk 3/20 at 140-41; Young 4/11 at 64 ("by the time we get a patent, we aren't using that piece of technology anymore").

[290] *See* Mowery 2/27 at 427. *Diamond v. Diehr*, 450 U.S. 175 (1981), held that a process claim that included use of a computer program was patentable subject matter. The Federal Circuit's ruling in *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U. S. 1093 (1999), made it clear that business methods can be patented. For a discussion of the history of software patents, *see* Cohen &

patentability of software and Internet-related business methods has spurred increased patenting and has presented challenges in locating the relevant prior art, much of which exists outside of traditional prior art sources.[291]

C. The Role of Competition in Spurring Software and Internet Innovation

Several panelists asserted that competition to commercialize the most recent technological advance drives innovation in the software and Internet industries, and that the patent system does not encourage innovation.[292] One panelist stated, for example, that "innovation generally is promoted by competition."[293] Another panelist similarly commented that "a competitive marketplace between similar or only slightly different businesses is all that is truly necessary to spur improvements."[294]

D. Alternative Means of Fostering Innovation

Participants discussed the role of two additional means for spurring innovation in the software industry: copyright, which is an alternative form of intellectual property, and open source software, which is developed without reliance on intellectual property protection.

1. Copyright

A number of participants noted that copyright exists as an alternative means for fostering software innovation.[295] "Copyright protects only the *expression* contained within a work," not "the underlying ideas expressed in that work."[296] Some commentators questioned whether it was necessary to have patent protection on software given the availability of copyright.[297] As one participant noted, for example, "[i]ndividual software programs are also protected by copyright, so that even without any patent protection, software would be a lucrative enterprise."[298] Two scholars offered similar conclusions in an economic study of innovation in the software industry in which they stated that

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Lemley, 89 CAL. L. REV. at 7; Graham & Mowery, *Intellectual Property Protection in the U.S. Software Industry* at 226-31. *See also infra* Ch. 4(II)(E).

[291] *See* Mowery 2/27 at 427.

[292] *See* Chaikovsky 2/27 at 385; Kohn 2/27 at 350; Friedman 2/27 at 354, 357; Musacchia 4/9 at 44-45.

[293] Kohn 2/27 at 350.

[294] Mary U. Musacchia, *Prepared Remarks* (4/9/02) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/musacchiamaryu.pdf (hereinafter Musacchia (stmt)); *see also* Musacchia 4/9 at 57-58. A panelist with expertise as a programmer stated that "it's clear to me that software patents are just an obstacle to the development of software. . . . Even patents covering ideas I would say are brilliant have caused tremendous obstruction in [the] progress of software." Stallman 4/9 at 17-18.

[295] *See* Kohn 2/27 at 350; Webbink (stmt) 3; Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* (Public Comment) 7, *at* http://www.ftc.gov/os/comments/intelpropertycomments/nonobviousness.pdf; Lee (stmt) 1.

[296] ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS § 3.3 at 31-32 (2003) (emphasis in original).

[297] *See* Webbink (stmt) 3; Kohn 2/27 at 350.

[298] Lee (stmt) 1.

"copyright protection for software programs . . . may have achieved a better balance [for promoting innovation] than patent protection."[299]

By contrast, one panelist observed that patents can be preferable to copyright for software, because patent protection also covers processes.[300] This perspective finds support in an analytical study that concluded that certain aspects of computer programs not protected by copyright law "are vulnerable to rapid imitation that, left unchecked, would undermine incentives to invest in software development."[301] The authors also noted that the extended period of protection available under copyright law has the potential to harm innovation and consumer welfare "by banning for seventy-five years functionally indistinguishable products, having independently created texts."[302] The scholars, however, expressed some concern that applying two intellectual property rights regimes to software may not always work smoothly: "No one knows just where the boundary line between these domains does or should lie."[303] The use of overlapping regimes has left "considerable uncertainty about the scope of protection available from each."[304]

2. Open Source Software

Commentators discussed the open source software movement and its role as an alternative means of fostering innovation. At the most basic level, open source software is software that is distributed with its source code so that the user may alter the program if she or he so chooses.[305] By contrast, most commercial software is distributed in compiled form that cannot be altered by the user.

The development of open source software occurs through the use of three key organizational principles.[306] These include: (1) the absence of most legal constraints on copying and use common to proprietary materials; (2) the accepting (and frequent public dissemination) of contributions from many developers; and (3) the confining of the right to modify the official version of the program to a smaller subset of individuals or a leader closely involved with the project.[307]

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[299] James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* (Public Comment) 20 (arguing that "software patents have been too broad and too obvious," and that copyright protections focus better on barring imitations while permitting development of "potentially valuable complementary contributions."), *at* http://www.researchoninnovation.org/patent.pdf (hereinafter Bessen & Maskin (stmt)).

[300] *See* Gable 3/20 at 136-37.

[301] Samuelson et al., 94 COLUM. L. REV. at 2310.

[302] *Id*. at 2430.

[303] *Id*. at 2347.

[304] *Id*. at 2346-47.

[305] *See* Zoe Konovalov, *The Economics of Open Source Software* (Public Comment) 5, *at* http://www.ftc.gov/os/comments/intelpropertycomments/konovalovzoe.pdf (hereinafter Konovalov (stmt)).

[306] *See* JOSH LERNER & JEAN TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE 6 (National Bureau of Econ. Research Working Paper No. 7600, 2000), *at* http://papers.nber.org/papers/w7600.pdf.

[307] *See* Webbink 3/20 at 98, 101; Konovalov (stmt) 15-16; Mark Ellis, *Comments regarding Competition and Intellectual Property* (Public Comment) 9-11, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ellismark.pdf; LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 6; Yochai Benkler, *Coase's Penguin, or, Linux and the Nature of the Firm*, 112 YALE L. J. 369, 374-75 (2002).

Open source software has received considerable attention in recent years due to: (1) its rapid adoption, particularly by expert users and corporations; (2) significant capital investments in open source projects by corporations such as Hewlett Packard, IBM, and Sun Microsystems; and (3) the hailing of its collaborative nature of development by business and trade press as an important organizational innovation.[308] Scholars have identified both disadvantages and advantages to open source methods. On one hand, "[c]ommercial projects have an edge on the current-compensation dimension because the proprietary nature of the code generates income."[309] On the other hand, open source may have certain cost advantages,[310] and may permit programmers to benefit from a range of delayed rewards.[311]

[308] *See* LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 6; Konovalov (stmt) 37-39. The emergence of open source software as an alternative means of fostering innovation has led one scholar to identify it as "an emerging third mode of production . . . in the digitally networked environment," which he titled "commons-based peer production," and distinguished from "the property- and contract-based modes of firms and markets." Benkler, 112 YALE L. J. at 374-75.

[309] LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 16.

[310] *See id.* (citing programmers' familiarity with open source software from university experience); Benkler, 112 YALE L. J. at 374-75, 377 (citing efficiencies in "large-scale collaborations in many information production fields" and increasing returns to "large- and medium-scale collaboration among individuals that are organized without markets . . . in the informational and cultural production system").

[311] *See* LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 17-18 (noting that open source methods permit outsiders to view an individual programmer's contribution to a project); Konovalov (stmt) 19-20.

E. The Implications of Patent Protection for Innovation

1. The Role of Patents in Spurring Innovation in the Software and Internet Industries

Participants discussed various ways in which software and Internet patents can spur innovation: (1) by preventing free riding and encouraging investment in innovation; (2) by encouraging disclosure of inventions; and (3) by fostering design-around innovation. Commentators were generally skeptical about the benefits of the patent system in these industries.

a. The Role of Patents in Preventing Free Riding and Encouraging Investment in Innovation

Panelists expressed differing views about whether patents play significant roles in preventing free riding and encouraging investment in innovation in the software and Internet industries. Some panelists stated that patents provide incentives to invest in R&D by deterring free riding.[312] One participant stated that "dynamic growth and robust innovation in the software industry in the United States [has been] coincident with the provision of patent protection to software-related inventions."[313] Other panelists took a different view, contending that the availability of patents on software and Internet-based business methods does not significantly encourage investment in

[312] *See* Kaplan 2/27 at 399; Alderucci 4/9 at 39-41; Sander 3/20 at 106.

[313] Microsoft (stmt) 5.

innovation.[314] Many of the panelists who expressed this view emphasized that competition provides incentives to innovate in the software and Internet industries. "Compared to the effect of competition in this industry, the current patent system has relatively little effect on the motivation to innovate," according to one panelist.[315]

Three panelists, two of whom were entirely opposed to the issuance of business method patents, commented that the patent term for business methods should be reduced to between three and five years.[316] One of these panelists commented, "three years is more in line with the development time and cost that . . . business methods face."[317]

b. The Role of Patents in Fostering Innovation Through Disclosure

Panelists also expressed differing views about whether software and business method patents foster innovation by forcing patent applicants to disclose their inventions. Some panelists expressed the view that the patent system spurs innovation by allowing "anyone to review the public disclosures in issued patents or published patent applications."[318] A number of other panelists disagreed, however, noting that the Court of Appeals for the Federal Circuit does not interpret current patent law to require patent applicants to disclose underlying technology, such as source code.[319] One of these panelists argued that without disclosure of the underlying technology, business method patent disclosures "fail to augment public knowledge," because "in many instances, the business process, by its nature, is public."[320] Another panelist stated that "we have to require that the person applying for the software patent files the source code behind that patent, because the source code is the invention."[321]

Some of the panelists expressed concern that the possibility of exposing oneself to allegations of willful infringement by reading another firm's patents reduces the value of patent disclosures. One panelist stated that "the [patent] system discourages you from looking very hard [at patent disclosures] because . . . simply by virtue of poking around to find out what patents exist you expose yourself to willfulness claims which can triple the amount of damages and exposure to attorney's fees."[322] A second panelist confirmed that the potential for being accused of willful infringement had

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[314] *See* Chaikovsky 3/27 at 343 (stating that Yahoo reached $120 billion market capitalization with only three issued patents); Friedman 2/27 at 357; Musacchia 4/9 at 44-45, (stmt) 2; Black 3/20 at 138; Webbink (stmt) 2.

[315] Friedman 2/27 at 354.

[316] *See* Misener 2/27 at 395-96; *see also* Musacchia (stmt) 4; Webbink (stmt) 4.

[317] Webbink (stmt) 4.

[318] Alderucci 4/9 at 40; *see also* Gable 3/20 at 118; Myrick 10/30 at 60.

[319] *See* Webbink 3/20 at 145; Burk 3/20 at 108; Musacchia (stmt) 2; Casey 4/9 at 32; Young 4/11 at 99-100; *see, e.g., Northern Telecom, Inc. v. Datapoint Corp.,* 908 F.2d 931, 941-43 (Fed. Cir. 1990); *Fonar Corp. v. General Electric Company,* 107 F.3d 1543, 1549 (Fed. Cir.), *cert denied*, 522 U.S. 908 (1997).

[320] Musacchia (stmt) 2.

[321] Young 4/11 at 99.

[322] Pooley 2/27 at 380.

deterred him from reading patents.[323] Another panelist reported that uncertainty in the patent system hinders the use of patent disclosures in a competitive manner.[324] The panelist summed up the problem with the statement "there's too much information and it is no longer meaningful."[325]

c. The Role of Patents in Fostering Design-Around Innovation

A number of panelists raised questions concerning the extent to which the patent system fosters useful design-around innovation in the software industry. Some complained that design-around efforts may prove costly, duplicative, wasteful, and sometimes technologically impossible.[326] One panelist stressed that entrenchment of a patented technology as a *de facto* standard might prevent design-around innovation from being adopted, even when it is technologically superior.[327] Others observed that programmers can only design around those patents that are published, and the absence of a publication requirement for *all* patent applications means "it may be years beyond the time that a particular piece of technology has hit the marketplace before it is evident that it, in fact, is covered by a form of patent protection."[328] The skepticism, however, was not universal. One panelist argued that forcing design-around efforts may be "the most significant way in which patents promote innovation," although he did not expressly tie his remark to the software industry.[329]

2. The Potential for Patents to Impede Innovation in the Software and Internet Industries

Panelists and participants discussed several ways in which patents might deter innovation: (1) by denying follow-on innovators access to necessary technologies; (2) by increasing entry barriers; (3) through business uncertainty and the expense required to avoid patent infringement; and (4) through the issuance of questionable patents.

a. Patents May Impede Independent Follow-On Innovation

Some participants cautioned that patents are likely to thwart beneficial follow-on R&D when innovation depends on incremental efforts, such as software and the Internet.[330] As one participant has

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[323] *See* Greenhall 2/27 at 420-21.

[324] *See* Friedman 2/27 at 411-12. Factors this panelist identified as causing uncertainty include the issuance of questionable patents and the process of judicial review of patents.

[325] *Id*.

[326] *See, e.g.,* Stallman 4/9 at 18-20, 38, and Richard Stallman, *The Danger of Software Patents, Speech by Richard Stallman at Cambridge University, March, 25 2002* (Public Comment) 4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/stallmanrichard.pdf; Musacchia 4/9 at 91; *see also* Cohen & Lemley, 89 CAL. L. REV. at 56 (noting that the courts may "apply the doctrine of equivalents too broadly in software infringement disputes, and thus may stifle efforts by second-comers to design-around existing patents").

[327] *See* Stallman 4/9 at 88-90.

[328] Webbink 3/20 at 99-100; *see infra* Ch. 5(II)(C)(4) for a discussion of patent publication requirements.

[329] Casey 4/9 at 85.

[330] *See, e.g.,* Stallman 4/9 at 17-18; Kohn 2/27 at 348-49 (stressing effects on development of complementary products); Bessen & Maskin (stmt) 2-3; League for Programming Freedom (stmt).

explained, "[A]n early patent holder has a potential claim against subsequent innovators. Anticipating the expected cost of such claims, a second innovator may choose to perform a sub-optimal level of R&D or, perhaps, not to invest in the innovation at all."[331] This argument, of course, has limits; failure to reward initial innovators for the benefits that they confer upon follow-on activity could leave inadequate incentives for the initial innovators.[332] Another panelist contended that "the speed of innovation in [the software industry] is so fast that the long periods of protection granted by patents is stifling subsequent innovation."[333]

b. Patents May Increase the Costs of Entry

In the software and Internet industries, innovation by firms and individuals with limited working capital may often be viable. Some participants, however, warned that patents can raise the cost of market entry or ongoing market participation and thereby deter such innovation.[334] Some claimed that software patentability has introduced new costs, such as the cost of obtaining a patent, determining whether a patent is infringed, defending a patent infringement lawsuit, or obtaining a patent license,[335] which may disproportionally affect small firms and individual programmers[336] and the open source community.[337] According to one commentator, "[T]he problem in the United States [software industry] . . . [is] that rights might be too *strong* to permit a healthy, competitive rate of entry."[338]

c. Avoiding Patent Infringement Is Costly and Uncertain

Avoiding infringement raises its own

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[331] James Bessen, *Hold-Up and Patent Licensing of Cumulative Innovations with Private Information* 1 (2002), *at* http://www.researchoninnovation.org/holdup.pdf; *see also* Samuelson et al., 94 COLUM. L. REV. at 2346.

[332] *See supra* Ch. 2(I) and (III)(A).

[333] Webbink (stmt) 4.

[334] *See id.*; Gregory Casamento, *Comments, FTC Hearings on Competition and Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/johncasamentogregory.htm; Lee (stmt) 1-2; Eric Buddington, *Comments Regarding Competition and Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/buddingtoneric.pdf (hereinafter Buddington (stmt)); League for Programming Freedom (stmt) 3-5; Stallman 4/9 at 96.

[335] *See* Gable 3/20 at 136 (stating that the preparation, filing and prosecution of a routine patent in the software area costs between $30,000 and $40,000); Lee (stmt) 2.

[336] Lee (stmt) 2 (observing that "although a few thousand dollars may not be a major expense for a large company, it is far too expensive for many small businesses and independent software developers who cannot even afford an office."); *see generally* Place 2/27 at 477-478; Nickolaus E. Leggett, *Comments Regarding Competition & Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/leggettnick.htm.

[337] *See* Stallman 4/9 at 96 (arguing that the open source movement, which often relies on volunteer programmers, is particularly vulnerable to cost increases resulting from the patenting of software). *See also* Robert M. Riches, *Comments regarding Competition and Intellectual Property* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipriches.pdf.

[338] Robert P. Merges, *A Comparative Look at Property Rights and the Software Industry*, *printed in* THE INTERNATIONAL COMPUTER SOFTWARE INDUSTRY: A COMPARATIVE STUDY OF INDUSTRY EVOLUTION AND STRUCTURE 285 (David Mowery ed., 1996).

set of concerns. In a setting with cumulative innovation and multiple surrounding patent rights, patent thickets may make avoiding infringement very difficult and give rise to defensive patenting and hold-up concerns.[339] Avoiding infringement can also be fraught with uncertainty, because the metes and bounds of software patent claims are often ambiguous.[340]

(i). Patent Thickets, Defensive Patenting and Hold-Up

A number of panelists confirmed the existence of a patent thicket in the software industry, which makes avoiding patent infringement very difficult.[341] A panelist who had studied patenting trends in the software industry stated that the industry poses unusual challenges, because there can be "potentially dozens or hundreds of patents covering individual components of a product."[342] Another panelist provided an anecdote to support the existence of a software patent thicket; he undertook a search to determine the patent landscape surrounding a particular patent relevant to his business and in the process identified 120 patents that appeared to overlap each other, as well as to be infringed by his own product.[343] Commentators noted that patent thickets are likely to arise in industries where innovation occurs on an incremental basis, such as the software industry.[344]

Defensive patenting has accelerated the development of a patent thicket in the software industry. Panelists explained that firms pursue defensive patenting: (1) to maintain detente with rivals; (2) to obtain portfolio cross-licenses from rivals; and (3) to raise a patent infringement counter-claim should a rival sue a firm for patent infringement.[345] One panelist commented that the process of obtaining defensive patents to obtain portfolio cross-licenses from rivals, and thereby maintain freedom to operate, is essentially an attempt "to solve the problem you're creating" by issuing patents on software in the first place.[346]

Another panelist observed that defensive patents have implications for innovation. Companies may have to divert resources from R&D to fund their defensive patent programs. The panelist issued a directive to his company requiring that they "reallocate roughly 20 to 35 percent of [their] developer's resources and sign on two separate law firms to increase [their] patent portfolio" for purely defensive reasons.[347] The engineers' time dedicated to assisting in the filing of defensive patents, which "have no . . . innovative value in and of

[339] *See supra* Ch. 2(III)(C).

[340] *See, e.g.,* Greenhall 2/27 at 376; League for Programming Freedom (stmt) 5.

[341] *See* Shapiro, *Navigating the Patent Thicket* at 120-121 (observing that a patent thicket has formed in the software and Internet industries); Mowery 2/27 at 427; Stallman 4/9 at 20; Burk 3/20 at 149; Greenhall 2/27 at 375-76.

[342] Mowery 2/27 at 427; *see also* Kohn 2/27 at 349 (complex software can contain "potentially hundreds of thousands" of patentable inventions).

[343] *See* Greenhall 2/27 at 375-76.

[344] *See* Telecky (stmt) 3; Teece 2/27 at 500.

[345] *See* Kohn 2/27 at 350-51; Friedman 2/27 at 356; Greenhall 2/27 at 375-76.

[346] Stallman 4/9 at 88.

[347] Greenhall 2/27 at 376.

themselves," could have been spent on developing new technologies, this panelist asserted.[348]

The existence of a software patent thicket significantly increases the likelihood of companies being held-up due to the difficulty of avoiding patent infringement. Commentators reported that a software program with hundreds of thousands of patentable ideas can be held-up by a patent that claims a single routine in the program.[349] Building up a patent portfolio by engaging in defensive patenting cannot always protect against hold-up; when small companies or NPEs engage in hold-up, they generally are not susceptible to pressure from patent infringement counter-claims.[350]

(ii). The Metes and Bounds of Patent Claims Are Ambiguous

Some panelists expressed concern that the subjective and ambiguous process of construing patent claims makes avoiding patent infringement uncertain and deters innovation.[351] Others asserted that a lack of an effective disclosure requirement exacerbated the difficulty of construing patent claims in the context of software patents.[352]

Two commentators described the impact of this uncertainty on their businesses:

> "[O]ne of the biggest risks I face is uncertainty in the marketplace. I can minimize my risk by understanding my competitor's products . . ., my products . . ., [and] what the consumers and customers want. But I've found . . . that I really can't understand the patent landscape and that I'm sitting with a nuclear bomb on top of my products that could go off at any point and cause me to simply not have a business anymore."[353]

> "For some software projects that I have worked on, I have personally spent over 30% of my time trying to ensure that I was not accidentally infringing on a patent . . . This results in an incredibly large amount of wasted labor, harms our nation's economy and results in less time spent on actual software innovation."[354]

d. Questionable Patents Create Uncertainty and Hinder Innovation

Many participants stated that the PTO issues too many questionable software

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[348] *Id.* at 377 and 420; *see also* Kohn 2/27 at 350-51.

[349] *See* Kohn 2/27 at 351-52; Pooley 2/27 at 382.

[350] *See* Chaikovsky 2/27 at 390-91; League for Programming Freedom (stmt) 6. For further discussion of hold-up issues in the context of patent thickets, *see supra* Ch. 3(IV)(E)(2)(c) and Ch. 2(III)(C)(2).

[351] *See* Greenhall 2/27 at 375-76; Lee (stmt) 2; League for Programming Freedom (stmt) 5; s*ee generally* Black 3/20 at 161-62 (discussing uncertainty from a business perspective).

[352] *See* Webbink 3/20 at 145; Burk 3/20 at 149-150.

[353] Greenhall 2/27 at 375.

[354] Lee (stmt) 1.

and business method patents.[355] They identified two main reasons. First, some argued that the PTO fails to examine all the relevant prior art and consequently issues patents that are either overly broad or obvious.[356] Panelists identified factors to which this lack of adequate consideration of prior art is attributable, including: (1) the informal nature of software development, especially among the open source community; (2) the rapidly changing and complex nature of the software and Internet industries; (3) the absence of a legal requirement for patent applicants to disclose source code; (4) the use of trade secrecy for almost 20 years of commercial software development; and (5) the relatively recent recognition of the validity of business method patents by the courts.[357]

Questionable patents may have a disproportionally adverse impact on entry by small firms and individuals who lack the resources to challenge such patents. As one software programmer commented, "the ease with which the US Patent Office has been granting patents in the last few years has already dampened my plans to write software as a primary business."[358] In contrast, a panelist from a larger firm suggested that incentives to innovate are not undermined by questionable patents.[359] The panelist observed that it is "a fairly straightforward exercise for our research department to investigate the relevant prior art [for an overly broad patent] and therefore obviate any further discussion on the matter."[360]

The lack of effective mechanisms for third-party challenges to patents compounds the harm to innovation caused by questionable patents, according to some. Panelists contended that the court system is too uncertain, time-consuming, and costly to examine questionable patents effectively.[361] They argued that the reexamination process also has significant defects: the challenging party is at a significant disadvantage procedurally and is then estopped from raising key issues in the courts.[362] Panelists advocated that reforms be made to the reexamination procedures so as to increase their effectiveness for challenging questionable patents and that the possibilities for pre-grant comment also be more fully utilized.[363]

A number of commentators maintained that the PTO's issuance of

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[355] For further discussion of business method patents *see infra* Ch. 4(II)(E).

[356] *See, e.g.,* Webbink (stmt) 2-3; Friedman 2/27 at 355; Gable 3/20 at 114-5.

[357] *See* Kohn 2/27 at 428; Gable 3/20 at 116-17; Lee (stmt) 3; Webbink (stmt) 2-3; *see also* Cohen & Lemley, 89 CAL. L. REV. at 42-46. For further discussion of challenges posed by business method patents, *see infra* Ch. 4(II)(E).

[358] Buddington (stmt) 1.

[359] *See* Alderucci 4/9 at 58.

[360] *Id*.

[361] *See, e.g,* Pooley 2/27 at 379; Friedman 2/27 at 411-12; Gable 3/20 at 155; Sander 3/20 at 156.

[362] *See* Gable 3/20 at 163; Pooley 2/27 at 405; Edward J. Black, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Testimony of Edward J. Black, President & CEO* (3/20/02) 7, *at* http://www.ftc.gov/opp/intellect/020320black.pdf.

[363] *See* Gable 3/20 at 163; Pooley 2/27 at 405; Misener 2/27 at 396; Black 3/20 at 126. For a discussion of recent reforms to reexamination procedures, *see infra* Ch. 5(III)(A).

questionable patents results in part from a lack of funding that is attributable to the diversion of PTO user fees to non-patent related matters.[364] Several panelists argued that if the PTO had more examiners, made a greater effort to keep experienced examiners, and gave patent examiners more time to spend on their initial examination, the PTO would issue fewer questionable patents.[365] "Improving patent quality will increase confidence in the validity of patents, thus making it easier for patent owners to commercialize their inventions and decreasing the possibility that potential defendants will have to address infringement allegations that ultimately prove to be without merit," one commentator stressed.[366]

F. Licensing Strategies to Navigate the Patent Thicket

As in the panels devoted to the computer hardware industries, software and Internet panelists discussed three licensing strategies that firms can use to navigate patent thickets: (1) cross-licensing; (2) patent pooling; and (3) standard setting.[367] Two panelists suggested that the process by which royalties are determined for patent licensing – one patentee at a time, with potential for royalty stacking and hold-up by patents on small pieces of much larger programs – exacerbates the problem of hold-up and lessens the effectiveness of the licensing strategy.[368] One panelist argued that there should be a reasonableness element to determining royalties, which should be based on the value of the contribution of the particular patented feature to the total product.[369] Such determinations need to be made at an early stage, he urged, so that royalty negotiations are not conducted under the threat of litigation, preliminary injunctions, and damages.[370] Another panelist suggested a mechanism for permitting a legal action by which a company could implead all relevant intellectual property owners to settle all outstanding royalty claims in a single forum.[371] Such a mechanism might be a means for addressing royalty stacking problems that may arise when royalties are negotiated sequentially.[372]

G. Conclusion

The software and Internet industries generally are characterized by five factors: (1) innovation occurs on a cumulative basis; (2) capital costs are low, particularly relative to the pharmaceutical, biotechnology and hardware industries; (3) the rate of technological change is rapid, and product life cycles are short; (4) alternative means of fostering innovation exist, including copyright protection and open source

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[364] *See* Alderucci 4/9 at 12-16; Musacchia (stmt) 4; Webbink 3/20 at 171; Gable 3/20 at 121-22; Microsoft (stmt) 5-6.

[365] *See* Gable 3/20 at 121-22; Alderucci 4/9 at 12-16; Microsoft (stmt) 5-6.

[366] Microsoft (stmt) 6.

[367] *See, e.g.,* Friedman 2/27 at 355; Greenhall 2/27 at 377, 417; Stallman 4/9 at 38. For further discussion of each strategy, *see supra* Ch. 3(IV)(F).

[368] *See* Kohn 2/27 at 351-52, 415, 429; Pooley 2/27 at 381-83.

[369] *See* Kohn 2/27 at 351-52, 415, 429.

[370] *See id.* at 415, 429-30.

[371] *See* Pooley 2/27 at 415-16.

[372] *See supra* Ch. 2(III)(C)(3).

software; and (5) the industries have experienced a regime change in terms of the availability of patent protection.

Panelists consistently stated that competition drives innovation in these industries. Innovation is also fostered by some industry participants' use of copyright protection or open source software. Several panelists discounted the value of patent disclosures, because the disclosure of a software product's underlying source code is not required.

Many panelists and participants expressed the view that software and Internet patents are impeding innovation. They stated that such patents are impairing follow-on incentives, increasing entry barriers, creating uncertainty that harms incentives to invest in innovation, and producing patent thickets. Panelists discussed how defensive patenting increases the complexity of patent thickets and forces companies to divert resources from R&D into obtaining patents. Commentators noted that patent thickets make it more difficult to commercialize new products and raise uncertainty and investment risks. Some panelists also noted that hold-up has become a problem that can result in higher prices being passed along to consumers.

CHAPTER 4 COMPETITION PERSPECTIVES ON SUBSTANTIVE STANDARDS OF PATENTABILITY

CHAPTER 4 COMPETITION PERSPECTIVES ON SUBSTANTIVE STANDARDS OF PATENTABILITY

Patent quality influences much of how the patent system and competition interact. The substantive standards and procedural criteria that govern patent rights have potentially significant and diverse competitive effects. In different settings, these patent rules may promote entry or give rise to market power. They may foster initial innovation, yet impede follow-on efforts. They may confer economic benefits or cause net economic harm.

Consequently, more patents in more industries and with greater breadth are not always the best answers for maximizing consumer welfare. A questionable patent can raise costs and prevent competition and innovation that otherwise would benefit consumers.[1] As Chapter 3 details, many panelists in knowledge-based industries such as biotech, computer hardware, and software asserted that, because of questionable patents, they must steer their innovative efforts away from potentially productive areas, accede to possibly unjustified licensing terms, or enter into cross-licensing agreements that effectively "contract out" of the patent system.

To understand patent quality, we look first to the substantive standards of patentability. They govern when to grant and uphold a patent as valid and how to determine the proper scope of a patent's claims. The substantive standards of patentabilty manage the patent system's "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. . . ."[2]

We bring a competition perspective to bear on these issues. A competition perspective assumes consumer welfare over time as the goal of both competition and patent policy and reflects the application of economic analysis to patent issues.[3] From a competition perspective, the standards for patentability should achieve four major policy objectives: (1) provide efficient incentives for innovation; (2) safeguard the patent system's disclosure functions; (3) avoid unnecessary restraints on competition;[4] and (4) minimize the sum of error and process costs and the detrimental effects of uncertainty.[5]

I. STATUTORY STANDARDS OF PATENTABILITY

A brief review of the statutory standards of patentability suggests that they are generally well-suited to achieve these

[1] *See generally* Chs. 1-3.

[2] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 146 (1989).

[3] *See supra* Ch. 1.

[4] For example, to avoid unnecessary restraints on competition, substantive patent standards should tend to support patentability only for those inventions that, "but for" the prospect of a patent, would not have been forthcoming as soon (or for which disclosure or commercial development would not have occurred as soon). *See supra* Ch. 1(I)(C)(1)(a).

[5] *See supra* Ch. 1(IV)(B)(5).

four policy objectives.[6] An invention must be novel[7] – that is, "[t]o obtain a patent, you must do something *new*."[8] This requirement tends to exclude from patentability inventions that already exist and may be subject to competition. The requirement thus sets proper incentives for innovation – rewarding that which is new, not imitative – and avoids unnecessary restraints on competition.[9] On the other end of the spectrum, the requirement that a claim must be "useful" tends to exclude areas of basic research from patentability, thus leaving such matters available for the development of competing inventions.[10]

A claimed invention also must be nonobvious. Some describe the nonobviousness doctrine as "the heart of the patent law."[11] It establishes a patentability step – a level of development beyond the prior art – that must be accomplished before a patent can issue.[12] As codified by Congress:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. . . .

35 U.S.C. § 103. A leading text explains, "Nonobviousness asks whether a development is a significant enough technical advance to merit the award of a patent"; it "can accurately be described as a

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[6] *See also* Box 4-1 for a summary of the statutory standards for patentability.

[7] Section 102 of the Patent Act sets forth a variety of tests for novelty, such as whether "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, ..." 35 U.S.C. § 102(a). One eminent nineteenth-century treatise writer described "novelty" as the consideration that an inventor provides to society to obtain a patent:

> An inventor does not become entitled to a patent merely by exercising his creative faculties in the production of an art [*i.e.*, process] or instrument. *The consideration for the grant of his exclusive privilege is the benefit which he confers upon the public by placing in their hands a means through the use of which their wants may be supplied.* If the same means has already been made available to them by the inventive genius of a prior inventor, . . . , no benefit results to them from his inventive act and there is no consideration for his patent. (Emphasis added).

1 WILLIAM ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22 at 305 (1890), *cited in* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 361 (3d ed. 2002).

[8] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 361.

[9] Novelty was not a major point of discussion during the Hearings and is not further addressed in this chapter. Thus, we do not discuss the complexities that can arise in the evaluation of whether a claimed invention is "novel." *See generally id.* at 361-539.

[10] 35 U.S.C. § 101. *See generally* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 254-58; ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK §§ 15.1-15.3 at 315-21 (2003). *See also infra* Ch. 4(I)(D).

[11] *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Herbert C. Wamsley Testimony July 10, 2002*, at page 20 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)).

[12] *See* Stoner 3/36 at 117; Scotchmer 4/10 at 60-61, 69; Ted O'Donoghue, *A Patentability Requirement for Sequential Innovation*, 29 RAND J. ECON. 654, 657 (1998).

'nontriviality' requirement in patent law."[13] The requirement that an invention be nonobvious preserves the public domain by creating a patent-free zone around the existing state of the art.[14]

Properly applied, the "nonobviousness" requirement can ensure that the patent system avoids patents that "hav[e no] social benefit[,] because . . . others would have developed the idea even without the incentive of a patent."[15] The "nonobviousness" requirement also can provide undiluted incentives for inventors to create nonobvious inventions, by prohibiting patents and avoiding royalties on obvious inventions,[16] and can avoid the costs of granting obvious patents, which "may create a proliferation of economically insignificant patents that are expensive to search and to license."[17]

A patent application also must meet certain disclosure requirements. A patentee must disclose the invention clearly enough so that one skilled in the art can understand it well enough to make and use it without having to undertake undue experimentation.[18] This "enablement" requirement tends to safeguard the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others in the art can

Box 4-1. ***The Statutory Standards for Patentability***

Patent law establishes the standards of patentability against which the PTO measures a patent application. These standards ask whether the claimed invention is:

- **patentable subject matter** under 35 U.S.C. § 101 (basically processes, machines, manufactures, and compositions of matter);
- **novel** under 35 U.S.C. § 102, which requires that the invention not be wholly anticipated by prior art or public domain materials;
- **nonobvious** under 35 U.S.C. § 103, which requires the invention to be beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field;
- **useful** under 35 U.S.C. § 101, which means the invention must be minimally operable towards some practical purpose; and
- whether the application meets the **disclosure requirements** under 35 U.S.C. § 112 by: (i) so completely describing the invention that skilled artisans are enabled to practice it without undue experimentation; (ii) providing a description sufficient to ensure that the inventor actually has invented what the patent application claims; and (iii) containing distinct, definite claims that set out the proprietary interest asserted by the inventor.

See generally ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 13.1 at 282 (2003).

[13] *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 644.

[14] *See* Thomas 2/8 (Patent Session) at 57; SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK § 17.1 at 370-71.

[15] MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 646 (citations omitted).

[16] *See id.* at 646-47.

[17] *Id*. at 647. *See generally supra* Ch. 3(IV) and (V).

[18] *See* 35 U.S.C. § 112.

learn.[19] The disclosure also must include a "written description" sufficient to show that the applicant was in possession of the claimed invention as of the applicant's filing date.[20]

Apart from some misgivings about the written description requirement,[21] no one at the Hearings disputed the usefulness or analytical aptness of these statutory criteria for patentability. Rather, the Hearings record tends to support a conclusion that the statutory standards for patentability account for competitive issues and do not require changes.[22] Panelists did not perceive the statutory standards of patentability themselves as sources of problems with patent quality or adverse competitive effects.

[19] *See generally* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 259-60. *See supra* Ch. 1(I)(A)(2) and (IV)(B)(2) and *infra* Ch. 4(II)(B).

[20] 35 U.S.C. § 112.

[21] *See, e.g.,* Janis 4/10 at 119-20 (stating that the written description requirement has been very difficult for the Federal Circuit to characterize in any meaningful way and that efforts to elucidate this requirement detract attention from enablement, which could be used more effectively); Thomas 4/10 at 128-30 (questioning the administrability of the written description requirement).

[22] *See infra* Ch. 4(II); American Intellectual Property Law Association (AIPLA), *AIPLA Testimony* (Public Comment) 16, *at* http://www.ftc.gov/os/comments/intelpropertycomments/aipla.pdf; Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 16, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipo.pdf (hereinafter IPO (stmt)).

II. THE INTERPRETATION AND APPLICATION OF THE STANDARDS OF PATENTABILITY

Hearings participants did raise questions and concerns about the interpretation and application of certain statutory standards, however. This Section considers these topics in turn, discussing the competitive implications of each doctrine and summarizing and examining testimony to identify both areas of harmony and points of concern. When the system is functioning well, from a competition perspective, the discussion highlights the reasons for harmony. When problems are evident, it offers recommendations for taking better account of competition considerations within the patent system. When difficulties may be emerging, it identifies relevant issues and suggests appropriate precautions.

A. The Interpretation and Application of the Nonobviousness Requirement

1. Significance for Innovation and Competition

The nonobviousness doctrine establishes a patentability step – a level of development beyond the prior art – that must be accomplished before a patent can issue. The interpretation and application of this doctrine can have a variety of effects on innovation and competition. To begin, the size of the required patentability step affects the innovation incentives of both initial and follow-on innovators. For the initial innovator, the size of the required patentability step affects the extent to which

it must share revenues with independent improvers; if the required step is too small, for example, an initial inventor must split royalties with improvers that otherwise could not patent in the "obvious" area around the initial patent.[23] For follow-on innovators, the size of the step required for patentability affects the choice between seeking ambitious or niche improvements.[24]

Second, a lax nonobviousness standard can generate proliferation or clutter problems -– the thickets, minefields, royalty stacking, anti-commons, and flooding problems identified by various panelists.[25] A profusion of minor patents can significantly limit freedom of operation and require costly licensing negotiations.[26] In some settings, such as in semiconductors, these hurdles may be inevitable to some degree,[27] but in other contexts the choice of obviousness standard may affect whether proliferation evolves.[28]

Box 4-2. ***Nonobviousness and Potential Competitive Concerns***

The nonobviousness standard defines the *level of development beyond the prior art* required for a patent to issue – that is, *the size of the required patentability step*. The size of the required patentability step can affect:

– innovation incentives of initial and follow-on inventors (who gets what rewards in what proportions?);

– the extent of patent proliferation problems (*e.g.*, if only a small step is required for patentability, a profusion of minor, "obvious" patents may require costly licensing negotiations and limit future firms' freedom of design); and

– the extent of any patent-related market power (a patent on a technically trivial development sometimes can create significant market power, but withholding patent protection from entrants through an overly rigorous nonobviousness standard may delay their contribution to competition).

Third, either an overly lax or overly restrictive nonobviousness standard may result in unwarranted market power. A patent on a technically trivial development can sometimes create significant market power.[29] When market power already is

[23] *See generally* Duffy 7/10 at 113 (lax nonobviousness doctrine "not pro-inventor . . . because it can decrease the royalties to . . . people who really did invent") and Duffy 10/30 at 110 (stating same principle).

[24] *See* Scotchmer 4/10 at 70. Follow-on innovators may be less likely to develop inventions that clearly fall short of that patentability step; without their own patent rights, such trivial improvers could face appropriation of their inventions by the initial innovator. *See* Scotchmer 4/10 at 69-70. Of course, to the extent that other appropriability mechanisms, such as first-mover advantages, are effective, the improver retains some incentive to develop follow-on inventions.

[25] *See*, *e.g.*, Duffy 10/30 at 63; Stoner 10/30 at 58; *supra* Chs. 2 and 3.

[26] *See, e.g.,* Duffy 7/10 at 110 (swarm of paltry patents may constitute a minefield). For discussion of issues that may be raised by a profusion of patents within a given industry, *see supra* Chs. 2(III)(C) and 3(IV) and (V).

[27] Several panelists indicated that technological limitations, the high ratio of patents to products, and the incremental nature of the innovation process all would contribute to the development of thickets in semiconductors irrespective of particular patent policies. *See, e.g.,* Detkin 2/28 at 668-70 (technological advance has led to consolidation of multiple functions on single chips and "[t]here's only a certain number of ways that you can connect transistors together," resulting in "unavoidable overlap"); Poppen 2/28 at 712 (semiconductor thickets largely a result of the technology); Lemley 2/25 at 39 (noting high ratio of patents to product); Fox 2/28 at 714-15 (stressing incremental inventions).

[28] *See, e.g.,* Barton 2/26 at 223. Indeed, the ability to surround a competitor's initial patent with technically trivial variants is a key element in flooding strategies. *See supra* Ch. 2(III)(C)(6).

[29] *See, e.g.*, R. Levin 2/6 at 102 (warning that market power can be a potentially serious consequence of a low threshold for patenting); Duffy 7/10 at 110-13

present, rather trivial patents may help to maintain or extend it. Thus, some panelists explained, portfolios of patents might be used to add breadth to an existing patent, creating a fence around its zone of exclusion.[30] Others suggested that existing market power may be extended beyond the life of the initial patent through an accumulation of minor improvement patents,[31] although such an extension would require some reason why competitors offering the now-unpatented core product could not adequately constrain pricing of the slightly improved version still protected by patents.[32] An overly rigorous nonobviousness standard may have its own market power effects; to the extent that withholding patent protection delays competition from entrants, an initial innovator's dominance may be extended.[33]

("technical triviality does not at all equal economic triviality," citing the example of the Selden patent on the automobile).

[30] *See, e.g.,* Cohen 2/20 at 31 and Wesley M. Cohen, *Patents: Their Effectiveness and Role* (2/20/02) (slides) at 14 (patents used to block substitutes by creating fences around core innovations), *at* http://www.ftc.gov/opp/intellect/cohen.pdf; Merges 2/26 at 162-65 (portfolios can add breadth); *supra* Ch. 2(III)(C)(5) (discussing patent fences).

[31] *See, e.g.,* Coffin-Beach 3/19 at 204-05; Scherer 7/10 at 180.

[32] *See supra* Ch. 2(III)(C)(5) (discussing patent extensions).

[33] *See* Merges 2/28 at 581-82; Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* (Public Comment) 2 (under a strong nonobviousness requirement "[c]ompeting proprietary technologies take longer to accumulate so the patent holder's profits are larger and last longer"), *at* http://www.ftc.gov/os/comments/intelpropertycomments/nonobviousness.pdf (hereinafter Hunt (Nonobviousness stmt)); O'Donoghue, 29 RAND J. ECON. at 656.

2. Analytic Tools to Balance Patent and Competition Concerns

In the context of nonobviousness, "but for" thinking may be useful to better align patent law with competition policy. The concept is simple: to ask whether an invention likely would emerge in roughly the same time frame – that is, without significant delay – "but for" the prospect of a patent. Analogously, one can ask whether disclosure and commercial development of the invention would have occurred as soon "but for" the prospect of a patent. As a theoretical matter, if, even without the prospect of a patent, the invention would emerge (and would be disclosed and commercially developed) without significant delay, then the invention does not warrant a patent.[34]

This test has roots in patent law: when a patent elicits little social benefit – such as when the invention could be expected anyway – patent law recognizes that withholding the patent and avoiding any costs to innovation and competition will maximize consumer welfare over time.[35] The test also accords with long-established

[34] *See supra* Ch. 1(I)(C)(1)(a). *See* Glynn S. Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363, 386 (2001); F. M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 443 (2d ed. 1980).

[35] *See Graham v. John Deere Co.,* 383 U.S. 1, 11 (1966) ("The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."); Edmund W. Kitch, *Graham v. John Deere Co.: New Standards for Patents*, 1966 SUP. CT. REV. 293, 301 (stating – prior to developing his prospect theory – "the basic principle on which the non-obviousness test is based: a patent should not be granted for an innovation unless the innovation would have been unlikely to have been developed absent the prospect of a patent"); 1 ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22 at 305, *cited in* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 361; *see generally infra* Ch. 6.

modes of antitrust analysis: antitrust law is accustomed to comparing the world with and without a suspect transaction.[36] To the extent that patent law confers its right to exclude only if necessary to create, disclose, or develop an invention, congruence between patent and competition policy is more likely.[37]

As noted earlier, application of the "but for" principle generally will not work in individual cases.[38] Some advances may be ripe due to underlying technological or regulatory change and would flow without patent protection.[39] Other inventions may require substantial fixed costs and would not be forthcoming without the shelter from imitation that patent protection affords.[40] Distinguishing these situations through case-by-case inquiry would be costly, time-consuming, and prone to error. Indeed, sorting out the need for any given patent might prove impossible when multiple inventions flow from a single research program. Moreover, if the cost of invention is much less than the subsequent cost of developing a commercial product, a "but for" test would have to consider whether the innovation would be commercially developed absent the patent.[41] "But for"

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[36] In evaluating mergers, the Antitrust Enforcement Agencies consider only merger-specific efficiencies, *i.e.*, only the efficiencies that are unlikely to be accomplished without either the merger or some other means having comparable anticompetitive effects. Federal Trade Commission and U.S. Department of Justice, Horizontal Merger Guidelines § 4 (1992), *available at* http://www.ftc.gov/bc/docs/horizmer.htm. In evaluating competitor collaborations under the rule of reason, "the central question is whether the relevant agreement likely harms competition by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of the agreement." Federal Trade Commission and U.S. Department of Justice, Antitrust Guidelines for Collaborations Among Competitors § 3.1 (April 2000), *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[37] Some tensions could still persist. The "but for" test states at most a necessary, not a sufficient, condition for patentability. An invention worth developing solely because of competitive advantages conferred by its patent rights could raise exclusionary concerns, yet would pass through a "but for" screen.

[38] The panelists widely recognized the standard's unsuitability for practical application. *See. e.g.,* Banner 10/30 at 71-72 (giving the concept a "D" as a practical test in light of the difficulties that it would pose for judge or jury); Myrick 10/30 at 60 ("unworkable"); John Love 2/28 at 635 (concern with imposing another level of uncertainty and complexity on examiners); Stoner 10/30 at 58 (need a "more practical sieve"); Kitch 10/30 at 51 ("but for" thinking not a test for application "on a retail basis" to individual innovations); *see also* Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L. J. 1, 19 (1992) (describing the "but for" test as "the conventional ideal standard of patentability" but concluding, "It would be impossible in most cases to apply this standard"); *supra* Ch. 1(I)(C)(1)(a).

[39] *See* Duffy 7/10 at 113-15 (suggesting that some methods may have become obvious once the Internet developed and that a combination of ibuprofen and a common cold remedy could be expected once ibuprofen became an over-the-counter drug); Fox 2/28 at 715 (constantly seeing multiple inventors independently coming up with the same invention once the "logical bases for that invention come into place").

[40] *See, e.g.*, Merges 2/28 at 580-81 (noting that "though something is extremely straightforward technically, it may be very very expensive to achieve" and urging that the nonobviousness standard take that into account); Merges, 7 HIGH TECH. L. J. at 48-50 (urging a relaxation of nonobviousness standards when R&D is very costly, in order to compensate for effects of risk aversion that might otherwise make innovation less likely). Any cost analysis would have to consider risks of failure, as well as cost in an individual case, lest only the cost of the one success in a field be counted *See* Scherer 7/10 at 127-28; Duffy 7/10 at 132. The analysis also should not penalize the efficient inventor, whose cost will be less than the norm. *See* Kitch 10/30 at 51-52.

[41] *See, e.g.,* Sobel 7/10 at 124-26; Scherer 7/10 at 126-27; Burk 7/10 at 129; Lunney 7/10 at 130-31; Dreyfuss 7/10 at 141-42 (adjust test to focus directly on risk of development). *But cf.* Duffy 10/30 at 133 (questioning whether patent system is really intended to encourage investment following the granting of the patent and

thinking also can account for the patent system's disclosure objectives, but further adjustments would be necessary.[42]

Yet the Hearing record as a whole showed very substantial support for "but for" thinking as an idealized, foundational principle[43] that can be a useful tool for shaping general policy analysis.[44] We will return to it after a review of current interpretations and applications of the nonobviousness doctrine.

3. Nonobviousness: Interpretation and Application in the Courts

Participants generally perceived a trend since the advent of the Federal Circuit toward reducing the size of the step required for patentability – that is, reducing the rigor of the nonobviousness standard.[45] Several participants voiced concern about too great an issuance of obvious patents.[46] Panelists

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suggesting that post-invention investments can be protected by subsequent patents).

[42] In fact, the patent system's disclosure function is reflected in the Supreme Court's language in *Graham* describing "the inherent problem" in formulating standards of patentability as "develop[ing] some means of weeding out those inventions which would not be *disclosed* or devised but for the inducement of a patent." *Graham*, 383 U.S. at 11 (emphasis added). *See* Lunney, 7 MICH. TELECOMM. & TECH. L. REV. at 385-86 (phrasing a "but for" standard in terms of whether the invention "would have been developed, commercialized and *disclosed* even without a patent") (emphasis added). If the patent system is viewed as a mechanism for increasing the efficiency of post-invention development, neither the "but for" test nor the obviousness standard may have a logical role. *See* Kitch 2/20 at 84-85; Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. LAW & ECON. 265, 284 (1977) (urging "substantial novelty" as the standard for patentability under the prospect theory).

[43] Herbert Wamsley summarized, "I suspect that everybody on this panel agrees that we should have a . . . test, one that finds nonobvious only inventions that wouldn't have been made otherwise or for which there's some incentive needed." Wamsley 7/10 at 139.

[44] As James Pooley concluded, "The 'but for' standard strikes me as a useful analytic tool to sort of check our direction in a policy sense, but not a particularly useful standard for measuring specific inventions." Pooley 10/30 at 55.

[45] *See, e.g.*, R. Levin 2/6 at 102-03 (nonobviousness standard "diluted"); Kitch 2/20 at 68 (Federal Circuit has "seemed to soften the non-obviousness test"); Lunney 7/10 at 97-99 and Glynn S. Lunney, Jr., *Patents, the Federal Circuit, and the Simply Property Perspective* (7/10/02) (slides) at 13, *at* http://www.ftc.gov/opp/intellect/020710glynnslunneyjr.pdf; Duffy 7/10 at 185; Dreyfuss 7/10 at 196-97; Hunt (Nonobviousness stmt) 2, 8; Cecil D. Quillen, Jr., *The U.S. Patent System: Is It Broke? And Who Can Fix It If It Is* (Public Comment) 3-5, *at* http://www.ftc.gov/os/comments/intelpropertycomments/quillenattachments/isitbrokewhocanfixit.pdf (hereinafter Quillen (U.S. Patent System stmt)); *see also* Lunney, 7 MICH. TELECOMM. & TECH. L. REV. at 366-80; Gerald Sobel, *The Court of Appeals for the Federal Circuit: A Fifth Anniversary Look at its Impact on Patent Law and Litigation*, 37 AM. U. L. REV. 1087, 1089 ("a climate more favorable to upholding the validity, and particularly the non-obviousness of patents has emerged"); Charles Weller, *Patent Reform by Daubert Litigation*, 2 EXPERT EVIDENCE REPORT 232, 234-35 (2002) (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/weller2.pdf. *But see* Polk 2/20 at 71-72 (nonobviousness standard has become "more uniform" but has not been lessened). Some of the panelists found the trend toward a less rigorous nonobviousness standard particularly pronounced in biotechnology contexts. *See* Kunin 7/10 at 27-28 (in biotechnology Federal Circuit has made it "fairly easy to pass muster" under nonobviousness requirement); Burk 7/10 at 29; Arti Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999) ("In considering DNA-based inventions, the CAFC has employed nonobviousness in a manner that dramatically lowers the bar for patentability and, therefore, significantly impoverishes the public domain."); *cf.* Dreyfuss 7/10 at 141-42 ("a lot of the watering down on nonobviousness has come in the chemical field").

[46] *See, e.g.,* Ziedonis 3/20 at 16 (consistent view expressed in semiconductor industry interviews was that "if we had to change one thing, let's just make it a little harder to get all of these very trivial inventions coming out from the patent office"); Scherer 7/10 at 53 ("the inventive content of the average U.S. patent is quite low"); Kohn 2/27 at 413; T.S. Ellis 7/11 at 109; John H. Barton, *Reforming the Patent System* (Public Comment) 1-2, *at*

spoke of serious clutter problems and issues involving market power maintenance and extension.[47]

Participants viewed the Federal Circuit's application of its "suggestion test" and its treatment of secondary factors such as "commercial success" as applications of nonobviousness doctrine that can result in "obvious" patents. As interpreted by the Supreme Court in *Graham*, nonobviousness requires a three-part inquiry:

> the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.[48]

Although the Court lists the key elements, it does not tell how to apply them.[49] The Federal Circuit has filled the gap in part through its "suggestion" test, which focuses on the extent to which "the prior art would have *suggested* to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success . . . ."[50]

The Supreme Court's *Graham* opinion also identified a number of "*secondary considerations*," including "commercial success, long felt but unsolved needs, [and] failure of others," that "may have relevancy" as "indicia of obviousness."[51] The Federal Circuit has required consideration of any evidence of these secondary characteristics and, at times, has given them considerable weight as means for overcoming what might otherwise be a *prima facie* case of obviousness under the primary *Graham* factors.[52]

a. Nonobviousness and the "Suggestion Test"

Section 103 requires two basic inquiries to determine "nonobviousness." First, what is the prior art for the claimed invention?[53] Prior art typically consists of documents – often patents and publications, although affidavits and testimony also may

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http://www.ftc.gov/os/comments/intelpropertycomments/bartonjohnh.htm; Cecil D. Quillen, Jr., *Testimony of Cecil D. Quillen, Jr. Presented at the Public Hearing on the Standard of Nonobviousness* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/quillenattachments/nonobviousness.pdf; Eric Buddington, *Comments Regarding Competition and Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/buddingtoneric.pdf.

[47] *See supra* Ch. 4(II)(A)(1).

[48] *Graham*, 383 U.S. at 17.

[49] *See* Duffy 7/10 at 116 ("[T]hese primary factors . . . sort of leave you off at the very point you think the analysis should start.").

[50] *Brown and Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000) (emphasis added).

[51] *Graham*, 383 U.S. at 17-18 (emphasis added).

[52] *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) ("Objective evidence [i.e., evidence of secondary considerations] . . . must be considered *before* a conclusion on obviousness is reached and is not merely 'icing on the cake'") (emphasis in original); *cert. denied*, 480 U.S. 947 (1987); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 ("evidence rising out of the so-called 'secondary considerations' must always when present be considered").

[53] *See* 35 U.S.C. § 103 (inquiry focuses on "differences between the subject matter sought to be patented and the prior art"); s*ee, e.g.,* Kesan 4/10 at 88 ("That's the first thing, knowing what the prior art is.").

present prior art[54] – that reflect one or more of the features or elements of the claimed invention. Comparing the claimed invention to the prior art requires identifying the major features of the claimed invention and determining the extent to which those features already exist in the prior art.[55] Second, what "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains[?]"[56] Patent practitioners sometimes shorten the term "person having ordinary skill in the art" to "PHOSITA."[57]

Sometimes all of the elements of a claimed invention exist not in any one document, but in a combination of different prior art references.[58] For example, in one case, the PTO rejected as obvious a patent application for a plastic orange garbage bag decorated with a face and lines that would look like a jack-o-lantern when filled with trash or leaves. There were four prior art references – two about conventional trash or lawn bags, and two about children's art projects to make jack-o-lanterns. When combined, these four prior art references held all of the major elements of the claimed invention. That fact alone was insufficient to meet the Federal Circuit's suggestion test, however, and thus did not establish obviousness.[59]

In discussing the decision of the Board of Patent Appeals and Interferences, which upheld the examiner's rejection of the patent application as obvious, the Federal Circuit stated:

> Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the children's art references . . . with the conventional trash or lawn bag references, nor does the Board make specific – or even inferential – findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness

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[54] *See, e.g., Sakraida v. Ag Pro Inc.*, 425 U.S. 273, 280 (1976) ("The scope of the prior art was shown by prior patents, prior art publications, affidavits of people having knowledge of flush systems analogous to respondent's, and the testimony of a dairy operator with 22 years of experience who described flush systems he had seen on visits to dairy farms throughout the country.").

[55] *See, e.g.,* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 44-48 (in drafting a patent around the prior art, "[i]t is often useful to construct a table listing the major features or elements of the invention and showing which of those features are shared by items in the prior art").

[56] *See* 35 U.S.C. § 103; Kesan 4/10 at 88 ("secondly, what is a person in that field, what do they think of that prior art.").

[57] *See* Kieff 4/10 at 77.

[58] If all of the elements already exist in a single prior art reference, "that's anticipation and we're done." *See* Kieff 4/10 at 80.

[59] *In re Dembiczak*, 175 F.3d 994 (1999). *Accord, Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, *absent some teaching or suggestion, in the prior art, to combine the elements.*") (emphasis added). *See, e.g.*, Thomas 2/8 (Patent Session) at 56-57; Duffy 7/10 at 117. Similarly, the PTO must identify a suggestion, teaching, or motivation for modifications to a piece of prior art before declaring such modifications obvious. *See* John F. Duffy, *Nonobviousness: The Economics and Legal Process of the Doctrine* (7/10/02) (slides) at 14, *at* http://www.ftc.gov/opp/intellect/020710johnfduffy.pdf (hereinafter Duffy Presentation).

analysis.[60]

This is one in a line of recent cases in which the Federal Circuit has rigorously imposed the suggestion test in overturning PTO findings of obviousness.[61]

(i). Hearings Record

Panelists identified the Federal Circuit's application of the "suggestion test" as a core issue in assessing nonobviousness and a focal point of current debate.[62] As PTO Deputy Commissioner for Patent Examination Policy Stephen Kunin phrased it, the Federal Circuit is insisting that the PTO find "the glue expressly leading you all the way" and that it "connect the dots . . . very, very clearly . . . ."[63]

Hearings participants generally agreed that the Federal Circuit's suggestion test asks a helpful question – *i.e.*, to what extent would the prior art "have *suggested* to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success . . . ."[64] Nonetheless, they disagreed with the Federal Circuit's recent applications of the test, which seem to require "specific and definitive [prior] art references with clear motivation of how to combine those references."[65] To illustrate problems with the "suggestion test," Professor Duffy pointed to the Selden patent on the automobile. Assuming that Selden was the first to mount the newly developed gasoline engine on a carriage, no specific prior art would have suggested the mounting, yet it is something that likely was obvious:

> Everybody seemed to know that if you got a new engine of any kind, you would put it on a carriage. That's the first thing that people did with just about any kind of engine, put it on a carriage with some gears and see how it works.[66]

Participants noted that Federal Circuit articulations of the suggestion test are not uniformly rigid. The court sometimes has stated that the suggestion need not be express, but can be "implicit from the prior art as a whole," or may come from "the knowledge of one of ordinary skill in the art" or from "the nature of the problem to be

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[60] *In re Dembiczak*, 175 F.3d at 1000.

[61] *See In re Sang-Su Lee*, 277 F.3d 1338 (Fed. Cir. 2002) (rejecting the PTO's finding that a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust those functions was obvious in light of separate prior art references describing (i) a television set with a display for adjusting audio and video functions and (ii) a video game display with a "demonstration mode" showing how to play the game); *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001); *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000); Wamsley 7/10 at 19-25; Kunin 4/10 at 47. Stephen Kunin cited the pre-Federal Circuit opinion *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981), which stated that "the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art," and concluded that "with [recent] cases like Dembiczak and Kotzab" it's like the approach based on the collective suggestion of the references "never existed in the law." Kunin 4/10 at 47; 7/10 at 137. *See infra* at Ch. 4(II)(A)(3)(a)(i).

[62] *See, e.g.*, Chambers 2/8 (Patent Session) at 98-99 ("from the standpoint of obviousness that's usually what the argument is about"); Duffy 7/10 at 117-18 ("suggestion test . . . has become extremely important"); Wamsley 7/10 at 19-25.

[63] Kunin 7/10 at 137.

[64] *Philip Morris,* 229 F.3d at 1124 (emphasis added).

[65] Dickinson 2/6 at 66.

[66] *See* Duffy 7/10 at 132-33.

solved."[67] Nonetheless, commentators such as Professor Duffy noted that references to implicit suggestions and suggestions from the nature of the problem to be solved may be "a point in the case law," but "not perhaps the feel of the case law."[68] Criticisms of recent opinions focus on the rigorous manner in which the Federal Circuit has applied the suggestion test, rather than the totality of the court's language.

Stephen Kunin contrasted some of the recent applications of the suggestion test with earlier interpretations that "would permit one . . . to look at the information from the perspective of one of ordinary skill in the art" and "glean the information . . . with some level of technical knowledge and skill."[69] As another panelist, Kenneth Burchfiel, has written, "the court's frequent emphasis on 'motivation' from the teachings of the prior art bypasses the knowledge of those of ordinary skill in the art, and restricts the obviousness inquiry to a literal reading of the disclosure of the prior art."[70] Summing up these developments, former PTO Director Q. Todd Dickinson stated:

> [T]he courts have required the Office to apply only specific and definitive art references with clear motivation of how to combine those references, and only that will suffice for this obviousness determination. . . . [T]he examiner could not even rely on the general knowledge that the examiner had in the field or even common sense for an obviousness determination.[71]

Several panelists recommended that the test be moderated.[72]

(ii). Analysis

Policy Issues. The Federal Circuit has repeatedly sought to protect inventors from findings of obviousness based purely on hindsight. "Good ideas may well appear 'obvious' after they have been disclosed, despite having been previously unrecognized."[73] As Judge Newman of the

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[67] *Kotzab*, 217 F.3d at 1370; *see In re Huston*, 308 F.3d 1267, 1280-81 (Fed. Cir. 2002) (quoting some of the same language from *Kotzab* reproduced in the text but finding adequate motivation in the prior art references themselves); *In re Thrift*, 298 F.3d 1357, 1363 (Fed. Cir. 2002) (same). *See generally In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003) (explaining that absent legal error or contrary factual evidence, the PTO's determination of the meaning of prior art references and the motivation to make the claimed invention that those references provide can establish a *prima facie* case of obviousness).

[68] *See* Duffy 7/10 at 119.

[69] Kunin 7/10 at 137.

[70] KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 84 (1995) (footnote omitted). *See generally* Barr 10/30 at 53-54 (arguing that current obviousness standards fail to reflect the skill of his firm's engineers, who "every day" independently invent things that have been deemed nonobvious); Quillen (U.S. Patent System stmt) 4 (criticizing the Federal Circuit's treatment of the person of ordinary skill in the art as "a literalist, without imagination or creativity . . . who is incapable of considering collectively the combined teaching of relevant prior art references unless 'motivated' to do so by explicit directions in the references themselves").

[71] Dickinson 2/6 at 66.

[72] *See, e.g.,* Duffy 7/10 at 120-21 and Duffy Presentation at 17; Wamsley 7/10 at 154-55; Banner 10/30 at 73-74; *cf.* Gambrell 10/25 at 19 (insistence on express references leads to patents that should not be issued); Merges 2/28 at 631 (implicit in the Supreme Court's *Graham v. John Deere* analysis is a "rejection of some of the more extreme Federal Circuit cases on the so-called suggestion test").

[73] *Arkie Lures, Inc.*, 119 F.3d at 956.

Federal Circuit noted at the Hearings, many patents are attacked on grounds of obviousness. "It's fuzzy ground. It's hard to decide, difficult to administer, even harder to set."[74] Thus, Federal Circuit "case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."[75] Otherwise, the Federal Circuit has said, "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight."[76] In addition, the Federal Circuit's application of the suggestion test arguably has the virtue of certainty and predictability,[77] and it helps to ensure fulfillment of the PTO's "obligation to develop an evidentiary basis for its findings."[78] One can readily see the validity of the Federal Circuit's concerns.

Yet, there are competing, and competitive, concerns to weigh on the other side of the ledger. A demand for specific and definitive motivating prior art references effectively raises the bar for finding obviousness[79] – thus permitting more patents to issue – and does so in a way that raises competitive concerns to the extent that it violates "but for" principles. As noted earlier, "obvious" patents can convey market power or provide means for its extension and can contribute to a proliferation of patents that increase search and licensing costs unnecessarily, so a standard that fails to weed out patents on obvious inventions can cause competitive harm.[80] Whether the goal is protecting against judgments based on hindsight or ensuring reviewable administrative records, a standard that requires suggestions or motivations exceeding what inventors actually need, or that rigidly insists upon concrete documentation of facts that by their very nature are not concretely demonstrable, could impair competition.

Interpretation of Section 103. Some of the patents recently upheld as nonobvious under the suggestion test may be obvious under the statutory standards. As noted in Professor Duffy's example of the Selden automobile patent, an invention may be obvious even if the combination of elements

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[74] Newman 2/6 at 45.

[75] *In re Dembiczak*, 175 F.3d at 999 (citing cases).

[76] *Id.*; *see also In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).

[77] One panelist praised the Federal Circuit's interpretations as "relatively crisp and objective and relatively easy to apply." Kieff 4/10 at 81. Another panelist, however, expressed doubt that application of the test would really be so clear-cut in practice. *See* Katsh 4/10 at 90-93.

[78] *See In re Sang-Su Lee*, 277 F.3d at 1344. Following the Supreme Court's determination that review of PTO findings of fact ought to proceed under the "substantial evidence test" rather than the less deferential "clearly erroneous" test, *see Dickinson v. Zurko*, 527 U.S. 150 (1999), the Federal Circuit has stressed the need for the PTO to ensure that each administrative record is amenable to review. *See In re Sang-Su Lee*, 277 F.3d at 1342, 1344-45; *In re Zurko*, 258 F.3d at 1385-86 (requiring "concrete evidence in the record" rather than "general conclusions about what is 'basic knowledge' or 'common sense'" for interpreting the consequences of particular items of prior art).

[79] *See* Kunin 4/10 at 47 ("cases like In re Kotzab, In re Sang Lee . . . make[] it extremely difficult to satisfy a 103 [obviousness] standard").

[80] *See supra* Ch. 4(II)(A)(1).

that it reflects was not specifically suggested or motivated in any prior art. The combination may nonetheless be "obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[81] Some applications of the suggestion test, however, appear almost to have read the PHOSITA out of the statute.[82] Inventive processes typically involve judgment, experience, and common sense capable of connecting some dots. The suggestion test, rigidly applied, assumes away a PHOSITA's typical levels of creativity and insight and supports findings of nonobviousness even when only a modicum of additional insight is needed.

Indeed, too rigorous an application of the "suggestion" test can operate as a one-way ratchet: it can help confirm obviousness, but it does not necessarily identify nonobviousness. The presence of "specific and definitive art references with clear motivation of how to combine those references"[83] may confirm the obviousness of an invention. In contrast, the absence of such prior art references does not provide any evidence about whether a PHOSITA could have combined prior art references to achieve the invention, given the typical level of insight in that field. In sum, the suggestion test, as it has been applied in some cases, seemingly understates levels of ordinary skill, awards patents for inventions that inevitably would be forthcoming, and potentially confers market power when competition need not be sacrificed.

In one very recent case, the Federal Circuit appears to have moved away from rigid application of the suggestion test, stating:

> As persons of scientific competence in the fields in which they work, examiners and administrative patent judges on the Board [of Patent Appeals] are responsible for making findings, informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art and the motivation those references would provide to such persons. Absent legal error or contrary factual evidence, those findings can establish a prima facie case of obviousness.[84]

This more flexible articulation might signal an approach that would better enable

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[81] 35 U.S.C. § 103.

[82] *See, e.g., In re Sang-Su Lee,* 277 F. 3d at 1340-45 (in rejecting patent application as obvious, PTO did not provide a "specific hint or suggestion in a particular reference," but instead relied on "the common knowledge and common sense of a person of ordinary skill in the art" and the fact that the claimed invention came from same field of endeavor as one prior art reference; the Federal Circuit vacated the conclusion of obviousness, stating that "'[c]ommon knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority."). The Federal Circuit has recognized that a suggestion may be express or implicit, *see Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205 (Fed. Cir. 2003); *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999), and has at times found implicit suggestions sufficient to demonstrate obviousness. *See, e.g., SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.,* 225 F.3d 1349, 1357 (Fed. Cir. 2000). But, as noted by Professor Duffy, that is not the "feel" of the case law. *See* Duffy 7/10 at 119.

[83] Dickinson 2/6 at 66.

[84] *In re Berg*, 320 F.3d at 1315 (affirming determination of obviousness in absence of legal error or contrary factual evidence sufficient to question findings made by the PTO as to teachings of prior art and motivation that prior art references would give a skilled artisan to make the claimed invention).

application of the suggestion test in ways sensitive to competitive concerns.

Recommendation. The Commission urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. Requiring concrete suggestions or motivations beyond those actually needed by a person of ordinary skill in the art, and failing to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

b. Nonobviousness and the "Commercial Success Test"

In *Graham v. John Deere,* the Supreme Court noted that:

> Such secondary considerations as *commercial success*, long felt but unsolved needs, failure of others, etc., *might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries *may* have relevancy.[85]

The Federal Circuit has elevated the importance of these so-called "objective factors" as considerations that potentially override conclusions of obviousness based on consideration of prior art:

> Objective evidence such as *commercial success,* failure of others, long-felt need, and unexpected results *must* be considered *before* a conclusion on obviousness is reached, and is not merely 'icing on the cake,' as the district court stated at trial.[86]

Hearings participants generally did not question the Federal Circuit's use of "secondary" or "objective" factors such as long-felt need,[87] but did question whether and, if so, under what circumstances, an invention's commercial success evidences its nonobviousness, and whether, as applied by the courts in practice, the commercial success standard merits the weight given to it as an "objective" factor.

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[85] *Graham*, 383 U.S. at 17-18 (1966) (emphases added).

[86] *Hybritech,* 802 F.2d at 1380 (emphases added, but not for third emphasis). *See* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 736 (stating that the objective factors have "grown in stature" since *Graham*). Although the Federal Circuit has stressed that "secondary [*i.e.*, objective] considerations are not secondary in importance to primary considerations," it also has explained that secondary/objective considerations will not always "carry sufficient weight to override a determination of obviousness based on primary considerations." *See Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991).

[87] *See* Katsh 4/10 at 97-98; *cf*. Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 830 (1988) (finding a direct connection between failure of others and nonobviousness but arguing that long-felt need depends on an inference that others were contemporaneously trying to produce a similar invention).

(i). Hearings Record

Participants expressed concern that courts might unduly rely on "secondary" or "objective" factors, such as commercial success, to rebut a *prima facie* case of obviousness based on the prior art. Yale University President Richard Levin and U.S. District Judge T.S. Ellis III, for example, voiced concern that the commercial success test has "diluted"[88] or "trivialized"[89] the obviousness inquiry.[90]

Legal scholars long have debated whether courts should consider an invention's commercial success as evidence of nonobviousness. Some conclude that any relevance of commercial success to nonobviousness rests on a chain of inferences, with weaknesses evident at each link.[91] In contrast, others see a measure of an invention's contribution to the field in the willingness of customers to buy it.[92] From a practical perspective, supporters stressed that secondary factors such as commercial success have value as objective guideposts for the obviousness inquiry.[93] Critics, in contrast, saw a vice in that virtue: several panelists expressed concern that juries find it too easy to avoid difficult questions about prior art and instead to focus on readily perceived facts about a product's success.[94]

Several panelists criticized how the Federal Circuit has *interpreted* the commercial success standard. Although the court requires a nexus between the invention

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[88] R. Levin 2/6 at 103.

[89] T.S. Ellis 7/11 at 109.

[90] President Levin noted that "[a] recent study documents how decisions by the Court of Appeals for the Federal Circuit have tended to substitute "secondary" for "primary" tests of obviousness, resulting in a standard that comes perilously close to 'if someone invested money in developing this invention, it must not be obvious.'" Richard C. Levin, *Testimony of Richard C. Levin, President, Yale University* (2/6/02) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/levinrichardc.htm (hereinafter R. Levin (stmt)), *citing* Glynn S. Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363 (2001).

[91] As Professor Kitch has explained:

> The argument involves four inferences. First, that the commercial success is due to the innovation. Second, that if an improvement has in fact become commercially successful, it is likely that this potential commercial success was perceived before its development. Third, the potential commercial success having been perceived, it is likely that efforts were made to develop the improvement. Fourth, the efforts having been made by men of skill in the art, they failed because the patentee was the first to reduce his development to practice. Since men of skill in the art tried but failed, the improvement is clearly non-obvious.

Kitch, 1966 SUP. CT. REV. at 332 (concluding that "[e]ach inference is weak"); *see also* Merges, 76 CAL. L. REV. at 838 (terming commercial success "a poor indicator of patentability" because "it depends on a long chain of inferences, and the links in the chain are often subject to doubt").

[92] *See* Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 9 (1989). *See generally* ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(b) at 170 (5th ed. 2001) (asserting, without explanation, that commercial success is persuasive evidence of nonobviousness).

[93] *See* Frankel 4/10 at 98-99; Dreyfuss 7/10 at 142-43; *see also* Dreyfuss, 64 N.Y.U. L. REV. at 8-10.

[94] *See* Pooley 10/30 at 56-57; Banner 10/30 at 72; Katsh 4/10 at 97-98 (referring to secondary factors in general); *cf.* Mossinghoff 10/30 at 70 (acknowledging attractiveness to juries). Nor are judges necessarily immune. Professor Kitch suggests, "Perhaps commercial success is a familiar distraction for judges confused by the facts." Kitch, 1966 SUP. CT. REV. at 332.

and the success, [95] it typically demands only that the invention *be* a success.[96] It does not require the patentee to demonstrate that the invention *caused* that success. Thus, if the patentee shows that the claimed features of the patent are coextensive with those of a successful product, such as when a patented paving stone has succeeded in the marketplace,[97] then the burden shifts to the challenger to present evidence to rebut the inference that the invention – rather than factors such as marketing, advertising, an incumbent's advantages, etc. – caused the commercial success.[98]

Some argued in favor of changing the test to require patentees to show that the invention *caused* the commercial success.[99] According to a panelist, such a standard prevailed in the pre-Federal Circuit era,[100] and the PTO continues to require that commercial success be "directly derived from the invention claimed" and not the result of "business events extraneous to the merits of the claimed invention."[101] One panelist objected, cautioning against requiring patentees to prove a negative – *i.e.*, that no other factor caused the invention's success.[102] Another panelist countered, however, that a patentee might reliably show causation from proof of positives: that "the problem existed for a long time and . . . the materials to solve that problem were in existence, but for the intellectual component."[103]

A number of panelists voiced concern

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[95] *See, e.g.,* Parkhurst 4/10 at 96-97; Duffy 7/10 at 120.

[96] *See Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991) ("prima facie evidence of nexus is established if there was commercial success and if the invention disclosed in the patent was that which was commercially successful"); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1394 (Fed. Cir.) ("It is sufficient to show that the commercial success was of the patented invention itself"), *cert. denied*, 488 U.S. 956 (1988).

[97] *See Demaco*, 851 F.2d at 1391-94.

[98] *See* HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(a) at 169-70. One recent opinion explains:

> A nexus between commercial success and the claimed features is required. However, if the marketed product embodies the claimed features and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to rebut the presumed nexus. The presumed nexus cannot be rebutted with mere argument; evidence must be put forth.

Brown & Williamson Tobacco Corp., v. Philip Morris Inc., 229 F.3d 1120 (Fed. Cir. 2000) (concluding that sufficient evidence had been put forward to rebut the presumed nexus).

[99] *See, e.g.,* Kesan 4/10 at 200-01 (urging that the test be restructured to require that "but for" the inventive activity the commercial success would not have occurred); Duffy 7/10 at 121 and Duffy Presentation at 17 ("[l]imit to situations where patentee can prove that no exogenous changes account for success").

[100] *See* Lunney 7/10 at 148; *see also* Merges, 76 CAL. L. REV. at 824-25 (collecting case authority comparing some pre-Federal Circuit opinions that had required that commercial success be the "direct result" of the claimed invention with Federal Circuit interpretations, viewed as merely requiring "some connection" between the invention and the success).

[101] United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 716.03(b) (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (hereinafter MPEP). *See also In re Huong*, 100 F.3d 135, 139-46 (Fed. Cir. 1996); *Ex parte Remark*, 15 U.S.P.Q. 2d 1998 (Bd. Pat. App. & Interf. 1990).

[102] *See* Dreyfuss 7/10 at 143-44; *see also* HARMON, PATENTS AND THE FEDERAL CIRCUIT § 4.6(a) at 170.

[103] Duffy 7/10 at 144-46.

that courts and juries do not always apply the current nexus requirement properly.[104] For example, panelists indicated that judges and juries have sometimes erroneously given weight to the success of a product as a whole, rather than focusing on the invention embedded in the product.[105] Others voiced concern that the Federal Circuit has sometimes given insufficient weight to challengers' identification of reasons other than the invention itself that explain an invention's commercial success.[106]

(ii). Analysis

As noted by some during the Hearings, application of the "secondary" or "objective" factors can give greater certainty in answering whether an invention is nonobvious. That certainty is problematic, however, when a factor – such as commercial success – is arguably an unreliable indicator of nonobviousness. Legal tests should achieve a proper balance between the costs they entail (including those of uncertainty) and their accuracy in result.[107] The commercial success test does not appear to achieve that balance.

To begin with, the commercial success test has no direct connection to the "technical advance" at issue in the nonobviousness inquiry.[108] Even if commercial success reflects a claimed invention's economic significance, economic significance does not necessarily reflect technical significance – as illustrated by the Selden patent on the automobile[109] – so a commercial success standard will not necessarily yield accurate nonobviousness results. The single source relied upon by the Supreme Court's *Graham* opinion justifies the commercial success test only through the inference that others had tried and failed,[110] and the separate objective factor that focuses directly on failure by others seems to take account of the same consideration with

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[104] *See, e.g.,* Kesan 4/10 at 201; Banner 10/30 at 72-73. *But cf.* Parkhurst 4/10 at 97 (effectiveness of nexus requirement can only be assessed on case-by-case basis).

[105] *See* Pooley 2/27 at 382-83 (juries fail to isolate the relevant success of an invention buried within a successful product); Banner 10/30 at 72. *See generally* Merges, 76 CAL. L. REV. at 826 (citing *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490 (Fed. Cir. 1985), as upholding a patent primarily on commercial success evidence even though the patented invention "played only a small part" in an overall generator testing service). In other instances, the court has been more careful to insist on a nexus between the commercial success and the specific invention claimed. *See, e.g., In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

[106] *See* Lunney 7/10 at 148-49 (Federal Circuit not giving much weight to showings of extraneous factors such as heavy advertising and distribution advantages); Merges, 76 CAL. L. REV. at 826-27 (Federal Circuit has given reduced weight to advertising and marketing advantages, citing, *inter alia*, *Hybritech*, 802 F.2d at 1382).

[107] *See generally* Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEXAS L. REV. 1, 16 (1984); Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974); Richard A. Posner, *An Economic Approach to Legal Procedure & Judicial Administration,* 2 J. LEGAL STUD. 399, 401 (1973).

[108] *See supra* Ch. 4(I).

[109] *See* Duffy 7/10 at 110-13.

[110] *See Subtests of "Nonobviousness"*: *A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169 (1964) (citing *S. H. Kress Co. v. Aghnides*, 246 F.2d 718 (4th Cir. 1957), *cert. denied*, 355 U.S. 889 (1958), for the explanation that a substantial latent demand would likely already have induced others to produce the invention if it had been obvious). Indeed, some of the Supreme Court's pre-*Graham* cases that gave weight to considerations of commercial success clearly arose in contexts of long-felt need and failure of others. *See Expanded Metal Co. v. Bradford*, 214 U.S. 366, 379-81 (1909); *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 445-46 (1902).

greater accuracy.[111]

Moreover, experience with competition analysis teaches that a product's commercial success may result from many factors other than the nonobviousness of a particular invention. Incumbents may have advantages over entrants. Vertical integration sometimes yields other advantages. Economies of scope may be present from simultaneously producing, distributing, or marketing other products. Inventions compatible to *de facto* or *de jure* standards in contexts that exhibit strong network effects may have commercial advantages over incompatible, but less obvious inventions.[112] Of course, these advantages will not always accrue, but the fact that they may arise suggests that a mere correlation between invention and success is not enough. Case-by-case inquiry into the *cause* of the product's success is necessary in court litigation, just as it is in PTO examination. In addition, the number of different reasons that may explain a product's commercial success and the fact that the patentee is likely to have the greatest access to relevant information counsel against a default rule that establishes a presumption that the invention caused the commercial success.

All of this is cause for concern, because the commercial success test raises significant issues from a competition perspective. For any given level of appropriability, commercially successful inventions are more likely than others to emerge even without the prospect of patent protection.[113] In addition, commercially successful patents are the ones most likely to confer market power.[114] Thus, the commercial success test could tend to allow grants of unnecessary patents that confer market power and could thereby work at cross purposes to the "but for" principles discussed *supra* in Ch. 4(II)(A)(2). Moreover, a nexus test that requires only that an invention be successful could cause competitive harm by systematically tilting the patent rules toward those whose preexisting prominence may make commercial success more likely.[115]

Recommendations. First, the Commission recommends that courts evaluate on a case-by-case basis whether commercial success is a valid indicator of the nonobviousness of the claimed invention. Second, the Commission recommends that patentees bear the ultimate burden of demonstrating that the claimed invention caused the commercial success. In the absence of these inquiries, application of the commercial success test errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

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[111] *See* Merges, 76 CAL. L. REV. at 874 (suggesting that courts link consideration of commercial success with that of failure by others).

[112] *See* Kesan 4/10 at 201; *see generally* Guerin-Calvert 2/20 at 214-221 (discussing network effects and competition).

[113] *See* Scherer 7/10 at 54 ("When it has commercial value, that's a stimulus to inventors, and sooner or later they're going to invent with or without the patent.").

[114] *See* Kitch, 1966 SUP. CT. REV. at 333-34.

[115] *See supra* note 112 and accompanying text.

B. Enablement, Written Description, and Best Mode

Section 112 of the Patent Act states a second set of doctrines crucial to patentability:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[116]

Section 112 gives rise to three distinct disclosure doctrines: written description, enablement, and best mode.[117] *See* Box 4-3 for further details.

1. Relationship to Patent Breadth

The disclosure doctrines play major roles in defining patent breadth – that is, how broad the claims are that an inventor may make. Patent breadth determines the extent of protection from competition that a patented invention receives. Products or processes within the patent's breadth infringe; those outside that breadth do not.

Frequently, much will be learned and developed after an initial invention is made: follow-on innovations will occur, and new uses will be found. The question then becomes, how many of these subsequent developments ought to be ascribed to the initial inventor and made subject to his or her patent? For example, in determining that an inventor who had obtained rat insulin cDNA could not validly assert a claim covering human insulin cDNA, the Federal Circuit applied an analysis based on one of the disclosure doctrines.[118]

The *enablement* inquiry asks how many of the future embodiments of a claimed invention the initial patent has made viable. A patent's claims may extend until they reach the boundary of what the patent enables – that is, the point at which a follow-on innovator must engage in undue experimentation to move beyond the original invention.[119] If a patent applicant claims more than he or she has enabled, the patent claim must be narrowed or rejected.[120] Nonetheless, because the examination determines enablement as of the time of the patent application, a patent claim can cover then-unknown, subsequent developments

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[116] 35 U.S.C. § 112.

[117] *See* SCHECHTER & THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARK § 18.1 at 394-404.

[118] *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

[119] *See* Merges 2/28 at 639-41 and 2/26 at 154-55. *In re Wands*, 858 F.2d. 731, 737 (Fed. Cir. 1988) ("Factors to be considered in determining whether a disclosure would require undue experimentation . . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

[120] *See* Chambers 2/8 (Patent Session) at 64-65; HARMON, PATENTS AND THE FEDERAL CIRCUIT § 5.2(b) at 200-01.

and uses.[121]

The courts and the PTO traditionally have used the *written description* requirement to police amendments to claims.[122] An applicant must show that the original written description of the claimed invention supports the matter introduced in any claim amendments. If the applicant does not thereby demonstrate possession of that matter when he or she first filed the application, the claim amendment cannot rely on the original filing date.[123] Recently, the Federal Circuit has extended its use of the written description requirement to invalidate some *initially* filed claims, particularly in biotech contexts, finding that without having undertaken the additional work necessary for a more detailed description, the applicant had not shown that he or she was truly in possession of the claimed invention.[124]

2. Significance for Competition: General Application of Disclosure Doctrines

a. Hearings Record

From a competition perspective, patent breadth raises a variety of potential concerns. If breadth is defined too broadly – that is, more broadly than is truly enabled – products that should be free to compete instead will infringe, and unwarranted market power may result.[125] Numerous business panelists voiced concerns about patents with undue breadth.[126]

In contrast, defining breadth too narrowly may unnecessarily subdivide patent rights, potentially adding to the number of patents and contributing to the growth of patent thickets. Breadth in some instances can affect the number of patents needed to produce a product (or a commercially viable line of products). It can affect whether an industry evolves along a discrete product model (with relatively few patents necessary per commercializable product) or along the complex product model (with many patents necessary per product) that is characteristic

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[121] *See* Duffy 10/30 at 107-09; Rai 4/10 at 127-28; Kunin 4/10 at 123-24; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 299-301; *In re Hogan*, 559 F.2d 595, 606-07 (C.C.P.A. 1977).

[122] *See, e.g.*, Chambers 2/8 (Patent Session) at 72-73; Rai 4/10 at 135-36; Merges 2/26 at 156-58; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998).

[123] *See* 35 U.S.C. § 120.

[124] *See, e.g.,* Chambers 2/8 (Patent Session) at 73-74; Rai 4/10 at 136; *Eli Lilly*, 119 F.3d at 1566-69.

[125] *See* Scotchmer 2/26 at 171 ("the thing that determines who gets to compete in the market is the distance between them that's required not to infringe"). *See* Scotchmer 4/10 at 71 (overly broad patents may enable excessive market power consolidation). Similarly, an unduly broad patent can obscure the competition that should exist and prevent antitrust enforcement to protect that competition. *Cf.* Scotchmer 2/26 at 130-31, 136 (IP Guidelines analysis depends on whether, absent a license, one firm would have infringed the other's patent); U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property § 3.3 (Apr. 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132 (horizontal relationship between licensor and licensee depends on whether they would have been actual or potential competitors in a relevant market absent a license), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

[126] *See, e.g.,* Kirschner 2/26 at 242; Friedman 2/27 at 411-12; Kohn 2/27 at 413; Fox 2/28 at 696; Thurston 3/20 at 34; Richard Stallman, *The Danger of Software Patents, Speech by Richard Stallman at Cambridge University, March, 25 2002* (Public Comment) 4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/stallmanrichard.pdf.

of thickets.[127]

Finally, patent breadth can have major consequences for follow-on innovation. Here the testimony split into diverging strands. One strand emphasized that broad initial patents may raise significant problems for follow-on innovation.[128] From this perspective, vesting the initial innovator with broad patent rights reduces the incentives of follow-on innovators and potentially impedes their access to upstream innovation inputs. Follow-on innovators, some argued, would receive high royalty demands or endure unwarranted design-around expense.[129] The opposing viewpoint stressed that broad initial patents may be beneficial, providing adequate rewards for initial innovators and furthering prospect theory goals of efficient future development.[130] They stressed that the holder of a broad initial patent generally will have incentives to find ways to foster follow-on activities.[131]

Box 4-3. ***Enablement, Written Description, and Best Mode***

Written description ensures that the inventor actually has invented what the patent application claims; the inventor must describe the invention sufficiently to show that he or she is in possession of the invention. *See, e.g.*, Chambers 2/8 (Patent Session) at 64; Kushan 4/11 at 102.

Enablement ensures that the *public* is put in possession of the invention, *i.e.*, enablement implements the patent system's disclosure requirement. An inventor must disclose the claimed invention sufficiently that a person skilled in the art can make and use it without undue experimentation. *See, e.g.,* Chambers 2/8 (Patent Session) at 63-68; Kushan 4/11 at 102; Kunin 4/10 at 122.

The **best mode** requirement adds a subjective test: if the inventor has developed techniques that he or she recognizes at the time of filing as the best way of carrying out the invention, those techniques must be disclosed. *See* Chambers 2/8 (Patent Session) at 64, 78-79.

Economic analysis substantially informed the follow-on innovation discussion. As discussed *supra* in Chapter 2(III)(B)(2), Professor Scotchmer focused attention on the division of profit between successive generations of innovation.[132] When the first generation lays the foundation for the second, the first innovator should receive some portion of the second

[127] *See* Cohen 2/20 at 37-38 (numerous patents per commercializable product implies "mutual dependence across firms' patent holdings") and 10/30 at 92-93 (explaining that in Japan, where patents tend to be narrow "everything is a complex product industry").

[128] *See, e.g.*, Scherer 7/10 at 54-55 ("early basic patents can retard or bar innovation by a downstream inventor or developer, slowing down the pace of technological advance"); Cohen 2/20 at 22 (broad patents problematic when innovation cumulative), 71 and 10/30 at 93-95 (citing research indicating "significant potential for problems" with access to upstream biomedical inventions); Langenfeld 2/20 at 10, 12, and James Langenfeld, *Innovation, Competition, and Intellectual Property: Providing an Economic Framework* (2/20/02) (slides) at 4, *at* http://www.ftc.gov/opp/intellect/langenfeld.pdf; Lemley 2/25 at 37-38; Rai 4/10 at 21-22 and 51-52.

[129] *See, e.g.*, Rai 4/10 at 19; Kesan 10/25 at 25-26.

[130] *See, e.g.,* Scotchmer 2/26 at 130-34, 171-72 and 4/10 at 68-69 (emphasizing the importance of "leading breadth" – an economic stake in things beyond what the initial innovator has actually invented); Kitch 2/20 at 81-84.

[131] *See, e.g.,* Kieff 4/10 at 163; Blackburn 2/26 at 264-65.

[132] *See* Scotchmer 2/26 at 128-30, 135-36 and 4/10 at 71. "The challenge is to reward early innovators fully for the technological foundation they provide to later innovators, but to reward later innovators adequately for their improvements and new products as well." Scotchmer, 5 J. ECON. PERSP. at 30.

generation profits.[133] According to Professor Scotchmer, an unduly narrow initial patent may allow competition from follow-on products to undermine the incentive for the initial innovation on which both generations rest;[134] at the same time, an unduly broad initial patent may stifle follow-ons.[135]

Different assessments of the likelihood of licensing distinguish the opposing views. Broad initial patents are most likely to support efficient follow-on activity if *ex ante* licensing occurs – that is licensing before the follow-on innovator makes investments. Once the follow-on innovator makes sunk investments, however, the follow-on innovator faces heightened exposure to opportunistic royalty demands.[136]

Several panelists questioned whether *ex ante* licensing would likely occur. They noted that it would likely be difficult to protect a follow-on innovator's not-yet-patented ideas during *ex ante* licensing negotiations; that negotiations focused on uncertain research results and inchoate patent rights typically have high transactions costs; that, especially given the early stage of the follow-on research, the initial and follow-on inventors may place significantly different relative values on their contributions; and that some initial innovators may refuse to license, wishing to maintain market power by developing follow-on products in-house rather than licensing to potential future competitors.[137] Others responded that transaction costs and the effects of uncertainty usually can be overcome.[138] Anecdotal information and case studies point both ways.[139]

b. Analysis

A synthesis of the follow-on innovation discussion suggests that if initial innovation is costly and follow-on innovation is relatively predictable, quick, and inexpensive, then in theory initial innovators should receive patents of greater breadth. In contrast, if initial innovation is inexpensive and follow-on innovation is relatively risky, time-consuming, and costly, then in theory initial innovators should receive narrower patents, leaving follow-on innovators greater opportunity for reward. Such an arrangement, in general terms, would serve efficiency goals by allocating

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[133] Scotchmer, 5 J. ECON. PERSP. at 31.

[134] Scotchmer 2/26 at 130.

[135] *Id.* at 135; Scotchmer, 5 J. ECON. PERSP. at 31 ("enough profit must be left for the second innovators so that they will invest if investing is efficient"); *see also* Stoner 2/26 at 118-19.

[136] *See, e.g.,* Scotchmer 2/26 at 135; Rai 4/10 at 19; *see also supra* Ch. 2(III)(B)(3). In contrast, some panelists argued that when improvements are significant and adequate information is available, awarding a blocking position to the follow-on innovator may sufficiently protect that innovator even if licensing negotiations are conducted *ex post*. *See* Parkhurst 4/10 at 93-94; Kieff 4/10 at 163-64.

[137] For more detailed discussion of possible licensing impediments, *see supra* Ch. 2(III)(B)(3); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1048-61 (1997); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1073-74 (1989). Professor Scherer highlights the potential for bargaining stalemates when the initial innovation involves basic research with little commercial value itself and the follow-on innovations require substantial investment. Frederick M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348, 1362 (2002).

[138] *See, e.g.,* Teece 2/26 at 210-11; Arora 2/25 at 88; Kieff 4/10 at 159-60, 199-200.

[139] *See supra* Ch. 2(III)(B)(3).

patent protection to the stage "where appropriability can make the greatest contribution to innovation." [140]

Current disclosure doctrines accord reasonably well with these goals. For example, enablement of a given embodiment depends in part on the amount of experimentation required and on the predictability of the art. When considerable experimentation is necessary, follow-on innovation is likely to be costly; the more stringent enablement requirements that follow from greater need to experiment reduce the breadth of the initial innovator's patent,[141] and expand the rewards potentially available to follow-on innovators. Similarly, less predictability makes follow-on innovation more costly; again the more stringent enablement requirements that follow reduce the breadth of the initial patent and provide opportunities for expanded follow-on rewards. These results are in line with the economic reasoning for settings in which initial innovation is inexpensive and follow-on innovation is costly[142] and accord with advice of antitrust innovation theorists.[143]

3. Significance for Competition: Disclosure Doctrines in Practice

a. Hearings Record

Variations in the predictability of the art and differences in the nature of the person having ordinary skill in the art (the "PHOSITA") necessarily require different levels of disclosure in different fields of endeavor. The distinctions do not arise because of special industry treatment under the statute; a single standard applies across industries and technologies. Rather, as already noted, an industry or technology where the art is more unpredictable requires greater disclosure.[144] Similarly, an industry or technology in which the PHOSITA is relatively unskilled requires greater disclosure than when the PHOSITA possesses greater ability.[145]

Panelists found differences in the disclosure requirements in different industries or technologies. Most typically, they contrasted software disclosures with those required for biotechnology.[146] Many

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[140] *See* Stoner 10/30 at 99-100.

[141] When more experimentation is needed, a given level of disclosure enables fewer future embodiments.

[142] *See* Merges 2/28 at 641-43 (suggesting that "where it is more costly to build on old inventions" enablement principles appropriately restrict the initial patent right). The correspondence, however, may not always be perfect. For example, if the initial innovator had to overcome the same unpredictable art or engage in the same type of experimentation as the follow-on innovator, the initial innovation may not have been inexpensive, as assumed, and there would be no basis for preferring one generation over the other.

[143] *See* Rubinfeld 2/25 at 19, 23 (when the strategy of innovation is unpredictable or random, a reasonably large number of innovation efforts is desirable – more innovation is likely with more diversity).

[144] *See, e.g.*, Kunin 4/10 at 122; Mossinghoff 10/30 at 113-14; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 290.

[145] *See, e.g.*, Burk 3/20 at 132-34 and 7/10 at 155-56.

[146] *See, e.g.*, Burk 3/20 at 107-10 and 7/10 at 155-56 (finding a much less rigorous disclosure requirement for software than for biotechnology inventions); Kesan 4/10 at 55, 121 (same); Rai 4/10 at 105-06 (same); Kunin 7/10 at 28, 191-92.

viewed the software disclosure requirements as relatively lax. Several cases have concluded that patent applicants need not reveal source code;[147] some panelists indicated that mere recitation of a program's function will be adequate.[148] Several panelists urged the requirement of greater software disclosures.[149] In comparison, panelists indicated that biotech disclosures have been rigidly policed, with genetic sequence codes often required to satisfy written description requirements.[150] Indeed, some found the disclosure requirements in biotech excessive, forcing inventors to take time tying down details that readily could be elucidated by others, and thereby delaying the raising of venture capital.[151]

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[147] *See, e.g., Robotic Vision Systems, Inc.*, 112 F.3d 1163, 1166-67 (Fed. Cir. 1997); *Fonar Corp. v. General Electric* Co., 107 F.3d 1543, 1548-49 (Fed. Cir.), *cert. denied*, 522 U.S. 909 (1997); *Hayes Microcomputer Products, Inc. v. Ven-Tel, Inc.*, 982 F.2d 1527, 1534 (Fed. Cir. 1992); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941-43 (Fed. Cir.) (stating that "[t]he possible design of superior software . . . is not relevant in determining whether the inventor has complied with the enablement requirement"), *cert. denied*, 498 U.S. 920 (1990).

[148] *See, e.g.*, Burk 3/20 at 108 ("essentially . . . no disclosure requirement for software;" neither code nor flowcharts are necessary) and 7/10 at 155 ("you don't need to give us the code . . . [y]ou don't need to give us a flow chart . . . just give us a functional disclosure, tell us what it does"); Kesan 4/10 at 56 (no policing of enablement in software; "functional descriptions" suffice, and system is "essentially giving patents to ideas"); Rai 4/10 at 106 ("incredibly broad claims without any disclosure whatsoever"); Kunin 7/10 at 191-92 ("mere functional description" adequate).

[149] *See, e.g.* Janis 4/10 at 118-19 (enablement standard for software could be made "much more rigorous with good effect"); Kesan 4/10 at 55-57, 120-21 (disclosure fails to show "how the algorithm is being tailored for use in this application"), 130 ("disclosures are so scant that you're really talking about basically taking another invention to actually enable what is disclosed"); Kieff 4/10 at 113 (suggesting that inventors submit source code); Burk 3/20 at 110-11. *See generally* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific*, 17 BERKELEY TECH. L. J. 1155, 1196 (2002) (suggesting that narrower patents resulting from more stringent disclosure requirements might better promote innovation in a software industry characterized by incremental improvements).

[150] *See, e.g.,* Burk 3/20 at 110, 134 ("You must have actually found the sequence even if one of ordinary skill would know how to find the sequence.") and 7/10 at 156, 160-61; Rai 4/10 at 105; Kunin 7/10 at 28; Boulware 10/30 at 158 ("the Federal Circuit is looking at written description and enablement very closely in the biotech area"). For the PTO's interpretation and implementation of written description requirements, *see* United States Patent and Trademark Office, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099 (2001).

[151] *See, e.g,* Burk 3/20 at 110-11, 134-35; Burk & Lemley, 17 BERKELEY TECH. L. J. at 1195-96 (suggesting that the narrow patents that follow from rigorous disclosure requirements may increase the potential for anticommons problems in biotechnology); *cf.* Merges 2/28 at 642 (discussing, as a general matter, the potential waste inherent in an unduly rigorous enablement standard); Rai 4/10 at 106 (arguing that although the written description demands for biotech are excessive, they will yield an economically desirable result if confined to upstream research).

Similar, though not identical, patterns emerged from testimony regarding the usefulness of patent disclosures in different industry contexts. The strongest criticism involved software, for which the predominance of industry panelists found patent disclosures of little value. *See, e.g.,* Webbink 3/20 at 145; Casey 4/9 at 32; Young 4/11 at 99-100 ("Software is not software without source code."); Barr 10/30 at 142; *cf.* Kahin 3/19 at 56 (software patents not read). *But see* Myrick 10/30 at 59-60 ("Software patents disclose an enormous amount"); Alderucci 4/9 at 40 (disclosures useful). In contrast, as noted *supra* in Chapter 3(II)(C), testimony from the pharmaceuticals industry almost uniformly indicated value in the patent disclosures. *See, e.g.,* Blackburn 2/26 at 319; Glover 3/19 at 174, 224-25; Coffin-Beach 3/19 at 212. Biotech industry testimony on this point was mixed. *Compare* Boulware 10/30 at 159 (patent literature looked at regularly) *with* Kirschner 2/26 at 318 (patents not a significant source of ideas) *and* Blackburn 2/26 at 319-20 (suggesting that patent literature may be more significant in pharmaceuticals than in biotech, but adding that patents enable information transfer through scientific literature). Semiconductor and high-tech hardware industry participants expressed diverse views. *See, e.g.,* Telecky 2/28 at 754 (disclosures useful); McCurdy 3/20 at 53 (patents seldom

b. Analysis

Critics of current disclosure requirements in particular industries typically argued that the Federal Circuit has an erroneous view of the predictability of the art or the skill of the PHOSITA.[152] They observed that these variables change over time as industries develop and mature, and they suggested that the patent system has not always kept current in its assessments.[153] They directed their criticisms toward the *application* of the disclosure requirements, not toward any fundamental problem inherent in the basic standards.

The role of disclosure requirements in shaping patent breadth and the consequences of that breadth for potential market power and cumulative innovation make the nature and effective application of the disclosure requirements a matter of significant competitive concern. Accurate, up-to-date assessments of the predictability of the art and of the abilities of the PHOSITA in evolving industries are important elements for achieving efficiency goals and harmonizing the patent and antitrust regimes.

C. Other Doctrines that Affect Patent Breadth

Other doctrines, beyond the disclosure requirements, also set and interpret the scope of a patent's claims and thus affect patent breadth. This section highlights two of these doctrines. The first is the use of "continuing applications" – that is, "continuations" – to redefine the scope of a patent's claims. The second is the application of the doctrine of equivalents in interpreting claims. Both can significantly affect competition.

1. Continuations and the Formulation of Claims

a. Hearings Record

The patent system has long struggled with problems that flow from delay and secrecy in handling patent applications. Until recently, patent applications were not public information. Years might pass between the filing of an application and the issuance of a patent. An applicant's competitors may have invested substantially in the interim in designing and developing a product and bringing it to market, only to learn, after the patent finally issues, that they are infringing someone else's claims. At that point, redesign might be prohibitively expensive, and the newly announced patentee might be in position to extract large

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disclose enough to allow practice of the invention without some work); Barr 2/28 at 756 ("I've actually never met an engineer that learned anything from a patent.").

[152] *See, e.g.*, Burk 3/30 at 133 (seeing an underestimate of the difficulty of writing software) and 7/10 at 155 (same); Rai 4/10 at 106 (Federal Circuit thinks everything in biotech is "incredibly unpredictable").

[153] *See, e.g.,* Burk 3/20 at 111-12 ("courts developing standards that might have applied 5, 10, 15 or even 20 years ago") and 7/10 at 198-99 (courts have not kept up with growing predictability of some biotech techniques); Kesan 4/10 at 120 (software has become more complex since the early cases governing enablement); *see also* Kunin 7/10 at 192-93 (increasing complexity of software inventions may have reduced the predictability); Burk & Lemley, 17 BERKELEY TECH. L. J. at 1199-1201 (explaining how reliance on precedent rather than the particulars of each case may lead to outdated conceptions of the PHOSITA's level of skill).

royalties.[154] Such a scenario raises the potential for what some panelists have termed "a hold-up."[155]

A statutory change that now requires all patent applications (other than those filed only in the United States) to be published 18 months after filing[156] may have considerably eased this problem with unanticipated "submarine" patents.[157] A PTO panelist indicated that 90% of current applications are so published.[158] Several panelists anticipated that the new publication rule would help substantially with submarine concerns,[159] although some indicated dissatisfaction with the remaining 18-month delay[160] and with excepting from publication patents filed only domestically.[161]

Another potential hold-up problem remains, however. Through the use of claim amendments during the prosecution process, a patent that states broader claims than those published at 18 months can still emerge.[162] To maintain the filing date of the original application, the original specification must contain support for the new claims.[163] If that is the case, the applicant may enlarge or otherwise modify the scope of its claims during the examination process.[164] The potential for anticompetitive hold-up increases the longer it takes for the broader claims to emerge. By filing one or more continuing applications[165] the applicant may extend the prosecution period – and the potential for working mischief by broadening claims – for years.

Panelists explained that continuations can serve legitimate functions when the applicant, or the applicant's attorney, has in

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[154] *See, e.g.,* Stallman 4/9 at 18-19 (describing unknowing infringement of patents kept secret during the application period as "stepping on . . . a land mine"); Barr 2/28 at 675-76.

[155] *See, e.g.,* Shapiro 11/6 at 15-16, 176.

[156] 35 U.S.C. § 122(b)(1). Applications that are filed only domestically, however, need not be made public. 35 U.S.C. § 122(b)(2)(B).

[157] *See also supra* Ch. 1(III)(A)(2)(a).

[158] John Love 2/28 at 647.

[159] *See, e.g., id.*; Kohn 2/27 at 429; Gable 3/20 at 118-19; Casey 4/9 at 32.

[160] *See* Oehler 2/26 at 254 ("18 months can seem like an eternity when you're caught in the middle of it trying to answer 'am I free to operate'").

[161] *See infra* at Ch. 5(II)(C)(4).

[162] *See, e.g.,* Katsh 4/10 at 193; Barr 2/28 at 676.

[163] 35 U.S.C. § 120. Similarly, novelty requirements prevent issuance of a patent on inventions "known or used by others in this country . . . before the invention thereof by the applicant for a patent," and the prohibition on derivation in theory bars issuance of a patent to one who "did not himself invent the subject matter sought to be patented . . . ." 35 U.S.C. §§ 102(a) and (f). *See* MERGES & DUFFY, PATENT LAW & POLICY: CASES AND MATERIALS at 398-403, 437-39.

[164] *See, e.g.,* Merges 2/26 at 156-58; Chen 2/28 at 718; Rai 4/10 at 135-36.

[165] The filing may take various forms. It may involve a new application, which might take the form of a "continuation application," retaining the original written disclosures and the original filing date; a "continuation-in-part," which adds some new matter to the disclosures and loses the original filing date insofar as its claims rely on the new matter; or a "divisional," which carves out what had been a separate invention within the original application while retaining the original filing date. *See* 35 U.S.C. §§ 120-21; 37 C.F.R. § 1.53(b); Chambers 2/8 (Patent Session) at 101-02. Alternatively, the filing may involve a request for continued examination, which works to extend the examination of the original application. 37 C.F.R. § 1.114. For ease of exposition, this discussion will refer to all of these variants, including those portions of continuations-in-part that maintain the original filing date, as "continuing applications" or "continuations."

essence missed its own product in the initial application[166] or when the applicant and examiner need to maintain an extended dialogue.[167] Several panelists expressed concern, however, regarding the use of continuation practice in ways harmful to competitors. They explained that some applicants keep continuations pending for extended periods, monitor development of the market, and modify their claims to ensnare competitors' products after sunk costs have been incurred.[168] One panelist voiced the further worry that continuations could be used to undercut standard setting organizations' disclosure rules.[169] None of the testimony offered justification for the use of continuation practice to broaden claims to cover competitors' subsequent products and to exploit the consequences of their subsequent sunk investments. As American Intellectual Property Law Association President Ronald Myrick summarized, "[T]he continuation practice we have today is not good. It's out of control."[170]

b. Analysis

Implications for Competition and Innovation Continuation practice can allow opportunistic behavior, such as post-filing modification of patent claims to capture competitors' products or processes that would not have infringed the original claims. Such opportunistic behavior can disrupt competitive activity. It wastes inventive resources that a competitor could have redirected, had it fully known the scope of an applicant/patentee's claims. It imposes redesign costs that might have been avoided if the competitor had had greater lead time. It fosters high royalties, inflated by a competitor's exposure to operational disruption from injunctive relief after sunk investments have been made. It magnifies potential competitors' risks and reduces their incentive to develop substitutes for the patentee's invention. Moreover, competitors' uncertain ability to predict from the written description at 18 months what the patentee ultimately will claim limits any opportunity to anticipate and avoid this exposure. Such behavior wastes resources, raises costs and risks, and potentially deprives consumers of the benefits of

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[166] *See* Barr 10/30 at 146; Chambers 2/8 (Patent Session) at 103; Telecky 2/28 at 720-21 (finding nothing wrong with "chang[ing] your mind as you see the art, and as you think about it, as to what your invention is," as long as the claims are supported by the disclosure). *But see* Poppen 2/28 at 692 ("an inventor ought to know what his invention is and shouldn't have to wait to see what everybody else is doing").

[167] *See* Armbrecht 3/19 at 68-69; *cf.* Myrick 10/30 at 179-80 (explaining possible use of continuations to correct the prosecution history).

[168] *See, e.g.,* Poppen 2/28 at 687-88; Mar-Spinola 2/28 at 715-16; Quillen 3/19 at 70-71; McCurdy 3/20 at 37; Rai 4/10 at 136; Barr 10/30 at 79, 146; Myrick 10/30 at 178 (warning that divisionals may be similarly used to "game the system"), 180; Cecil D. Quillen Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. BAR J. 1, 6 (2001). *See generally* Banner 10/30 at 181-82 (continuations a problem).

[169] *See* Stoner 10/30 at 145-46 (noting that continuations might be used "to spring a new patent claim on firms that are producing pursuant to a standard" absent a controlling disclosure requirement).

[170] Myrick 10/30 at 177; *see also* Myrick 10/30 at 180 (use of continuation practice as marketplace develops to capture what was never in the applicant's mind "an exceedingly troublesome thing"). Such conduct, however, may not give rise to an offense under patent law. *See, e.g., Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (holding that amending a claim to cover a competitor's product learned about in the course of the prosecution process was not in itself evidence of deceitful intent relevant to charges of inequitable conduct and stating, in *dictum*, that it was not "in any manner improper"), *cert. denied*, 490 U.S. 1067 (1989).

innovation and competition.[171]

Suggestions for Reform of Continuation Practice Patent reform efforts have long focused on how to remedy the opportunistic broadening of patent claims to capture competitors' products. The 1967 President's Commission on the Patent System determined that "it is desirable that claims never be broadened after publication," but concluded that it might be impossible to enforce an all-inclusive prohibition.[172] The Hearings suggest that the same types of concerns persist and will likely remain a problem in the future unless changes are implemented.[173] Suggestions for dealing with the problems identified in continuation practice include extending and making greater use of the doctrine of prosecution laches,[174] imposing time limits on broadening claims,[175] and creating intervening rights to protect competitors who become exposed to infringement claims by virtue of continuations.[176]

Analysis Any of the remedies listed above could address competitive concerns. A remedy, however, should protect legitimate uses of continuing applications, as well as deter anticompetitive uses of continuations. Creating intervening or prior user rights[177] would most directly cure

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[171] For a general discussion of hold-up problems raised by unanticipated patents *see* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam Jaffe et al. eds., 2001). Indeed, the Commission's complaint in a pending administrative proceeding cites continuations as an element contributing to broader, alleged anticompetitive conduct involving claim modifications during a patent applicant's participation in standard-setting activities. *Rambus Inc.*, No. 9302 at ¶¶ 37-38, 47-69 (Complaint June 18 2002), *available at* http://www.ftc.gov/os/adjpro/d9302/020618admincmp.pdf.

[172] REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, *reprinted in* TO PROMOTE THE PROGRESS OF THE USEFUL ARTS, SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 90TH CONG., 1ST SESS. 39 (1967). The President's Commission recommended imposing time limits on continuing applications. *Id*. at 26.

[173] Although some panelists suggested that a 1995 change in patent term – from 17 years after issuance to 20 years after filing – limits the ability to prolong examinations, *see, e.g.,* Telecky 2/28 at 721 and Detkin 2/28 at 729, other testimony indicated that 20 years was more than enough time to abuse continuation practices. *See* Poppen 2/28 at 693. Moreover, some predicted that the use of continuations to broaden or otherwise add to literal claims will increase, given current trends toward narrowing the doctrine of equivalents (discussed *infra* in Ch. 4(II)(C)(2)). *See, e.g.,* Mossinghoff 10/30 at 144-45; Myrick 3/19 at 48; Thomas 10/30 at 105-06.

[174] The Federal Circuit has approved a PTO rejection of patent claims on grounds that the applicant had forfeited his right to a patent under the doctrine of prosecution laches by filing twelve continuations over a period of eight years without advancing the prosecution of his application. *See In re Bogese II,* 303 F.3d 1362 (2002); *see also* Chen 2/28 at 718-19 (PTO exploring possibilities for rejecting applications based on prosecution laches). The doctrine of prosecution laches also potentially provides a defense to an infringement action when the patentee has engaged in unreasonable and prejudicial delay in securing the patent's issuance. *See Symbol Technologies, Inc. v. Lemelson Med., Educ., & Research Found.*, 277 F.3d 1361 (Fed. Cir.), *cert. denied*, 123 S. Ct. 113 (2002).

[175] *See* Poppen 2/28 at 692-94 (suggesting barring broadening of claims 18 months after filing); Chen 2/28 at 718 (18-month limit on broadening claims "an interesting idea . . . one way to promote some level of certainty"); *cf.* Katsh 4/10 at 139 (suggesting a time limit on continuations).

[176] *See* Myrick 10/30 at 180-81 (suggesting "intervening rights or some such thing that would protect the later entrant in the marketplace against these patents that show up so tardily").

[177] Analysts have not always distinguished these terms with consistency. For present purposes, we use "prior user rights" to refer to absolute defenses against infringement actions and "intervening rights" to refer to protections that, in whole or in part, depend on a court's weighing of the equities, as exemplified, respectively, by provisions in 35 U.S.C. § 273(b) and 35 U.S.C. § 252, discussed below.

potential competitive problems without interfering with legitimate needs for continuations, reducing business uncertainty without increasing costs of error. Such rights should shelter inventors and users that infringe a patent only because of claim amendments following a continuation, provided that the sheltered products or processes are developed or used (or the subject of substantial preparation for use) before the amended claims are published.[178] This would protect third parties from hold-ups derived from any extended period of secrecy made possible by continuations, while allowing the patent to be enforced against those who would have infringed a properly described pre-continuation claim[179] or who had timely opportunity to gain knowledge of the amendments.

Protections sheltering the legitimate expectations and investments of third parties affected by late-date claim amendments have substantial precedent. Limited intervening rights already are available under 35 U.S.C. § 252 to third parties who infringe a patent because of a broadening of claims through post-grant reissue, a procedure that, in cases of "error without any deceptive intention," allows certain claim amendments *after* a patent has issued.[180] The intervening rights proposed herein would provide protection to third parties similarly confronted with late-date claim amendments *during* the course of the prosecution process. The courts, however, have applied existing intervening rights narrowly[181] and likely would need to broaden them to confer meaningful protection in light of investments made or business commenced by the third party and the likely costs and full economic consequences of any redesign to avoid infringement. Regarding prior user rights, Congress in 1999 enacted such protections to shelter some third parties from infringement claims based on business method patents.[182] More broadly, the 1992 Advisory Commission on Patent Law Reform, in conjunction with a separate recommendation to determine patent priority on a first-to-file basis, proposed conferring prior user rights on those who "in good faith" use, or make

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[178] Whether amended claims are published upon the filing of continuations depends upon the specific continuation format used and the way that amendments are presented, and often is "[a]t applicant's option." *See* 37 C.F.R. § 1.215; American Inventor's Protection Act of 1999 Questions and Answers § C (Eighteen-Month Publication), *available at* http://www.uspto.gov/web/offices/dcom/olia/aipa/infoexch.htm.

[179] The phrase "properly described claim" refers to claims that satisfy the written description requirement of 35 U.S.C. § 112. The intervening or prior user right would not be defeated by a pre-continuation claim that exceeds the applicant's written description.

[180] *See* 35 U.S.C. § 251.

[181] *See, e.g., Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1361 (Fed. Cir. 2001) (refusing to consider intervening rights in view of defendant's unclean hands from willful infringement); *Seattle Box Co. v. Industrial Crating and Packing, Inc.*, 756 F.2d 1574 (Fed. Cir. 1985) (leaving unanswered whether intervening rights would have been available for anything more than bundles made from pre-reissue inventory); J. Christopher Carraway, *The Uncertain Future of Enforcing Patents that Have Been Broadened through Reissue*, 8 FED. CIRCUIT B.J. 63, 68, 74 (1998) ("The grant of equitable intervening rights is extremely rare, however, most likely out of discomfort with allowing a party to continue to infringe a patent. . . . Although one who has designed around the original claims may be protected from paying damages on any pre-reissue activity, . . . equitable intervening rights to continue production of the originally noninfringing product are almost universally denied, thereby destroying investments made in creating and building the market for the product.").

[182] *See* 35 U.S.C. § 273(b) (sheltering those who reduced a business method to practice at least a year before the patent application and used the method before the effective filing date).

substantial preparation for using, an invention before the filing date of a subsequently issued patent.[183]

Recommendation. Accordingly, the Commission recommends the enactment of legislation to protect from infringement claims a third party who reduces to practice, uses, or makes substantial preparation for using a process, machine, manufacture, or composition of matter ("product or process") prior to first publication of a claim covering that product or process in a continuing application, provided that no parent application[184] contained a properly described claim covering the product or process prior to the third party's reduction to practice, use, or substantial preparation for use.[185]

2. Doctrine of Equivalents

a. Hearings Record

Several panelists addressed claim interpretation issues under the doctrine of equivalents.[186] The doctrine of equivalents "protects [a patent holder] against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention."[187] It does so by allowing a claim to be construed to cover more than its literal language, thereby extending patent breadth.[188] The answer to the question of when changes are "only insubstantial" thus can become an important determinant of patent breadth.

Some panelists favored the doctrine of equivalents as a means to protect patentees from imitators who might otherwise escape infringement by tinkering in trivial ways with patented products or

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[183] ADVISORY COMMISSION ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE 11, 21 (1992) (Recommendation I-A), *available at* http://world.std.com/obi/USG/Patents/overview.

[184] "Parent application" is used broadly here to encompass all predecessors in a string of continuing applications.

[185] The Hearing record does not permit assessment of the extent to which reissue proceedings have been used to broaden patents to cover competitors' products after the competitors have made their sunk investments, nor does it explore the justifications for broadening reissue. It nonetheless appears that reissue in some instances may be used like continuations "to encompass activity by a competitor." *See* United States Patent and Trademark Office 21st Century Strategic Plan, *Permit Assignees to File Broadening Reissue* 1 (April 2, 2003), *at* http://www.uspto.gov/web/offices/com/strat21/action/lr1fp55.htm. To the extent that reissue poses, or develops in a way that poses, comparable competitive problems to those raised by continuations, corresponding protections, including a possible broadening of existing intervening rights, ought to be considered.

[186] Other discussion dealt with literal claim interpretation, in particular the effects of the ruling in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), that claim interpretation is a matter of law, not fact. Although panelists noted that the ruling had been expected to increase certainty by vesting interpretation issues in judges rather than juries, *see e.g.,* T.S. Ellis 7/11 at 113 (finding that certainty has increased) and Barr 10/30 at 185, some observed that achieving certainty has now been delayed until appeal of the trial judge's conclusions. *See, e.g.,* Weinstein 2/27 at 451; Katsh 4/10 at 103-04; Kunin 7/10 at 37; Banner 10/30 at 182-83; *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 12 FED. CIRCUIT B.J. 1, 32 (2002) (advocating statutory reform that would permit "[e]xpedited appeals of a limited number of claim construction issues"). Neither the Hearing record nor the academic literature permits a sorting of competitive consequences.

[187] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*., 535 U.S. 722, 727 (2002).

[188] *See, e.g.*, Sung 2/8 (Patent Session) at 128; Wamsley 7/10 at 14; *Festo,* 535 U.S. at 731-32; HARMON, PATENTS AND THE FEDERAL CIRCUIT § 6.3(a)(ii) at 343.

processes.[189] It may be unrealistic, some thought, to expect patentees to foresee and provide against all such tinkering; the inherent limits of language may ensure that whatever words are chosen will prove insufficient to cover every eventuality.[190] Others, however, stressed that leaving claim boundaries obscure increases uncertainty and makes negotiation and business planning more difficult.[191] One panelist noted a further effect of the doctrine: it forces competitors to steer away from designs that would come close to literal infringement and instead direct their efforts toward beneficial, leapfrog innovation.[192] The same effect, however, could also be viewed as permitting uncertainty to enhance the patentee's right to exclude,[193] suggesting that an unduly broad doctrine of equivalents can have a competitive downside.

b. Analysis

Recent trends show a narrowing of the doctrine of equivalents.[194] The Supreme Court's earlier decision in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*[195] and its more recent decision in *Festo*[196] narrow the doctrine through application of prosecution history estoppel.[197] Other recent cases have kept tight rein by insisting on element-by-element comparisons with literal claims[198] and by deeming matter disclosed in the specification but not included in the literal claims to be excluded from the doctrine's operation.[199]

In deciding how to interpret and apply the doctrine of equivalents, both the Supreme Court
and the Federal Circuit have explicitly noted and discussed the tradeoffs involved.[200] The Supreme Court stated:

> It is true that the doctrine of equivalents renders the scope of patents less certain. . . . If competitors

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[189] *See* Sobel 7/10 at 173-178.

[190] *See* Dreyfuss 7/10 at 83; Sobel 7/10 at 172.

[191] *See, e.g.,* Kieff 4/10 at 38-39; Kesan 4/10 at 196-97.

[192] *See* Sobel 7/10 at 175.

[193] *See id*. at 80.

[194] *See* Wamsley 7/10 at 13-15.

[195] *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997).

[196] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*., 535 U.S. 722 (2002).

[197] As explained by *Festo*, "When . . . the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo*, 535 U.S. at 733-34. The Court in *Festo* resolved questions regarding the nature of amendments that give rise to this estoppel and the circumstances under which some equivalents may still infringe. *Id*. at 735-41. The Federal Circuit has recently remanded the case for trial court determination whether one of those circumstances – the possibility that the equivalent was unforeseeable at the time of the claim amendment – was present. *Festo Corp. v. Soketsu Kinzoku Kogyo Kabushiki Co*., 344 F.3d 1359 (Fed. Cir. 2003).

[198] *See, e.g., Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317 (Fed. Cir. 2002); *see also* Sung 2/8 (Patent Session) at 128-29 ("Ninety-nine of the elements or limitations may be identical in nature but the court is still going to only focus on that one particular element to decide is that change in that element substantial or insubstantial.").

[199] *See Johnson and Johnston Assoc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (*en banc*).

[200] *See supra* Ch. 1(III)(A)(2)(b) and *infra* Ch. 6(I)(B)(1)(C).

> cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. . . . . Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.[201]

The Supreme Court concluded that, if the doctrine of equivalents were to be discarded, Congress should do so and not the Court.[202] These cases reflect decisions made with an awareness of the importance of public notice as well as a concern for the patentee's ability to secure the benefits of its patent.

D. Utility and Research Issues

One question is how to determine when an invention has evolved to the point that it should receive a patent. If patents covered very basic research, for example, then patent law could deter much follow-on innovation by independent inventors. If, in contrast, an inventor could not receive a patent on an invention ready for commercialization, that would substantially undermine the incentives of the patent system. Two means exist to address these issues. First, the statutory standard of utility requires that an invention be "useful" to receive a patent.[203] Second, a common-law "experimental use" exemption has developed, upon which researchers sometimes rely to exempt their activities from infringement claims.

1. The Utility Standard

Inventions must be "useful" to support issuance of a patent. As it has evolved, the utility standard is relatively lenient and typically is not a significant barrier to patentability.[204] It has had some application, however, in biotechnology and chemistry, in which inventions may be forthcoming before their precise use is known.[205]

The utility doctrine may be important in protecting basic research from premature patenting. Analysts have characterized the utility requirement as "a timing device, helping to identify when an invention is ripe for patent protection."[206] Its use relates to concerns that patents on basic research, very far upstream, may impede follow-on innovation by virtue of effects on incentives

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[201] *Festo*, 535 U.S. at 732.

[202] *Id.* at 739.

[203] 35 U.S.C. §§ 101 and 112.

[204] *See, e.g.,* Thomas 2/8 (Patent Session) at 39-40 ("generally that's a very lenient standard"); Caulfield 3/19 at 183 (utility test "a very big screen through which a lot of material goes"); Rai 4/10 at 106 (utility standard "low"); Kunin 4/10 at 123-24 (a single utility provides protection against all uses); Kieff 4/10 at 126 (questioning need for separate utility requirement); *but cf.* Kushan 4/11 at 85-86 (outlining how applicant's utility characterizations might be used to greater effect in applying other criteria of patentability).

[205] *See, e.g.*, *Brenner v. Manson*, 383 U.S. 519 (1966); *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); Thomas 2/8 (Patent Session) at 40-42.

[206] *See* Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2087 (2000).

and on access to upstream technology.[207] Commentary from the last few years has focused in particular on how inventors may have to combine a high number of basic patents to yield a downstream product. Some worry that too early patenting will create an "anticommons," a setting in which follow-on technology is inadequately developed because too many upstream owners each hold separate patent rights.[208] Analysts concerned with patenting "too close to the laboratory bench"[209] have urged application of a somewhat more rigorous utility standard as a means to avoid such consequences.[210]

The PTO has responded to concerns such as these by issuing (and revising) a set of Utility Examination Guidelines.[211] These Guidelines require that before a patent can issue, there must be a utility well-established in the art (a utility that would be immediately appreciated by a person of ordinary skill in the art), or the applicant must have asserted a specific, credible, and substantial utility.[212] The Guidelines, as revised in 2001, have largely been well received,[213] and the Hearing record does not highlight substantial competitive issues regarding utility examination.

2. Experimental Use and Research Tools

The experimental use defense for research activities has been described as "a very nascent, ill-developed principle from a few early cases in the 19th century."[214] Case law traditionally has exempted research activities that are noncommercial and "for amusement, to satisfy idle curiosity, or for

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[207] *See, e.g.*, Caulfield 3/19 at 158-62; Rai 4/10 at 23-24, 51-52. S*ee generally supra* Ch. 4(II)(B)(2).

[208] *See, e.g.,* Thomas 2/8 (Patent Session) at 43-44; Scherer 7/10 at 56-57; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

[209] Thomas 2/8 (Patent Session) at 42.

[210] *See, e.g.,* Barton 2/26 at 222; Rai 4/10 at 23-24 (suggesting cautious use of the utility standard to limit patenting in "certain narrow [upstream] areas," but warning that the utility standard ought not to be set too high as a general matter).

[211] United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg.1092 (2001) (current guidelines).

[212] *See Id*. at 1098-99; Thomas 2/8 (Patent Session) at 45; Chambers 2/8 (Patent Session) at 46-47.

[213] *See, e.g.,* Beier 2/26 at 297 ("the stakeholders are largely pleased"); Rai 4/10 at 23-24 ("applaud[ing]" the PTO for taking an "appropriately cautious approach"); Biotechnology Industry Organization, *Testimony* (2/26/02) 6, 8, *at* http://www.ftc.gov/opp/intellect/020226davidwbeier.pdf; *see also* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 299 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) *available at* http://books.nap.edu/books/0309086361/html/285.html#pagetop (hereinafter *Research Tool*). *But cf*. Bendekgey 2/26 at 304 (Utility Guidelines not a "huge improvement").

[214] Thomas 2/8 (Patent Session) at 30. The doctrine often is traced to an 1813 opinion by Supreme Court Justice Story on circuit. *See Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) ("It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects"). There is no general statutory exemption covering experimental use of patented inventions. 35 U.S.C. § 271(e)(1) provides a limited exemption from infringement for uses reasonably related to the development and submission of information in order to secure Food and Drug Administration approval of pharmaceutical drugs.

strictly philosophical inquiry."[215] The strength and contours of the defense have not been fully tested; as several panelists testified, corporations typically have not sued universities.[216] Some, however, have questioned whether the truce will endure,[217] and, if it does not, whether the existing experimental use doctrine will afford much protection.[218]

The situation grew more complicated in October 2002 with issuance of a Federal Circuit opinion rejecting application of the experimental use defense.[219] The court ruled the defense inapplicable "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry . . . ."[220] Moreover, the court determined that research projects with no commercial applications "unmistakably further" a research university's "legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[221] Although the panelists differed regarding how much precedential power to attach to the opinion's holding,[222] the discussion indicated that the opinion could unsettle expectations regarding the availability of an experimental use defense and could have a chilling effect on university research.[223]

Panel discussion of the research exemption highlighted three distinct

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[215] *See Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

[216] *See, e.g.,* Blackburn 2/26 at 325; Dickinson 10/25 at 187; Mossinghoff 10/30 at 168.

[217] *See* Merrill 10/30 at 169; *cf.* Caulfield 3/19 at 183 (patentees increasingly demanding royalties from universities).

[218] *See, e.g.,* Sung 2/8 (Patent Session) at 136-38 (seeing no experimental use exception, "broadly" speaking and describing it as "potentially anachronistic" and "extremely difficult" to establish); Cohen 10/30 at 152 (seeing an "extraordinarily narrow" exemption); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17-24 (2001).

[219] *See Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003).

[220] *Id.*, 307 F.3d at 1362.

[221] *Id.*

[222] *Compare* Cohen 10/30 at 161 (arguing that the case essentially deprives universities of the experimental use defense because research is the business of a university) *with* Kitch 10/30 at 165-66 (arguing that Duke asserted a very broad position – that anything used by a university in research cannot infringe – and suggesting that a more targeted research defense might be better received) *and* Mossinghoff 10/30 at 168 (case presents a unique set of facts and consequently is not of much guidance). The case involved Duke's use of laser equipment that incorporated components covered by a former employee's patents.

[223] *See* Cohen 10/30 at 149-52, 162-63 (noting potentially significant chilling effect on those who previously assumed that they were protected by experimental use defense). The precise meaning of the Federal Circuit's opinion remains in debate. In seeking *certiorari*, Duke University argued that, by its rulings regarding the legitimate business of universities, the opinion necessarily bars application of the experimental use defense to private universities. Petition for a Writ of Certiorari, at 14, *Duke University v. Madey* (No. 02-1007) (2002). In contrast, the United States opposed *certiorari* on grounds that by remanding for consideration of both "the legitimate business that Duke is involved in *and* whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," 307 F.3d 1351, 1363 (emphasis added), the court preserved the traditional, narrow experimental use defense. *See* Brief of Amicus Curiae for the United States, *Duke University v. Madey* (No. 02-1007), *available at* http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html.

scenarios.[224] One involves research on a patented invention to see how or if it works. Panelists generally supported a research exemption for this purpose.[225] A second scenario involves research to improve a patented invention, either creating a blocking situation (in which both the initial and the follow-on innovator need licenses to use the other's invention) or designing around the initial patent. This case was cast as a middle ground, invoking potentially conflicting goals of fostering competition for improvements and protecting incentives of, or coordination by, the initial innovator.[226] Panelists expressed a range of views – from support through uncertainty and doubt – whether this research should be exempted.[227] Third, there is the possibility of using a patented item as a research tool to create an unrelated product. Panelists generally voiced objections to exempting patented items produced for use by researchers.[228]

a. Analysis

Both scholarly analysis and Hearing participants favor an experimental use defense in the first setting.[229] Research to determine if or how a patented invention works essentially makes effective the required enablement disclosure. Indeed, some of the panelists suggested that such activity is already covered by the experimental use defense.[230] The primary issue, then, appears to be whether a more explicit affirmation would be useful.

Extending an experimental use defense to infringement arising through use of tools to develop unrelated products appears problematic. Inventors of tools used by researchers need an income stream from those who use their inventions. The Hearing record provides no basis for exempting such tools from patent protection, and leading scholarly commentary agrees.[231]

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[224] *See* Duffy 10/30 at 170-74; *see also* Eisenberg, 56 U. CHI. L. REV. at 1074-76.

[225] *See, e.g.,* Kitch 10/30 at 167; Duffy 10/30 at 171.

[226] *See* Duffy 10/30 at 160, 172-74.

[227] *See, e.g.*, Barton 2/26 at 172 (supporting compulsory licensing, with or without royalty, for research in this context); Duffy 10/30 at 172 (noting Professor Kitch's nodded assent to statement of reservations), 173-74 ("a hard question"); Kitch 10/30 at 167.

[228] *See, e.g.,* Barton 2/26 at 221; Bendekgey 2/26 at 258-59, 267-68; Kitch 10/30 at 163-64, 166 (emphasizing adverse effect on incentive to produce equipment for researchers). Some panelists identified a separate variant of the third research category. They focused on a subset of patented research tools that are not sold as products in the marketplace, but rather are used only to develop products that are sold. An example might be a patent on a target or receptor used in biotechnology. *See* McGarey 11/6 at 159; Blackburn 2/26 at 260-61. The Hearing record, however, did not resolve whether this subset warranted separate analysis for purposes of an experimental use defense. *Compare* McGarey 11/6 at 159 (distinguishing, in a context of discussing reach-through royalties, "broad enabling tools that are not destined to be products themselves one day" from tools that are "produce[d] as a product") and Caulfield 3/19 at 158-59, 161-63 (recommending a research exemption to encourage genomic research) *with* Blackburn 2/26 at 262-63 (viewing patent protection as essential for maintaining proper incentives and raising venture capital for future research tool development).

[229] *See* Eisenberg, 56 U. CHI. L. REV. at 1074-75.

[230] *See* Armitage 3/19 at 186. In fact, this first scenario was expressly referenced by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. at 1121. *See supra* note 214. A defense of this nature is typically available abroad. *See* Duffy 10/30 at 171.

[231] *See* Eisenberg, 56 U. CHI. L. REV. at 1074. Citing concerns over increasing royalty stacking problems in biotechnology, one author advocates compulsory licensing, under reasonable, reach-through royalty arrangements, of research tools used in developing other products. *See* Mueller, 76 WASH. L. REV. at 58. A recent

Use of a patented invention in research directed toward its own improvement poses the most difficult problem, because it affects the division of profits between initial and competing follow-on innovators, both of which need adequate incentives if their independent contributions are to be sustained.[232] Arguably, such use could be justified as essentially an extension of disclosure requirements.[233] Some have argued that a research exemption for improvers might be "consistent with the overall thrust of our patent system"[234] and is widely accepted abroad.[235] Others note that so long as follow-on research yields a product or process that infringes the initial patent, the initial patentee will share in any follow-on benefits even if the research is deemed non-infringing. Nonetheless, they concede, the patentee would be harmed if the research designs around the patent.[236] With such offsetting incentive effects, the ideal balance is unclear.

The Federal Circuit's ruling in *Madey v. Duke University* has a potential to upset the equilibrium regarding research uses of patented inventions and may heighten any problems raised by uncertainty over the reach of the experimental use defense. This warrants continued attention as the implications of these recent developments in the law become better understood.

E. Business Method Patents: An Illustration of Transition Issues

Section 101 of the Patent Act states, "Whoever invents or discovers *any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof*, may obtain a patent . . . ."[237] Despite this broad mandate, courts have long interpreted certain types of inventions as unpatentable. Traditional common law

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survey, however, indicates that, at least thus far, the negotiation breakdowns and royalty stacking problems suggested by anticommons theories have not significantly blocked biomedical research. *See* Cohen 10/30 at 149; Walsh, et al., *Research Tool* at 297-300. Moreover, a panelist explained that many significant research tools are now covered by National Institutes of Health requirements ensuring nonexclusive licensing, *see* Boulware 10/30 at 155-57, and this may mitigate some of the concerns regarding research tools in biotechnology.

[232] Of course follow-on innovation may also come from other routes: an initial innovator with a broad patent covering future development might pursue, or license others to pursue, the follow-on innovations. *See, e.g.*, Kitch 2/20 at 83-84; Scotchmer 2/26 at 129-30.

[233] *See Integra Lifesciences I, Ltd. v. Merck KgaA*, 331 F.3d 860, 875, 878 (Fed. Cir. 2003) (Newman, dissenting) (arguing that the prohibition of improvement research cannot be squared with the framework of patent law and distinguishing between research into the technology used in patents and the use in research of patented products or methods). In some settings, such as with some methods and processes, follow-on innovators may develop improvements simply from knowledge of the nature of the patented invention; in other settings, such as in software contexts in which the program must be run in order to support any improvement efforts, the patented invention must be used. Plainly, the need to secure a license in order develop an improvement is more a matter of the nature of the invention than of any general patent law principle.

[234] *See* Duffy 10/30 at 173-74; *see also* MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1008 ("Traditionally, patent law has operated on the assumption that other inventors remain free to seek improvement patents within the claims of an earlier patent.").

[235] *See* Duffy 10/30 at 172-74 ("de facto, there is a research exemption like that in U.S. law. It's called Europe."); MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 1015-16; Mueller, 76 WASH. L. REV. at 37-39.

[236] *See* Eisenberg, 56 U. CHI. L. REV. at 1076.

[237] 35 U.S.C. § 101 (emphasis added).

exceptions include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter and, for many years, business methods.[238] Over time, however, these common law exceptions to patentability have eroded.[239]

The applicability of § 101, and its common law exceptions, to business methods received particular attention during the Hearings.[240] According to the PTO, business methods follow software controlled microprocessors as the next step in the "unbroken evolutionary path" in business data processing.[241] As one panelist stated, "99 percent of . . . business method inventions are automated techniques for doing something that people used to do in a nonautomated way."[242]

Some Hearing participants observed that whenever common law exceptions to patentability erode, a transition period ensues during which the patent system struggles to adapt its standards and procedures to apply to the new technology.[243] Presumably, patent quality may suffer during this period.[244] Society's experience with patents on "automated financial or management data processing methods (*Business Methods*)" exemplifies both such a transition period and the initiatives that may be required to minimize the problems posed during the transition.[245] At the Hearing, discussion suggested that the challenge these transition periods pose lies not only in resolution of whatever specific problems arise when examining these newer subject matters, but – perhaps of greater importance – in the anticipation of and proactive treatment of those problems before they fully

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[238] *See*, *e.g.*, Thomas 2/8 (Patent Session) at 25-27, 32, and John Thomas, *Patent Law & Policy: An Introduction* (2/8/02) (slides) at 17, *at* http://www.ftc.gov/opp/intellect/jayth1.pdf and 4/11 at 73; Sung 2/8 (Patent Session) at 139.

[239] *See*, *e.g.*, Nydegger 4/11 at 106-07; Thomas 4/11 at 70. In two landmark decisions, *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980), and *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), the Supreme Court held, respectively, that man-made, living organisms and computer software constitute patentable subject matter under Section 101.

[240] Though business method patents were discussed intermittently throughout the Hearings, the following sessions provided sustained treatment: 2/27 (pm); 3/19 (am); 3/20 (pm); and 4/11 (am).

[241] *See generally* AUTOMATED FINANCIAL OR MANAGEMENT DATA PROCESSING METHODS (BUSINESS METHODS), USPTO WHITE PAPER (March 2000) (emphasis added), *at* http://www.uspto.gov/web/menu/busmethp/ (hereinafter PTO BUSINESS METHOD WHITE PAPER).

[242] Kushan 4/11 at 113-14.

[243] *See*, *e.g.*, Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 589 (1999).

[244] John Love 2/27 at 467 (The PTO undertook the Business Method Initiative "partially in response to a public concern about the quality of patents that were being issued in the business method area . . . ."). *See also* Merges, 14 BERKELEY TECH. L.J. at 589 (noting that the scope of the transition problem may be worse for business methods than in the early years of software and biotech patents owing to the "simple matter of overall volume" – the rapid increase in the number of business method applications filed).

[245] *See* PTO BUSINESS METHOD WHITE PAPER at iv (The PTO Business Method Initiative culminated in a white paper that "discusses the patent history of business data processing, the transition this technology is beginning, and the initiatives the USPTO is engaged in to keep pace with this transition and to improve quality in the examination of this technology."). In 1999, Congress took steps to ease the transition to an era of business method patenting by creating a defense to infringement allegations in the form of prior user rights covering third parties who (i) reduce a business method to practice at least a year before the filing of a patent application and (ii) use that business method before the application's effective filing date. 35 U.S.C. § 273(b). *See supra* Ch. 4(II)(C)(1).

materialize.[246]

More fundamentally, the continuing debate regarding business method patents raises the issue of the proper boundaries of patentable subject matter and provides an opportunity to consider some of the ongoing controversies (including the relationship between innovation and patents) underlying the patent system more generally. As these issues arise in fresh contexts, policy makers should use the opportunities to ensure that the patent law reflects an integration of competition values.

1. Legal Status of Business Method Patents

In *State Street Bank & Trust v. Signature Financial Group*, the Federal Circuit ruled that business methods can be patented.[247] The court held, "[s]ince the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method."[248] Whatever the status of business method patents prior to 1998,[249] *State Street* clearly sanctioned their use prospectively. The Federal Circuit's ruling launched a surge in the number of business method patent filings, though, in absolute terms their numbers remain relatively small.[250] In its 2000 White Paper on business methods, the PTO noted that *State Street* "triggered an awareness of the 'business method claim' as a viable form of patent protection. We are at the beginning of a change in the approach to how inventors choose to describe their inventions."[251]

2. Application of Patentability Criteria to Business Methods

Panelists had decidedly mixed assessments regarding both the quality of business method patents issued to date and the prospects for improving quality in the future. In general terms, some worried that the level of abstraction and the multi-disciplinary nature of many business methods prevent efficient application of traditional patent standards.[252] Others, however, found little cause for concern; like other areas of patent growth, they reasoned, business method patenting will undergo a maturation process that will eliminate initial

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[246] Aharonian 2/27 at 551.

[247] *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999).

[248] *State Street*, 149 F.3d at 1375.

[249] Panelists expressed a wide range of opinions about whether *State Street* accurately captured the prior treatment of business methods under patent law. *Compare* Thomas 4/11 at 71 ("[P]atent law has been concerned about business methods from the very beginning. The earliest common law antecedent . . . said business methods are out.") *with* Dickinson 2/6 at 67 (stating that business method patents have been issuing "since the mid-1860's on").

[250] Dickinson 2/6 at 68. The PTO assigns most computer-implemented business method patent applications to Class 705, which encompasses automated business data processing technologies. PTO BUSINESS METHOD WHITE PAPER at 6. In FY 1999, the 2658 Class 705 applications represented approximately 1% of all applications filed with the PTO. *Id*. at 7. In FY 2000, 7800 Class 705 applications were filed, out of which the PTO issued 899 patents. In FY 2001, the PTO anticipated 10,000 Class 705 applications would be filed, with over 400 patents issued from among them. Joy Y. Xiang, *How Wide Should the Gate of "Technology" Be? Patentability of Business Methods in China*, 11 PAC. RIM L. & POL'Y J. 795, 828 n.103 (2002).

[251] PTO BUSINESS METHOD WHITE PAPER at iv.

[252] *See*, *e.g.*, Kahin 4/11 at 18-20.

difficulties.[253] Panelists tended to focus upon the application of several traditional patentability criteria – nonobviousness, written description, and enablement – when assessing PTO grants of business method patents.[254]

a. Nonobviousness

As discussed previously, nonobviousness is at the core of patent law, and prior art is at the core of nonobviousness.[255] The PTO recognized that inventors' increased patenting of business methods required changes in the examination process, including a shift in the examiner knowledge base.[256] Locating prior art is particularly difficult for business methods. In part this stems from the infrequency with which such patents previously were sought.[257] Other factors – the absence of a drive to publish within business method fields (unlike, for example, the sciences), and the fact that commercial practices in question often only exist in the "heads of business persons" – are systemic problems that may be more unique to business methods.[258]

Given the centrality of prior art to nonobviousness determinations, the effective identification of non-patent prior art is critical to ensuring that the PTO issues quality business method patents. Accordingly, former PTO Director Dickinson undertook the Business Method Initiative, which had two primary goals: 1) the identification of sources of non-patent literature, and 2) the creation of mandatory fields of search for examiners.[259] Identifying sources of non-patent prior art more generally is likely to be an ongoing task for the PTO, as technological advances multiply and the number of patent applications continues to rise.[260]

Assessing prior art poses an additional challenge for the PTO. Is the automation of an existing business method inherently obvious? The PTO responded to this challenge by implementing another level

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[253] *See*, *e.g.*, Myrick 10/30 at 186-87; Stoll 4/11 at 170. For a recent empirical study concluding that Internet business method patents "were no worse than patents in general in the late 1990s . . . and may have been better than average," *see* John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERK. TECH. L. J.— (forthcoming 2003), *in draft at* http://papers.ssrn.com/sol3/delivery.cfm/SSRN_ID421980_code030727560.pdf?abstractid=421980.

[254] *See*, *e.g.*, Kushan 4/11 at 104, 113; Janis 4/11 at 65-66.

[255] *See supra* Ch. 4(II)(A).

[256] *See generally* PTO BUSINESS METHOD WHITE PAPER at 8-10.

[257] *See, e.g.,* Gable 3/20 at 116-18.

[258] Thomas 4/11 at 111. Recent research, however, cautions against overemphasizing distinctions between business method patents and other patents based on the accessibility of prior art. *See* John R. Allison & Emerson H. Tiller, *Internet Business Method Patents*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY at 259, 260 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) ("We conclude that criticisms of Internet-related patents that focus on prior art in particular should be taken with some caution, as we find the statistical differences between these patents and more general patents to be small and, if anything, to suggest that Internet-related patents are well supported by prior art references."), *available at* http://books.nap.edu/books/0309086361/html/260.htm#pagetop.

[259] Love 2/27 at 467-68.

[260] For example, when the Commission on Patent Law Reform sat over ten years ago, *see supra* Ch. 1, Box 1-5, the Commission recommended that the PTO create its own database, because "the technology develops so rapidly that you really are not going to find in the patent database the real prior art . . . ." Taylor 2/27 at 473.

of review of business method patents by a more senior examiner or examination panel, known as a "second pair of eyes." The PTO recognized that applying patentability criteria to emerging technologies may be difficult or, at minimum, might differ from their application to more established subject matter, and that more senior examiners could assist with the tough judgment calls that ensue. PTO Group Director for Cryptography and Security Technology Center (TC 2100) John Love noted that the allowance rate for Class 705 (covering most computer-implemented business methods) has consistently decreased since the program was introduced and interpreted this as an indication that patent quality has increased.[261] Presumably, a second review of this nature might heighten the quality of patentability determinations in other areas of emerging technology as well, as recently suggested by the PTO's 21st Century Strategic Plan.[262]

b. Written Description

Panelists expressed concern that business method patents will contain claims that encompass every manner of implementing a particular business model.[263] In theory, rigorous application of the written description requirement, which ensures that the inventor has invented what the patent application claims, might avoid such results.[264] Some of the panelists suggested difficulties with describing business methods, however.[265] As one panelist noted, the general concern is the difficulty of providing a consistent vocabulary to describe abstract subject matter such as high-level software patents and business method patents.[266] Another panelist framed the issue in terms of the inherent difficulty of "defin[ing] an idea."[267]

c. Enablement

Several panelists argued that business method patents, which frequently encompass software-automated or online processes, are not enabling. As discussed previously, enablement ensures the public is in possession of the invention, *i.e.*, it implements the patent system's disclosure

[261] John Love 2/27 at 475. Love stated the allowance rate for Class 705 was 55 percent in 2000 (the reforms were in place for the second half of 2000) and 45 percent in 2001. *Id*. at 470-71. Love further stated that the reduction in Class 705 patents issued indicates improved searching on the part of the PTO for prior art and, he hoped, the narrowing of claims so that they more closely capture a patentee's innovative contribution. *Id*. at 475.

[262] United States Patent and Trademark Office 21st Century Strategic Plan, *Patent Quality Improvement: Expansion of the Second-Pair-of Eyes Review* (April 2, 2003), at http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm. *See infra* Ch. 6(III)(A)(2).

[263] Kushan 4/11 at 114. Mr. Kushan, the author of the PTO's guidelines for computer-implemented inventions, stated that patents containing claims that encompass every manner of implementing a particular business model should not issue and that stringent written description requirements could play a preventative role. Kushan 4/11 at 114.

[264] Kushan 4/11 at 114. *See generally supra* Ch. 4(II)(B) (discussing written description requirements). The enablement and utility doctrines might also prevent the improvident granting of such patents. Kushan 4/11 at 114-15.

[265] *See*, *e.g.*, Kahin 4/11 at 112; Young 4/11 at 112.

[266] Kahin 4/11 at 112.

[267] Young 4/11 at 112.

requirement.[268] Without the publication of the underlying source code, however, some panelists questioned whether that requirement was met.[269] For example, Mr. Kushan observed that the higher-level discussion of software currently required may not be sufficient to prove the patent works in the manner claimed or to reveal any dependence on a particular implementation.[270] Toward that end, Mr. Kushan believes that requiring patentees to post their source code, somewhat analogous to the micro-organism deposits in the biotech area, would help achieve "the goal of satisfying public need and access to an operable invention."[271]

3. Patentable Subject Matter

Although all panelists agreed that improvement in the application of traditional patentability criteria to business methods was necessary, they disagreed as to whether such improvement would be sufficient. On one side, Mr. Kushan argued that improvement of business method patents must come through keeping the PTO's examination "focused on the measurement criteria of inventiveness as opposed to the definitional criteria of eligibility. . . ."[272] By contrast, Professor Kahin argued, "we ought to be willing to draw lines around patentable subject matter. And I say this recognizing that this is a chronic policy problem in an age of porous boundaries, that it is hard to maintain lines. But the alternative is to swallow the world, and I don't think that's what the patent system should be doing."[273] A number of panelists discussed the viability or value of a "technicity" requirement for drawing the line regarding patentable subject matter.[274]

The record offers substantial guidance concerning patentable subject matter more generally.[275] On one hand,

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[268] *See supra* Ch. 4(II)(B).

[269] *See also supra* Ch. 4(II)(B)(3).

[270] Kushan 4/11 at 102.

[271] Kushan 4/11 at 102. For a contrary view, *see* National Academy of Sciences Board on Science, Technology, and Economic Policy, Conference on the Operation of the Patent System: Insights from New Research 222 (Transcript of Proceedings Oct. 22, 2001) ("the Patent Office doesn't want the source code, because they have nowhere to store it, and they have nowhere to get access to it in a useful way"), *at* http://www7.nationalacademies.org/step/transcript1022_PDF.pdf (Testimony of Robert Sterne).

[272] Kushan 4/11 at 24.

[273] Kahin 4/11 at 20.

[274] *See, e.g.*, Thomas 4/11 at 55 ("point of patentable distinction involves . . . manipulation of natural laws . . . concerning physical elements"); Musacchia 4/9 at 26 (urging United States to move toward European and Japanese approaches requiring industrial application and technical features); *cf.* Hughes 2/28 at 622 (European discussions on software and business methods "could be very revealing to us"). According to the European Patent Office, "in order to be patentable, an invention must be of a technical character to the extent that it must relate to a technical field, must be concerned with a technical problem and must have technical features in terms of which the matter for which protection is sought can be defined in the patent claim." *Available at* http://www.european-patent-office.org/news/pressrel/2000_08_18_e.htm. Panelists disagreed as to what this meant as a practical matter. *See*, *e*.g., Stoll 4/11 at 162 (noting that "anecdotally many, many attorneys have told me they are patenting both software and business methods in Europe"); Thomas 4/11 at 174 (noting that the UK and French patent offices "have spoken out against business methods, but the German Patent Office seems in favor of them").

[275] The precise boundaries of the patent system's domain are still unresolved. Although the Supreme Court's *Chakrabarty* opinion observes that "Committee Reports . . . inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man,'" 447 U.S. at 309, the Court immediately adds, "This is not to

defenders of business method patents stressed that universality of patentable subject matter has been a significant factor in U.S. technological development.[276] They argued that in the absence of clear empirical evidence, the default position should be that an invention is patentable. Stated alternatively, they suggested that the promotion of innovation should be presumed unless empirical evidence to the contrary exists.[277] On the other hand, critics argued that business method patents do not foster incentives to innovate, because business methods traditionally evolve in response to competition and internal business needs, without regard to legal rights to exclusivity.[278] In other words, it is unclear whether business method patents satisfy "but for" principles.[279] Moreover, Yale University President Richard Levin noted possibilities for the exercise of market power and the impairment of follow-on innovation.[280]

Recommendation. Given the complexity of the issues and the diversity of views reflected in the Hearing record, the Commission makes no recommendation for judicial or legislative action to reconsider or restrict the patentability of business methods. Nonetheless, in light of the uncertainty surrounding the benefits and the possible competitive downside from extending patent coverage to new fields, future extensions, and any future reconsideration, by courts or by Congress, of patentable subject matter extensions, require – at a minimum – a conscious policy choice, in addition to a searching and rigorous application of the other patentability criteria. In assessing such future issues, decision makers should ask whether the extension of patentability will "promote the Progress of Science and useful Arts" or instead will hinder competition that can function effectively to spur innovation. Such consideration is consistent with the historical interpretation of Section 101, which typically recognizes that granting patent protection to certain things, such as phenomena of nature and abstract intellectual concepts, would not advance the patent system's Constitutional goals.

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suggest that § 101 has no limits or embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Id*.

[276] *See* Jeffrey R. Kuester & Lawrence E. Thompson, *Risks Associated with Restricting Business Method and E-Commerce Patents*, 17 GA. ST. U. L. REV. 657, 685 (2001); Kuester 4/11 at 44-45; IPO (stmt) 16 (describing patents as a bedrock of the economic incentive to innovate in all technologies).

[277] Kuester & Thompson, 17 GA. ST. U. L. REV. at 680-81; Kuester 4/11 at 37-38, 44, 115-16; Nydegger 4/11 at 184.

[278] *See*, *e.g*., Musacchia 4/9 at 24-26; Young 4/11 at 61, 63-64; Thomas 4/11 at 57-59.

[279] *See supra* Ch. 4(II)(A)(2).

[280] *See* R. Levin (stmt) 2 ("There are potentially serious consequences of a low threshold for patenting in emerging technology areas. A patent, after all, grants an exclusive right, and in some cases it can confer power in product and innovation markets. We should be very wary of creating unwarranted market power by granting unwarranted patents."); *see also*, Langenfeld 2/20 at 18; Thomas 4/11 at 60; Kushan 4/11 at 114; Robert M. Hunt, *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the Economy?*, Q1 BUSINESS REVIEW 5, 14 (2001) (finding reason to question whether business method patents will provide significant incentives to innovate). Hunt also stresses the need for "more careful empirical research on the effects of increasing the availability of patents in high technology industries" to give policymakers "more and better information about the costs and benefits of the ongoing changes in our patent system." *Id*.

III. CONCLUSION

The Hearings highlighted both the potential benefits and potential harms of patents. Clearly, they help foster innovation. At the same time, the testimony identified a number of potential adverse effects, including greater market power, higher costs and risks for competitors, and higher costs and reduced incentives for independent follow-on innovation. The presence of both potential benefits and potential harms implies a need for making tradeoffs and judicious policy choices. In deciding issues at the interstices of the patent statutes, in amending those statutes, and in making determinations about patentable subject matter, policymakers should strive to take conscious account of the likely effects on innovation and on competition, with the goal of adopting policies that contribute most to consumer welfare over time.

In some cases, "but for" thinking can provide useful guidance for overall policy directions. For example, to the extent that the suggestion test for nonobviousness lacks convincing correlation to the likelihood that invention would occur or that it would be disclosed and developed without the patent, the test raises the potential for conferring exclusionary rights without offsetting social benefit. The Commission, therefore, urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. Failure to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art may be unnecessarily detrimental to competition.

Competitive considerations help inform other substantive aspects of the patent system. They raise questions about the commercial success test for nonobviousness and confirm the importance that courts evaluate, case by case, whether commercial success is a valid indicator of the nonobviousness of the claimed invention and that patentees bear the ultimate burden of demonstrating that the claimed invention caused the commercial success. They suggest that current disclosure doctrines accord reasonably well with economic goals at a systemic level but that accurate, up-to-date assessments of the predictability of the art and of the abilities of the PHOSITA in evolving industries are important elements for harmonizing the patent and antitrust regimes. They suggest the need to monitor carefully the consequences of *Madey v. Duke University* for the vitality of follow-on innovation and the functioning of the experimental use defense.

Finally, competition concerns suggest the need for a legislative change. The Hearing record indicates that current continuation practice disrupts business certainty and harms competition by permitting applicants to broaden their claims after competitors have developed their products and incurred sunk costs. The Commission recommends that legislation be enacted providing intervening or prior user rights that would protect third parties from hold-ups made possible by continuations.

CHAPTER 5 COMPETITION PERSPECTIVES ON HOW PROCEDURES AND PRESUMPTIONS AFFECT PATENT QUALITY

CHAPTER 5 COMPETITION PERSPECTIVES ON HOW PROCEDURES AND PRESUMPTIONS AFFECT PATENT QUALITY

This Chapter shifts the analysis toward procedures and presumptions and their effects on patent system quality. Assuming the substantive standards of patentability as given, this Chapter assesses the competitive impact of the principal procedures and presumptions that the patent system uses to examine, reexamine, and litigate patent validity.

In theory, to ensure patent quality, the patent system needs procedures and presumptions that work efficiently as screens, first, to protect against improvidently granted patents or patents of improper breadth, and next, to weed out any patents that are granted improvidently or with improper breadth despite the first screen. As a practical matter, however, significant questions can arise about which procedures work most efficiently to achieve high quality for commercially significant patents. For example, a recent article by Professor Lemley asserts that "the PTO doesn't do a very detailed job of examining patents, but we probably don't want it to."[1] Professor Lemley notes that most patent applications involve claims of little economic significance,[2] and argues that therefore "it is much cheaper for society to make detailed validity determinations in those few cases [in which patents are challenged] than to invest additional resources examining patents that will never be heard from again."[3] Thus, improvement of patent quality requires consideration of how best to invest limited resources.

Patent quality also raises process and transactions cost issues, such as how long it takes, and how much it costs, for the PTO to issue a patent and for the court system to issue a final determination of patent validity. Other questions concern how patent procedures and presumptions can affect business uncertainty.

This Chapter offers no overall assessment of patent system quality, but notes certain danger signals and focuses on identifying ways to improve procedures and presumptions that affect patent quality. The discussion shows first that patent quality may have significant effects on competition. It then looks inside the patent system to assess issues surrounding patent examination, reexamination/opposition, and litigation, highlighting in each instance ways in which a competition perspective may inform the evaluation and recommending steps that might be taken to better address competition concerns.

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[1] *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1495, 1497 (2001).

[2] *See also FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Lawrence J. Udell Testimony Feb. 28, 2002*, at page 568 (small percentage of patents actually reaches the market) (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)); Linck 4/9 at 30 (only a fraction of one percent of patents are actually litigated); Taylor 10/25 at 51-52; F. Scott Kieff, *Summary of Proposed Testimony* (Public Comment) 3-4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/harvardlaw.pdf (hereinafter Kieff (stmt)).

[3] Lemley, 95 NW. L. REV. at 1497.

I. IMPACT ON COMPETITION

Professor Jonathan Levin identified three economic consequences that, depending on potential infringers' chosen response, may flow from issuing patents of questionable validity.[4] First, such patents may slow follow-on innovation by discouraging firms from conducting research and development in an area out of fear that they may be infringing. Of course, to the extent that fear of infringement discourages firms from entering a market, there may be distortions in prices and in resource allocation as a result of any ensuing market power. Second, even if the research does go forward, such patents may induce unnecessary licensing. Payment of royalties on an invalid patent distorts the incentive system that the patent system was designed to provide. Third, if instead the patent is challenged in litigation, the ensuing costs are a drain on the system. The impact of uncertainty complicates all of these potential economic effects. This section discusses the testimony on each of these issues.

Discouraging Entry and Innovation: Several panelists expressed concern over the potential effects on entry and competition. Judge T.S. Ellis, III, for example, noted that high litigation costs are a disincentive to market or use a process or product "close to the border to the patent scope," consequently, "improperly expanding" patent boundaries.[5] Other panelists stressed the impact on research and development, suggesting that improperly awarded patents may distort firms' research choices and influence them to shun whole areas of R&D activity.[6] Moreover, litigation threats can scare away venture capital.[7]

Inducing Unnecessary Licenses and Royalty Payments: For firms that choose to continue their R&D or production activities, taking a license and paying royalties on the questionable patent is another alternative. If the royalties are less than the expected value of potential litigation costs, firms may prefer to pay for the license.[8] A number of panelists indicated that small firms, unable to bear the costs of litigation, are particularly likely to be forced to license,[9] although some noted that large firms, with greater exposure,

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[4] J. Levin 10/25 at 20-21.

[5] *See* T.S. Ellis 7/11 at 110. Others voiced similar concerns. *See, e.g.,* Thomas 2/8 (Patent Session) at 60; Pooley 2/27 at 379; Webbink 3/20 at 100.

[6] *See, e.g.*, Kirschner 2/26 at 244-45, 308-09; Earp 2/26 at 291; Friedman 2/27 at 411-12; Josh Lerner, *Into the Patent Thicket* (2/20/02) (slides) at 7, at http://www.ftc.gov/opp/intellect/lerner.pdf (hereinafter Lerner 2/20 Presentation); Caulfield 3/19 at 161; *see also* Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J. L. & ECON. 463 (1995) (finding that a firm's willingness to patent in biotechnology subclasses in which others already hold patents varies inversely with the firm's projected litigation costs).

[7] Lerner 2/20 at 188-89. Of course, doubtful claims will not always have serious consequences. Some panelists explained that demand letters asserting dubious claims often, after reasonable inquiry, may be simply ignored or may be easily countered by citing back readily found prior art. *See, e.g.,* Garner 10/25 at 15-16; Hart 4/9 at 36-37.

[8] *See, e.g.,* Casey 4/9 at 68-69; Kesan 4/10 at 152-54.

[9] *See, e.g.*, Lerner 2/20 at 159; Kahin 3/19 at 89-90; *cf*. Webbink 3/20 at 100 (small firms particularly exposed when invalid claims asserted); Gambrell 10/25 at 18 (same). *See generally*, E. Bruce Barnes, *Comments Regarding Competition & Intellectual Property* (Public Comment) 1 (independent inventors are harmed when others assert questionable patents), *at* http://www.ftc.gov/os/comments/intelpropertycomments/barnesebruce.pdf.

are also subject to *in terrorem* effects.[10] In either case, entering an unnecessary license reduces the licensees' rewards and distorts their incentives to innovate or compete.

Imposing Litigation Costs: A third possibility is litigation. The record is replete with discussion of the cost of litigation and its potential to operate as a drag on the system.[11] Although some panelists questioned whether patentees would frequently expose questionable patents to a litigated judgment,[12] others noted that cases are litigated and lost all the time,[13] and that patentees limit their exposure to a loss by accumulating a range of claims from broad to narrow, so that a more limited, fall-back position will remain.[14]

Impact of Uncertainty: Contributing to each of these effects is the massive uncertainty that numerous panelists described as characteristic of the patent system.[15] The validity of patents emerging from the PTO often is subject to question and not resolved until the end of litigation. The scope of the patents, both in terms of their literal claims and the operation of the doctrine of equivalents, often is unclear. When unpublished applications and lengthy continuations are added to the mix, uncertainty is further magnified.

Panelists identified numerous impacts of uncertainty:

(i) Uncertain patent rights pose severe difficulties for business planning: they undermine competitors' decisions about where to channel R&D and what products to market.[16] Several panelists voiced frustration at their firms' inability to know if they are infringing.[17]

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[10] *See* Kushan 10/25 at 22-23.

[11] *See, e.g.*, Aharonian 2/27 at 460-61; Kahin 3/19 at 89-90; Musacchia 4/9 at 93; Kesan 10/25 at 26; Barr 10/30 at 78; *see also* AMERICAN INTELLECTUAL PROPERTY LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 22 (2003) (presenting survey results reporting (i) the median cost of participating in patent infringement litigation with less than $1 million at risk as $290,000 through discovery and approximately $500,000 through trial and appeal; (ii) the median cost of participating in patent infringement litigation with between $1 million and $25 million at risk as approximately $1 million through discovery and $2 million through trial and appeal; and (iii) the median cost of participating in patent infringement litigation with more than $25 million at risk as approximately $2.5 million through discovery and $4 million through trial and appeal).

[12] *See* Kieff 4/10 at 169-70; Myrick 10/30 at 95-96.

[13] *See* Katsh 4/10 at 181.

[14] *See* Pooley 10/30 at 102; Thomas 10/30 at 103-04.

[15] As Professor Teece explained, "[T]here are a lot of fuzzy boundaries around intellectual property, unlike real property . . . . it's only when subsequently tested in court that you know that in fact these claims are valid." Teece 2/26 at 202-03.

[16] *See, e.g.,* Sung 2/8 (Patent Session) at 109-10; Blackburn 2/26 at 295 (if "you go to your head of R&D" and ask "'Can I do this,'" he says, "'Well, invest the 800 million and I'll tell you in 10 years whether you can do it or not.' And that's unacceptable."), 306-07; Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipo.pdf. *See generally* Wamsley 7/10 at 140-41 (patentee's competitors need to know what the patent rights in their industry are).

[17] *See, e.g.,* Greenhall 2/27 at 375-76 ("I really can't understand the patent landscape . . . I'm sitting with a nuclear bomb on top of my products"); Barr 10/30 at 28, 99; Banner 10/30 at 182-83.

(ii) Uncertainty heightens investment risks and equates to costs.[18]

(iii) Uncertainty hinders the raising of capital.[19]

(iv) Uncertainty disrupts the working out of licenses.[20]

(v) Uncertainty induces litigation that imposes costs and interferes with competition and innovation.[21]

II. PATENT EXAMINATION

A. Data on Overall Performance

The Hearing record documented a surge in patent applications, described by PTO Director James Rogan as an "unprecedented explosion."[22] Applications have doubled in the last twelve years, and are increasing about 10% per year.[23] With yearly application totals approximating 300,000, they arrive at the rate of about 1,000 each working day.[24] In 2001, the PTO issued approximately 190,000 patents.[25]

A corps of some 3,000 examiners must deal with the flood of filings.[26] Many

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[18] *See, e.g.,* Fox 2/28 at 696 (finding "pervasive uncertainty" in the patent system); Black 3/20 at 161.

[19] *See, e.g.,* Teece 2/26 at 204-05 (markets are always implicitly discounting the value of patents untested in court) and David J. Teece, *Intellectual Property, Valuation, and Licensing* (2/26/02) *(*slides) at 4 and 5, at http://www.ftc.gov/opp/intellect/020226davidjteece.pdf; Ziedonis 3/20 at 18.

[20] *See, e.g.,* Teece 2/26 at 203-04, 220.

[21] *See* Teece 2/26 at 203-04; Wamsley 7/10 at 195.

[22] Rogan 2/6 at 26.

[23] *See* Lerner 2/20 at 157; Chambers 2/8 (Patent Session) at 86; James Langenfeld, *Innovation, Competition, and Intellectual Property: Providing an Economic Framework* (2/20/02) (slides) at 6, *at* http://www.ftc.gov/opp/intellect/langenfeld.pdf (hereinafter Langenfeld Presentation). The record suggests numerous possible explanations for this surge in patenting activity, without establishing their relative significance. Some panelists attributed the increase in patent applications to an increase in the value of patents as motivators of innovation. *See, e.g.,* Rogan 2/6 at 26 ("the value of patents as business portfolio assets has increased, their validity has become more predictable"); Dickinson 2/6 at 68-69 ("investors feel more secure in the patent system"). Some viewed the increased applications, at least in part, as a reflection of greater research and development activity. *See, e.g.,* Mossinghoff 2/6 at 82-83; Dickinson 2/6 at 68; *see also* Paul F. Morgan, *Personal Comments for the Joint FTC and DOJ Public Hearings on Intellectual Property Law Beginning February 6, 2002 Entitled: "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*" (Public Comment) 6, *at* http://www.ftc.gov/os/comments/intelpropertycomments/morganpaulfattachment.pdf; Daniel Wilson, *Are We Running out of New Ideas? A Look at Patents and R&D*, FRBSF Economic Letter No. 2003-26, at 1 (Sept. 12, 2003) (observing that over the period between 1953 and 2000, R&D performed by private firms outpaced the growth in patents issued to U.S. residents). PTO Director Rogan pointed out that "the area[s] in which patents could be obtained expanded," Rogan 2/6 at 26, and former PTO Director Dickinson made note of increased filing by foreign applicants. Dickinson 2/6 at 68. Others offered less benign explanations. For example, Cecil Quillen viewed the increased filings as "a direct consequence of the Federal Circuit's lowered standards of patentability." Cecil D. Quillen, Jr., *The U.S. Patent System: Is It Broke? And Who Can Fix It If It Is* (Public Comment) 12, *at* http://www.ftc.gov/os/comments/intelpropertycomments/quillenattachments/isitbrokewhocanfixit.pdf. *See generally* Ziedonis 3/20 at 15-16. Several panelists stressed the role of defensive patenting as contributing to the surge in patent applications. *See supra* Ch. 3(IV)(E)(2) and (V)(E)(2)(C). Adding a further level of complexity, some testimony emphasized that explanations for patenting may vary from industry to industry. *See, e.g.,* Cohen 2/20 at 29-33.

[24] *See* Chambers 2/8 (Patent Session) at 86; Langenfeld 2/20 at 17 and Langenfeld Presentation at 6.

[25] Dickinson 2/6 at 65.

[26] *See* Chambers 2/8 (Patent Session) at 84.

of the panelists saw need to provide examiners more time per examination.[27] Lacking official statistics, panelists varied in their estimates of the amount of time available to examine an application from start to finish, but all indicated that it was very short. Participants stated estimates of 24.9 hours at the outside, but often half that;[28] 21 hours;[29] 20 to 25 hours;[30] 18 hours;[31] 8-18 hours;[32] and more than 11-12, but "not a lot of hours"[33] to read and understand the application, search for prior art, evaluate patentability, communicate with the applicant, work out necessary revisions, and reach and write up conclusions.[34]

Even with rapid handling, backlogs have been building, and pendency has been lengthening. Several panelists from a cross-section of industries indicated that current pendency periods are a significant problem.[35]

Solid data on patent quality were limited. Some panelists took comfort in the PTO's patent quality review data,[36] and some viewed an increase in the number of prior art references cited in patents as an indication that the system is functioning

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[27] *See, e.g.*, Dickinson 2/6 at 64-65 ("Patent examiners need more time to examine."); Kirschner 2/26 at 242-43 (time constraints "clearly inadequate" for a meaningful examination of a biotech patent application); Gable 3/20 at 121; Kesan 4/10 at 100 (time constraints do not allow adequate search for software prior art).

[28] Chambers 2/8 (Patent Session) at 88.

[29] Seide 3/19 at 219.

[30] Kirschner 2/26 at 243.

[31] Burk 3/20 at 167; *see also* Lemley, 95 Nw. U. L. REV. at 1500 (examiners spend an average of 18 hours during course of a patent prosecution); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314 (2001) (estimating, based on an interview with the President of the Patent Office Professional Association, that the average time allocated for examiners to address an application is 16-17 hours).

[32] Kesan 4/10 at 100.

[33] Chen 2/20 at 194.

[34] Scholars have identified other factors that could interlink with limited examination time in ways that detract from patent quality. According to one researcher, the examiner compensation system functions through a combination of base salary and bonuses, with bonus points "accumulated only for 'dispositions,' i.e., final allowances or rejections of patents." Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L. J. 577, 607 (1999). Some have suggested that given opportunities to continue prosecutions even after rejections, "the only way to earn bonus points with confidence is to allow a patent application," *id.*, resulting in "a strong incentive to issue patents to persistent applicants, rather than to continue rejecting the applications." Lemley, 95 NW. U. L. REV. at 1496 n.3. Others seem to share concerns over the potential impact of examiner time-management rules on patent quality. *See*, *e.g.*, David Hricik, *Aerial Boundaries*: *The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage*, 44 S. TEX. L. REV. 205, 228-229 (2002); Thomas, 2001 U. ILL. L. REV. at 324-325; s*ee also*, Dickinson 10/25 at 78 (suggesting that examiners may be reluctant to question applicants directly unless they receive "time credit" for doing so); Kushan 10/25 at 78 (same).

[35] *See, e.g.*, Misener 2/27 at 396; Barr 2/28 at 678; Armitage 3/19 at 134; Gable 3/20 at 117; Young 4/11 at 63-64.

[36] *See* Dickinson 2/6 at 66-67 (finding that the data show "a remarkable consistency in quality over the long-term"); John Love 2/27 at 466-67 and John J. Love, *Steps Taken to Improve Patent Quality* (2/27/02) (slides) at 4, *at* http://www.ftc.gov/opp/intellect/020227johnlove.pdf (hereinafter John Love Presentation) (showing error rates of 5.5%, 6.6%, and 5.4% in fiscal years 1999, 2000, and 2001, respectively); *see also* United States Patent and Trademark Office, *FY 2002 USPTO Performance and Accountability Report* 18 (2003) (showing an error rate of 4.2%), *at* http://www.uspto.gov/web/offices/com/annual/2002/.

adequately.[37] Others, though, sharply questioned the adequacy of patent quality. One panelist, Professor Lemley, found that 45-46% of all patents litigated to final results are held invalid.[38] Another, Cecil Quillen, maintained that, when corrected for the effects of continuation applications and continuations-in-part, the PTO's grant rate, defined in terms of applications allowed as a percentage of application disposals, reached 98% in 2000, considerably higher than in Europe (67%) and Japan (64%).[39] "The comparative lack of rigor by the USPTO is apparent," Mr. Quillen concluded.[40] The PTO's Deputy Commissioner for Patent Examination Policy, Stephen Kunin, disputed this[41] and a recent article by a PTO senior legal advisor states that the challenged calculations double-count many patents awarded through continuing applications; calculates that 74-75% of original applications ultimately resulted in patents; and concludes that the grant rate in the United States is comparable to that in Europe and Japan.[42]

B. *Ex Parte* Nature

Patent examinations are conducted on an *ex parte* basis, involving an examiner and an applicant, but no third parties. This has several consequences for patent system quality.

First: The public is unaware of the existence of the patent application and the nature of its claims until the application is published. Under the procedures enacted in 1999, most patent applications are now published 18 months after filing.[43] A subset of applications, however – those that are only filed domestically – need not be published; their applicants may "opt out" of the publication requirements and maintain the secrecy of their applications until the

[37] *See* Merges 2/28 at 591, 634, *referring to* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B. U. L. REV. 77, 101-03 (2002) (treating citations to prior art as a proxy for the rigor of examination and finding that such citations nearly tripled between 1976-78 and 1996-98).

[38] *See* Lemley 2/25 at 41-42; John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 205 (1998). The result should be interpreted with caution: self-selection in bringing and settling suits makes it unlikely that patents litigated to final results are fully representative of patents as a whole. *Cf*. Lunney 7/10 at 92-93 (discussing self-selection bias in cases appealed to the Federal Circuit).

[39] *See* Quillen 3/19 at 31-33; Cecil D. Quillen Jr., *FTC/DOJ Hearings on Competition and Intellectual Property Law in the Knowledge-Based Economy: Statement of Cecil D. Quillen, Jr.* (3/19/02) 7 (stating also that, after adjustment for continuing applications and assuming a two-year lag, 95% of applications filed were granted in 2000), *at* http://www.ftc.gov/opp/intellect/020319cecilquillen.pdf (hereinafter Quillen (3/19 stmt)). For a fuller treatment, providing more detail regarding the underlying assumptions, *see* Cecil D. Quillen Jr. et al., *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office – Extended,*12 FED. CIR. BAR J. 35 (2002); *see also* Cecil D. Quillen Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent Office*, 11 FED. CIR. BAR J. 1 (2001).

[40] Quillen (3/19 stmt) 7.

[41] *See* Kunin 7/11 at 184 (PTO "will publish papers to show that the asserted allowance rates are quite overstated"); *see also* Mossinghoff 10/30 at 143-44 (stating that the cited numbers are "not valid").

[42] *See* Robert A. Clarke, *U.S. Continuity Law and its Impact on the Comparative Patenting Rates of the US, Japan and the European Patent Office*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 335 (2003). A recalculation of Mr. Clarke's results, *id*. at 340, 343, using his own methodologies to focus just on the three most recent years in the data sample indicates for the United States that 77-81% of original applications ultimately resulted in patents.

[43] *See supra* Ch. 4(II)(C)(1).

patent issues.[44]

Second: Because the proceeding is *ex parte*, the examiner is largely on his or her own in conducting prior art searches, a focal point of the examination process. Panelists expressed considerable concern that the PTO often may lack adequate access to prior art. They indicated that difficulties are particularly acute when non-patent prior art is important[45] and in new areas of technology, *e.g.*, software and biotechnology, and new fields of patenting activity, *e.g.*, business methods.[46] Some argued, however, that over time patent prior art in these new areas inevitably builds up and searches improve,[47] and they stressed that when specific problem areas have been identified, the PTO has undertaken substantial initiatives to enhance access to non-patent literature.[48] Others, however, questioned whether prior art problems will necessarily be solved in fields characterized by limited or abstract patent disclosures or lacking a culture favoring non-patent publication.[49] Some panelists concluded that internal PTO upgrades can accomplish only so much because the most relevant information is in the hands of applicants and their competitors.[50]

Information in the hands of applicants is the focus of the duty of candor.[51] PTO regulations provide:

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[44] *See* 35 U.S.C. § 122(b)(2)(B).

[45] *See, e.g.,* Lerner 2/20 at 162-63; Taylor 2/27 at 473 (discussing software); Scherer 7/10 at 69; Banner 10/30 at 75; *see also* Allison & Lemley, 82 B. U. L. REV. at 102 (finding, from a study of citations in a random sample of issued patents, that the "absence of non-patent prior art is particularly striking," despite having increased considerably during the twenty-year period studied).

[46] *See, e.g.,* Kirschner 2/26 at 289; Bendekgey 2/26 at 304; Friedman 2/27 at 355-56; Mowery 2/27 at 426; Aharonian 2/27 at 455-57; Webbink 3/20 at 100; Gable 3/20 at 114-15; *see also supra* Ch. 4(II)(E).

[47] *See, e.g.,* Mowery 2/27 at 426-27; Merges 2/28 at 633; Gable 3/20 at 117-18.

[48] *See, e.g.,* Chen 2/20 at 198-99 (describing the Business Methods Patent Initiative implementing an outreach program for improving access to non-patent prior art) and 2/27 at 424-25 (same); John Love 2/27 at 467-69 (same) and John Love Presentation at 6-10; *cf.* Alstadt 3/19 at 42 (noting efforts to improve search capabilities and examiner training with regard to computer-related technology). *But cf.* Taylor 2/27 at 473 (noting that longstanding recommendations for developing internal databases of non-patent prior art have not been implemented).

[49] *See, e.g.*, Kesan 4/10 at 57 (in software, "[T]here is no prior art being built up . . . because . . . the knowledge, the disclosure is not there"); Thomas 4/11 at 111 (finding no drive to publish business method prior art); Kahin 4/11 at 112 (the more abstract the subject matter, the more difficult to develop a consistent vocabulary).

[50] *See, e.g.,* Chen 2/26 at 300 (competitors have best access); Kesan 4/10 at 144-47 (those best informed are patentee and its competitors); Kushan 4/11 at 89 (inventors know more than the examiner about the technology and where to search for prior art); *see also* Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L. J. 763, 766-67 (2002). A PTO proposal to shift search functions to commercial contractors would not affect access to information in the hands of applicants and their competitors. *See* United States Patent and Trademark Office 21st Century Strategic Plan, *Certification of Searching Authorities* (April 2, 2003), *available at* http://www.uspto.gov/web/offices/com/strat21/action/q8p07_01.htm.

[51] Mechanisms for securing access to relevant information in the hands of competitors are addressed in the discussion of reexamination and opposition, *infra* at Ch. 5(III). Further mechanisms, authorizing third parties to file protests prior to publication of an application and to submit patents or publications (but no explanations thereof) within two months following publication of an application, have been little used. *See* 37 C.F.R. §§ 1.99 and 1.291; Dickinson 10/25 at 77-78; ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 19.7.2 at 452-53 (2003). *See generally infra* note 141 (discussing third

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . . .

37 C.F.R. § 1.56. This duty has several limitations. It imposes no requirement to search. The applicant must reveal material prior art that already is known but has no obligation to conduct a search that would bring additional prior art to his or her attention.[52] Moreover, the duty of candor is confined to the inventor named in the application and the attorneys and other persons who are substantively involved in preparing the application.[53] Consequently, prior art known to others in the inventor's laboratory may not have to be revealed.[54] Finally, the PTO's Manual of Patent Examining Procedure states that the agency "does not investigate" duty of disclosure issues and "does not . . . reject" applications on that basis.[55]

Third: The *ex parte* nature of the proceeding leaves the examiner on his or her own to evaluate and challenge applicants' assertions. Because the courts have placed the burden on the PTO to demonstrate grounds for rejecting a patent, rather than on the applicant to demonstrate that it meets the statutory criteria, difficulties in assembling responsive evidence work in favor of patent applicants. As the Court of Customs and Patent Appeals explained:

> We think the precise language of 35 U.S.C. § 102 that "a person shall be entitled to a patent unless," concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103 . . . [56]

The Federal Circuit has continued to place the burden of demonstrating unpatentability on the PTO.[57] Thus, "the burden of proof is on the examiner . . . . essentially the examiner has to establish a prima facie case of unpatentability on any of the patentability criteria."[58]

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party reluctance to submit prior art citations).

[52] *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 2001.06 (8th ed. 2001) (describing the duty in terms of "information [the covered individuals] are *aware* of") (emphasis original), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (hereinafter MPEP); Taylor 2/27 at 485-86.

[53] 37 C.F.R. § 1.56(c).

[54] *See* Taylor 10/25 at 53-54.

[55] *See* MPEP § 2010 (explaining that such Office determinations "would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest"); Chambers 2/8 (Patent Session) at 90. *See generally* Taylor 2/27 at 485-86 (noting the difficulty of policing a search requirement).

[56] *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967). The language relied upon, that a "person shall be entitled to a patent unless" appears in § 102 of the Patent Act, dealing with novelty but not in § 103 (dealing with nonobviousness) or § 112 (dealing with enablement, written description, best mode, and utility).

[57] *See, e.g., In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

[58] Kunin 4/10 at 85; *see also* Chambers 2/8 (Patent Session) at 88; John Love 2/28 at 627, 645.

Yet the PTO lacks testing facilities, and assertions that cannot be overcome by documentary evidence promptly identifiable by the examiner often must be accepted.[59] The PTO's Stephen Kunin made the agency's quandary plain:

> [T]o a large degree when the going gets tough, certainly the applicant is in the position to have the experts to do the testing, to submit documentary evidence to show why the examiner should allow the case. And, of course, as I said, we don't have laboratories, and we don't have independent experts in that regard. So therefore, we are really compelled to accept some of that, particularly from the standpoint of the fact finding, that is presented to us.[60]

The allocation of burden, coupled with examiners' limited ability to probe applicants' assertions, may explain the significant presumptions that favor applicants during patent examinations. Many of the key issues are rebuttably presumed in the applicant's favor.[61] Thus,

> "If the examiner does not produce a *prima facie* case [of obviousness], the applicant is under no obligation to submit evidence of nonobviousness."[62]
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> "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement . . . unless there is a reason to doubt the objective truth of the statements contained therein . . . ."[63]
>
> "The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with the assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution."[64]
>
> "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed."[65]

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[59] *See, e.g.,* Chambers 2/8 (Patent Session) at 70, 88-89; Thomas 4/10 at 141.

[60] Kunin 4/10 at 167.

[61] One panelist summarized, "[P]atent applicants are in a really great position because by filing an application they're presumptively entitled to receive the grant." Thomas 4/10 at 141.

[62] MPEP § 2142.

[63] MPEP § 2164.04 (citation omitted); *see also* Chambers 2/8 (Patent Session) at 70 ("when the application comes in there's a presumption at the Patent and Trademark Office that it is enabled"); *In re Marzoochi*, 439 F.2d 220, 223-24 (C.C.P.A. 1971).

[64] MPEP § 2165.03.

[65] United States Patent and Trademark Office, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112 ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1105 (2001) (noting, however, that applicants should show support in the original disclosure for new or amended claims); s*ee* Chambers 2/8 (Patent Session) at 97, 100.

> "Office personnel . . . must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement."[66]

Even when examiners develop a *prima facie* case against patentability, they often lack the ability to probe behind the expert affidavit filed by the applicant in response, and the PTO may be compelled to accept the affidavit's opinions and assertions.[67]

Fourth: Some testimony suggested that the PTO's *ex parte* exposure only to applicants in the course of its examination processes might limit its perspectives in ways that favor issuing patents. Panelists cited recent PTO planning documents, subsequently revised, that had identified patent applicants, rather than the general public, as the agency's customers, and that had viewed the agency's mission as helping those "customers" get patents.[68] Some warned that these narrow perspectives could affect examiners' perceptions of their roles[69] and might influence the agency to advocate unwarranted expansions of patent protection.[70]

C. Analysis

The Hearing record suggests that enhancing examiners' access to and ability to appreciate and deal with prior art and reducing uncertainty regarding pending patent claims could improve patent quality and remove impediments to competition. Turning first to the prior art issues, this section focuses on opportunities to learn more from applicants.[71] It discusses, without recommendation, proposals for increasing applicants' duty of candor by imposing certain duties of inquiry and then presents recommendations that (i) applicants submit relevance statements, upon request of the examiner, describing the prior art cited in connection with the patent application and (ii) the PTO enhance its use of examiner inquiries during the patent prosecution process. Then, directing discussion to business certainty regarding pending patent

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[66] United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1098-99 (2001) (hereinafter Utility Examination Guidelines). *See* Chambers 2/8 (Patent Session) at 96 (indicating that assertions of utility, if plausible, are accepted for utility determination purposes, but may be further scrutinized as part of the enablement inquiry).

[67] *See* Kunin 4/10 at 166-67; Chambers 2/8 (Patent Session) at 98; Utility Examination Guidelines, 66 Fed. Reg. at 1099 (examiners must accept opinion from qualified expert that is based on relevant facts whose accuracy is not questioned; "it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered").

[68] *See, e.g.,* Kahin 3/19 at 84, 86 and Brian Kahin, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (3/19/02) (slides) at 3, *at* http://www.ftc.gov/opp/intellect/020319briankahin.pdf; *see also infra* Ch. 6(III)(A)(3).

[69] Chambers 10/25 at 31-32 (examiners now view their role as serving patent applicants rather than protecting the public from bad patents).

[70] *See, e.g.,* Kahin 3/19 at 85 and 10/25 at 190-91.

[71] For discussion of ways to improve access to third parties' expertise and prior art, *see infra* at Ch. 5(III).

claims, it recommends building upon the current 18-month filing requirement by eliminating the opportunity of those who file only domestically to opt out of publication.

1. Duty of Candor

Hearing testimony generally indicated that, so far as it goes, the duty of candor induces substantial compliance.[72] Indeed, rather than a withholding of prior art, the more typical strategy may involve flooding the examiner with more citations than can be adequately reviewed.[73] In general, the record suggests that existing duties serve a useful function in prompting significant disclosure.[74]

Some of the panelists urged that the duty of candor be expanded to impose some obligation to search.[75] Indeed, the PTO's 21st Century Strategic Plan initially included a proposal to supplement the duty of candor by imposing a requirement that the applicant search prior art already in his or her possession.[76] Another modification discussed during the Hearings would extend the disclosure duty to an inventor's co-employees. Some panelists opposed expanded search duties as adding to patent preparation costs, raising difficult enforcement problems, fueling frivolous inequitable conduct defenses, or not necessarily contributing additional useful disclosure.[77]

The Hearing record does not permit full assessment of the proposed revisions to the duty of candor. The cost of added search responsibilities is unclear, as is the ability to enforce effectively new obligations. Given these uncertainties, and the skepticism expressed by panelists with diverse backgrounds and varying viewpoints regarding potential benefits of an expanded duty, the Commission makes no recommendation on this topic.

2. Relevance Statements

Citing applicants' proclivity to

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[72] *See, e.g.,* Gabel 3/20 at 168; Taylor 10/25 at 53. *But cf.* Burk 3/20 at 168 (characterizing current duties as "toothless" in the sense that noncompliance penalties are rare).

[73] *See, e.g.*, Thomas 4/10 at 167-68; Kesan 4/10 at 171-72 ("You just simply . . . throw everything over the fence") and 10/25 at 61; *but cf.* Garner 10/25 at 70-71 (no flooding in the "garden variety" case). Once the patent issues, the panelists explained, any prior art cited to an examiner is virtually "bulletproof" in court, so applicants may benefit from flooding the examiner with citations. *See, e.g.,* Kesan 4/10 at 171 and 10/25 at 61.

[74] *See, e.g.,* Taylor 10/25 at 53; Chambers 10/25 at 65 (duty of candor serves a useful function in an *ex parte* system); Gambrell 10/25 at 69-70; Garner 10/25 at 70; Kushan 10/25 at 73 (current rule "overall . . . is providing the right kind of impetus to disclose"). *But cf.* Linck 10/25 at 55 (arguing that firms would provide more useful information if not for the fear of violating the duty of candor).

[75] *See, e.g.,* Aharonian 2/27 at 457. *See generally* Gambrell 10/25 at 70 (duty of candor should be strengthened).

[76] United States Patent and Trademark Office 21st Century Strategic Plan*, Mandatory Information Disclosure Statements (IDS)*, P-09 at 3 (June 3, 2002). On February 3, 2003, the PTO announced, based on "feedback" received in the interim, that the proposal has been dropped. *See* United States Patent and Trademark Office, The 21st Century Strategic Plan, *available at* http://www.uspto.gov/web/offices/com/strat21/index.htm.

[77] *See, e.g.,* Taylor 2/27 at 485-86, 10/25 at 54; Thomas 4/10 at 167 (questioning need for strengthening duty of candor); *cf.* Parkhurst 4/10 at 168 (finding the current duty of candor at about the right level). One panelist testified that the PTO's proposal to require applicants to search documents in their own possession had aroused substantial opposition from members of the patent bar. *See* Dickinson 10/25 at 50-51.

overwhelm examiners with numerous prior art citations, resulting in lots of "information" but little "knowledge,"[78] some panelists suggested that this burden could be better managed, and examination quality enhanced, if applicants were required to state the relevance of the materials cited.[79] PTO testimony indicated that this could significantly lighten examiners' burdens.[80] Indeed, the 2002 version of PTO's 21st Century Strategic Plan proposed requiring applicants to provide statements of relevance when citing more than 20 prior art references,[81] but that proposal has now been withdrawn.[82]

At the Hearings, relevance statements drew criticism on two accounts. Some of the testimony expressed concern that even slight errors in description could fuel claims of mischaracterization and inequitable conduct.[83] Other testimony focused on the cost.[84] One panelist noted that the PTO at one time required a synopsis of references but abandoned the requirement because of the expense that it had imposed in requiring attorneys to understand and properly describe all references.[85] Suggesting an alternative, two panelists indicated that it might be useful merely to require that applicants identify the most relevant references.[86] Another urged that any problem with excessive references could be managed by allotting examiners additional time in relation to the amount of prior art cited and collecting correspondingly greater fees.[87]

Recommendation. The Commission recommends that the PTO amend its regulations to require that, upon request of the examiner, applicants submit statements of relevance regarding their prior art references. The Hearing record suggests that such statements could materially enhance examiners' ability meaningfully to analyze applications during the finite time available, reducing the opportunity for error and enhancing the efficiency of the examination

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[78] *See* Kesan 10/25 at 60-61.

[79] *See* Kesan 4/10 at 147-48, 171-73 and 10/25 at 62; Parkhurst 4/10 at 168; *cf.* Aharonian 2/27 at 458-59 (urging that a way be found for applicants to better identify how their invention improves on the prior art).

[80] *See* Kunin 4/10 at 164 ("because there's no requirement in the existing rules to identify relevancy of, in particular, U.S. patents, then the burden obviously is substantially on the examiner to acquire all the information").

[81] 21st Century Strategic Plan*, Mandatory Information Disclosure Statements (IDS)*, P-09 at 3 (June 3, 2002).

[82] *See* The 21st Century Strategic Plan, *available at* http://www.uspto.gov/web/offices/com/strat21/index.htm. The plan's current version, nonetheless, continues to acknowledge the potential benefit of relevance statements: applicants seeking to take advantage of a proposed accelerated examination procedure would need to "identify . . . [references] deemed to be the most closely related to the claimed subject matter and include a relevancy discussion for each reference identified." United States Patent and Trademark Office 21st Century Strategic Plan*, Accelerated Patent Examination* 2 (April 2, 2003), *at* http://www.uspto.gov/web/offices/com/strat21/action/aep10.htm.

[83] *See* Chambers 10/25 at 63-64; Garner 10/25 at 70. *See generally* Dickinson 10/25 at 50-51 (noting the patent bar's concern that prior art descriptions could raise malpractice issues).

[84] *See, e.g.,* Garner 10/25 at 71.

[85] *See* Chambers 10/25 at 63.

[86] *See* Gambrell 10/25 at 67-68; *see also* Kesan 4/10 at 173 ("some [references] are more important than others. And the Patent Office should know that.").

[87] *See* Garner 10/25 at 165-66.

process.[88] Objections appear surmountable. Requiring the submissions only upon the examiner's request would appropriately confine costs; when prior art references are small in number or readily reviewed and understood, applicants may face no additional burden, and the examiner sometimes may narrow the issues before selecting particular references for explanation. Indeed, current practice requires applicants to provide a "concise explanation of the relevance, as it is presently understood" of foreign-language prior art,[89] so it is clearly possible to provide explanations when benefits are likely to be high.[90] Although concern that mandatory statements of relevance could give rise to dubious allegations of inequitable conduct is well taken, the record suggests that the law in recent years has developed in ways that reduce the potential for abuse.[91] Given the need to draw more fully upon applicants' knowledge to improve patent quality within the limitations of the examination system, selective requirement of relevance statements would provide a useful, and potentially highly beneficial, new tool.

3. Examiner Inquiries

A number of panelists suggested that greater use could be made of PTO Rule 105, which permits examiners to request "such information as may be reasonably necessary to properly examine or treat the matter . . ."[92] Under existing regulations, such requests might seek, for example, copies of patent or non-patent literature used in the invention process or related to the claimed invention; a description of any search that had been conducted; and identification of whatever products or processes the claimed invention improves.[93] Proponents argued that Rule 105 presents substantial opportunities to improve patent examinations[94] but noted that it has not been much used, perhaps because of examiners' time constraints.[95] Very recently, however, PTO proposed amending Rule 105 to make expanded use of examiner inquiries by placing greater emphasis on seeking information through interrogatories and clarifying the record through stipulations.[96] Particularly in view of these proposals, requests for relevance statements,

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[88] Even a critic of the proposal implicitly acknowledged that relevance statements could provide benefits. *See* Garner 10/25 at 166 (suggesting fee discounts for applicants who state the relevance of references). *cf.* Kushan 10/25 at 74-75 (questioning the value of relevance statements, given that examiners can read and understand the material, yet acknowledging value in pointing examiners to the specific portion of a reference warranting greatest attention).

[89] 37 C.F.R. § 1.98(a)(3)(i) and § 1.56(a).

[90] *See* Parkhurst 4/10 at 168 (suggesting that relevance disclosure practices pertinent to foreign language prior art be extended to prior art in English).

[91] *See* Kesan 4/10 at 147 ("The standards for inequitable conduct, especially the intent requirement, have been set very high."); Wamsley 7/10 at 18-19 (suggesting that with clarification of the law as to materiality and intent in fraud and inequitable conduct cases, "we don't see as many people raising complaints of that nature now").

[92] 37 C.F.R. § 1.105.

[93] 37 C.F.R. § 1.105(a)(1).

[94] *See*, *e.g.,* Thomas 4/10 at 176-78; Parkhurst 4/10 at 168-69; Kushan 4/11 at 89-90 and 10/25 at 75-76; Dickinson 10/25 at 78.

[95] *See* Thomas 4/10 at 176-77; Kushan 4/11 at 90 and 10/25 at 78.

[96] *See* United States Patent and Trademark Office, *Changes to Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan*, 68 Fed. Reg. 53816, 53832, 53852-53 (Sept. 12, 2003).

as discussed *supra* in Ch. 5(II)(C)(2), might appropriately be added to the examples of authorized examiner inquiries.[97]

Recommendation. The Commission recommends a concentrated effort to use examiner inquiries more often and more extensively. As panelist Jeffrey Kushan emphasized, "to get better quality and shrink the amount of work," there is need to call more on the knowledge in possession of applicants, who typically "know more about the technology than the examiner does, and where you might find something that might be relevant."[98] Unfortunately, one aspect of the governing regulation appears counterproductive:

> Any reply that states that the information required to be submitted is unknown and/or is not readily available to the party or parties from which it was requested will be accepted as a complete reply.[99]

As discussion at the Hearings indicated, such ready acceptance of excuses might hinder the rule's effectiveness,[100] and the Commission urges that the regulation be reformulated to permit reasonable follow-up and to encourage more complete disclosure.

[97] *Cf.* United States Patent and Trademark Office, 68 Fed. Reg. at 53832 (indicating that expanded application of Rule 105 would cover inquiries directed at an "applicant's interpretation of which portions of each claim correspond to the admitted prior art in the specification").

[98] *See* Kushan 4/11 at 89.

[99] 37 C.F.R. § 1.105(a)(3).

[100] *See* Thomas 4/10 at 177-78.

4. Publication of Applications

As explained *supra* at Ch. 5(II)(B), most patent applications are now published 18 months after filing. Although applicants who file only domestically may opt out of such publication, roughly 90% of all applications are published.[101] Several panelists found the publications beneficial and emphasized their contribution to business certainty and rational planning.[102]

[101] *See* John Love 2/28 at 647 ("very few people opt out of publication"). Patent applicants are protected from pre-issuance copying of their inventions by statutory royalty rights, provided that the patent ultimately issues. 35 U.S.C. § 154(d).

[102] *See, e.g.,* Oehler 2/26 at 253; John Love 2/28 at 647; Gable 3/20 at 118-19; Casey 4/9 at 32. Other testimony, however, sounded a cautionary note. *See* Hayes-Rines 3/19 at 116-17 (cautioning against creating publication rules without studies to determine effects on independent inventors). As described by one commentator, the 18-month publication requirement enacted in 1999 was compromise legislation, an effort to reconcile the interests of those who wanted the benefits of early access to patent disclosures and those who sought to preserve that information as trade secrets until the time of patent issuance. *See* Reiko Watase, *The American Inventors Protection Act of 1999: An Analysis of the New Eighteen-Month Publication Provision*, 20 CARDOZO ARTS & ENT. L.J. 649, 667 (2002). Proponents of pre-grant publication cited, *inter alia*, the value of early disclosure of new technology and the benefits to business planning from reducing exposure to unanticipated "submarine" patents. *See id.* at 672-73, 676-78. Opponents argued that pre-grant publication would be "particularly damaging for small business entities and individual inventors because their trade secrets would be revealed to the public before patent rights are granted, allowing larger companies to exploit their trade secrets." *Id*. at 667-68. The statutory royalty rights provided by 35 U.S.C. § 154(d) dealt with these concerns for cases in which a patent ultimately issues; the ability to opt out of publication by filing only domestically addressed concerns of those whose inventions prove unpatentable. *See id*. at 679, 682. For additional background concerning the debates leading up to the 18-month publication requirement, *see Symposium, Early Patent Publication: A Boon or a Bane? A Discussion on the Legal and Economic Effects of Publishing Patent Applications after Eighteen Months,* 16 CARDOZO ARTS & ENT. L.J. 601 (1998).

Some panelists suggested that further benefits could flow from publishing all applications after 18 months.[103] American Intellectual Property Law Association President Ronald Myrick expressly recommended eliminating the ability to opt out of publication,[104] and this proposal is part of the PTO's 21st Century Strategic Plan.[105] Similarly, both the 1992 Advisory Commission on Patent Law Reform[106] and the 1966 President's Commission on the Patent System[107] recommended early publication of all applications. As the 1966 Report explained, "Early publication could prevent needless duplication of the disclosed work, promote additional technological advances based on the information disclosed, and apprise entrepreneurs of their potential liability."[108]

Recommendation. In view of the benefits of publication to business certainty and the potential competitive harms and hold-up opportunities that flow from unanticipated "submarine" patents,[109] the Commission recommends legislation requiring publication of patent applications 18-months after filing, whether or not the applicant also has sought patent protection abroad.[110] The PTO could use its planned public comment period to explore the costs and benefits of mechanisms for according any necessary protection to independent inventors.[111]

III. REEXAMINATION, OPPOSITION, AND REVIEW

Considerable discussion at the Hearings focused on issues of reexamination and proposals for opposition and post-grant review. Current procedures have significant limitations, and several of the panelists suggested possible enhancements. Panel discussion made evident that, in this area, choices necessarily reflect the initial goals. As one panelist phrased it, much follows from determining whether the intention is to provide a mechanism for limited error

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[103] *See* Myrick 3/19 at 21 and 10/30 at 127; Casey 4/9 at 32; *cf.* Oehler 2/26 at 254 (emphasizing that even 18 months can "seem like an eternity" to a firm trying to determine if it is free to operate).

[104] *See* Myrick 3/19 at 21 and 10/30 at 127.

[105] United States Patent and Trademark Office 21st Century Strategic Plan*, Eighteen Month Publication – Elimination of Non-Publication and Redaction Exceptions and Exclusions of Plant Applications* (April 2, 2003), *at* http://www.uspto.gov/web/offices/com/strat21/action/lr1hp67.htm. The PTO indicates that as a first step, it will publish, and receive comments on, the proposed legislative change. *Id*.

[106] THE ADVISORY COMMISSION ON PATENT LAW REFORM, REPORT TO THE SECRETARY OF COMMERCE 23 (Aug. 1992) (Recommendation III-A(i): "Publish patent applications within 24 months from the earliest priority date claimed . . ."), *available at* http://world.std.com/obi/USG/Patents/overview .

[107] REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM at 16 (Recommendation VII: "Publication of a pending application shall occur eighteen to twenty-four months after its earliest effective filling date . . ."), *reprinted in* TO PROMOTE THE PROGRESS OF THE USEFUL ARTS, SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 90TH CONG., 1ST SESS. (1967) (hereinafter 1966 REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM).

[108] *Id*. at 17.

[109] *See supra* Ch. 4(II)(C)(1).

[110] To protect against pre-issuance imitation following publication of the applications, the provisional royalty rights already provided by 35 U.S.C. § 154(d) should extend to all applications published after 18 months. *See supra* note 101.

[111] *See supra* notes 102 and 105.

correction or to afford a serious alternative to litigation.[112]

A. Current Procedures

The PTO traditionally has employed an *ex parte* reexamination procedure. Any person at any time may file a request for reexamination, and if the request raises a substantial new question of patentability affecting any claim of the patent, reexamination is commenced.[113] The same *ex parte* procedures that apply to initial examinations govern traditional reexamination.[114] Patentees often invoke reexamination themselves, seeking to insulate their patents from late-surfacing prior art by cutting back the claims.[115] Potential infringement defendants frequently forgo reexamination, preferring the safeguards available in court and fearing that reexamination might weaken their position in litigation.[116]

Since 1999 patent law has also provided an *inter partes* reexamination proceeding. Any person at any time may request such a proceeding, and if the request identifies a substantial new question of patentability, the PTO Director opens an *inter partes* proceeding.[117] The procedures parallel those of initial examinations, but require service of documents on the third-party requester and permit the requester to file written comments each time the patent owner files a response to an action on the merits.[118] The requester thus has some ability to participate in writing, but no opportunity for discovery, cross-examination, or oral presentations. Third-party requesters are estopped from asserting in litigation the invalidity of any claim on any ground that the requester "raised or could have raised" during the *inter partes* proceeding.[119] Prior to enactment of a statutory amendment in November 2002, requesters could not appeal adverse decisions to the federal courts.[120] *Inter partes* reexamination has been rarely used – only four times between its enactment in 1999 and the time of the Hearing record.[121] Panelists cited concerns with the estoppel and (original) appeal provisions as well as fears that reexamination would unduly favor the patentee as reasons why *inter partes* reexamination has been virtually ignored.[122]

Both types of reexamination limit the issues that may be considered. The proceedings are confined to issues of novelty

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[112] *See* Janis 4/10 at 182-84.

[113] 35 U.S.C. §§ 302-04. In addition, the PTO's Director may order a reexamination on his or her own initiative. 35 U.S.C. § 303.

[114] Nydegger 4/11 at 134.

[115] *See* Hall 2/28 at 760-63 (citing data showing 50% of reexaminations are requested by the patentee); Mowery 2/27 at 408 (same); Telecky 2/28 at 759, 762.

[116] *See, e.g.,* Lerner 2/20 at 196; Seide 3/19 at 220; Casey 4/9 at 69-71; Janis 4/10 at 182-83; Nydegger 4/11 at 134-35.

[117] 35 U.S.C. §§ 311-313.

[118] *Id.* § 314.

[119] *Id.* § 315(c).

[120] *Id.* § 315(b) (amended 2002).

[121] *See* Kunin 7/10 at 70; Nydegger 4/11 at 141 ("[T]hat is virtually no effect. It is, for all practical purposes, unsuccessful.").

[122] *See, e.g.*, Janis 4/11 at 125-26; Stoll 4/11 at 130; Burchfiel 4/11 at 131-32; Kesan 4/10 at 150-51 and 10/25 at 85; Kushan 10/25 at 105.

and nonobviousness based on prior art in the form of patents or printed publications.[123] Reexamination does not permit challenges to enablement, written description, best mode, or utility.

B. Proposals for Reform

The Hearings addressed several different proposals for reform. Most fit within one of three categories.

1. Enhanced *Inter Partes* Reexamination

Some panelists urged that reexamination procedures be improved.[124] They focused greatest attention on *inter partes* reexamination. Participants indicated that the recent enactment of legislation to permit third-party requesters to appeal adverse decisions to the Federal Circuit will prove a significant step toward making *inter partes* procedures viable.[125] Several argued that a necessary further step is some loosening of the estoppel provisions, perhaps by invoking estoppel only if the third party appeals to the Federal Circuit.[126] A number of panelists also focused on the scope of reexamination, urging that it be broadened to cover topics such as enablement and written description.[127]

2. Post-Grant Opposition/Review

Other testimony supported a move toward post-grant oppositions or reviews.[128] Under these proposals, third parties would have more extensive participation rights than under *inter partes* reexamination. Thus, they might have opportunity to present oral testimony, cross-examine experts, and engage in limited discovery.[129] Such a proceeding normally would entail a fact-finding hearing before an adjudicator with greater legal training than most examiners possess. Subject matter might be broadened beyond novelty and nonobviousness to

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[123] *See* Chambers 2/8 (Patent Session) at 91-92; Janis 4/11 at 126 (suggesting that the limited subject matter discourages use of reexamination procedures).

[124] *See, e.g.,* Dickinson 2/6 at 65-66 ("the reexamination system is a very valuable one but it needs additional reform"); Gable 3/20 at 163; Linck 4/9 at 30, 68 and 10/25 at 17, 97-98; Kushan 10/25 at 106. (Panelists sometimes saw merit in multiple proposals, and identifying them as supporting one approach should not suggest their opposition to others.)

[125] *See, e.g.,* Bendekgey 2/26 at 303; Linck 10/25 at 82; Biotechnology Industry Organization, *Testimony* (2/26/02) 6 n.30, *at* http://www.ftc.gov/opp/intellect/020226davidwbeier.pdf.

[126] *See, e.g.,* Beier 2/26 at 301; Linck 4/9 at 66-67 and 10/25 at 82; Casey 4/9 at 71; Janis 4/10 at 185; Kushan 10/25 at 105-06. *But cf.* Garner 10/25 at 166-67 (arguing that third parties should be willing to present their prior art in reexamination rather than saving it for future litigation); Parkhurst 4/10 at 186 (if reexamination were broadened to include all attacks on validity, some form of estoppel could be retained).

[127] *See, e.g.,* Janis 4/10 at 184 (include enablement and other patentability issues); Parkhurst 4/10 at 186 ("open [reexamination] up to all attacks"); Kushan 10/25 at 100-01, 105-06 (include enablement and written description, with a time limitation); Dickinson 10/25 at 90-91 (urging expansion of Director-initiated reexaminations to include enablement and written description issues). Former Director Dickinson urged expanded use of Director-initiated reexaminations in general. *Id*. at 170.

[128] *See, e.g.,* R. Levin 2/6 at 103-04; Kirschner 2/26 at 244-45; Earp 2/26 at 291-92; Janis 4/10 at 184 and 4/11 at 146-47; Kunin 7/10 at 70; *see also* Gerald J. Mossinghoff, *Post-Grant Review of Patents: Enhancing the Quality of the Fuel of Interest*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 231 (2003).

[129] *See* Kushan 10/25 at 102-03.

include additional issues relevant to validity. Europe and Japan both have post-grant opposition procedures,[130] and the PTO has included a proposal for post-grant review in its 21st Century Strategic Plan.[131]

Skeptics feared that opposition procedures will be abused. They saw possibilities for expense and delay.[132] For example, former PTO Director Q. Todd Dickinson, although supporting an enhanced reexamination/opposition system, drew attention to the fears that have been expressed by the independent inventor community that oppositions could be used to impede their ability to assert their patents.[133] Some panelists questioned whether oppositions can ever meaningfully substitute for litigation,[134] and others expressed doubt that competitors will risk "paint[ing] big targets on themselves" by actively opposing others' patents.[135]

3. Pre-Grant Opposition

Other participants urged implementation of a pre-grant opposition system.[136] This would allow active participation by third parties prior to issuance of a patent. Some urged that pre-grant opposition would have the advantage of introducing third-party participation before the PTO is on record with a position, thereby avoiding any undue tendency to affirm prior acts.[137] Others, though, warned that the potential for delay and harassment may be particularly acute with regard to pre-grant opposition, which by its nature can slow issuance of a patent.[138]

C. Analysis

As former Director Dickinson explained, reexamination and opposition are means for "competitors to interact" with the patent process "much more efficiently and effectively" to "improve . . . the quality of patents that issue."[139] The various proposals for improving reexamination or creating a post-grant review process offer significant opportunities for enhancing patent quality and raising business certainty and focus directly on what are most likely to be economically significant patents. Such steps

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[130] *See, e.g.,* Earp 2/26 at 238, 291-92 (Europe); Nydegger 4/11 at 135-38, 144-45 (Europe); Thomas 4/11 at 142-45 (Europe); Maebius 4/11 at 149 (Europe), 150-52 (Japan).

[131] United States Patent and Trademark Office 21st Century Strategic Plan*, Post-Grant Review of Patent Claims* (April 2, 2003), *available at* http://www.uspto.gov/web/offices/com/strat21/action/sr2.htm; Kunin 7/10 at 70.

[132] *See, e.g.,* Beier 2/26 at 298 (citing delays experienced under the Japanese opposition system); *cf.* Linck 4/9 at 68 (oppositions are very time-consuming) and 10/25 at 81-82 (clarifying that she is "really not an opponent" of opposition systems).

[133] *See* Dickinson 10/25 at 88.

[134] *See, e.g.,* Gambrell 10/25 at 107-09.

[135] *See, e.g.,* Myrick 10/30 at 61 (noting the concern without rejecting the concept of opposition systems).

[136] *See* Kesan 4/10 at 150-52, 187-90 (noting a decline in the vigor of opposition activity in Japan and Germany following a switch from pre-grant to post-grant oppositions); Scherer 7/10 at 55; John H. Barton, *Reforming the Patent System* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/bartonjohnh.htm.

[137] *See* Kesan 4/10 at 150-52, 189-90.

[138] *See, e.g.,* Kunin 7/10 at 70-71 (citing foreign experience with pre-grant opposition).

[139] Dickinson 10/25 at 87-88.

help to promote competition and to foster continued innovation.[140] The Commission supports efforts to develop effective post-grant review procedures.

1. Efficient Quality Enhancement

Post-grant review offers substantial opportunities to improve patent quality by drawing upon the information and expertise of competitors. Under an *ex parte* system, access to competitors' knowledge is limited, at best.[141] In contrast, a competitor engaged in an administrative challenge to a patent will be well-positioned to supply the best prior art, as well as the expertise necessary to probe beneath the surface of an applicant's affidavits and declarations. As one panelist phrased it, "[W]hen you have an opposition procedure, those people who have information that is not within the domain of the patent examiner will bring that information forward and get the job done properly."[142]

Moreover, post-grant review offers a market-based means to focus the most intensive inquiry on the most significant patents. Trying to perfect all examinations might be exorbitantly costly and highly inefficient.[143] Too many applications are examined, and most involve claims of little economic significance.[144] Post-grant review lets the market decide which patents are worth the cost of intensive review and uses that market-based selection to reduce error costs while holding process costs down. Rather than spreading finite resources too thinly to do much good, it directs them toward important cases.[145]

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[140] *See id.* at 87 ("if you improve the re-examine/opposition system, you'll improve competition"), 89; *see also supra* Ch. 5(I).

[141] Pursuant to 35 U.S.C. § 301, "Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent." To date, however, this provision has been little utilized. *See, e.g.,* Casey 4/9 at 69 (expressing concern that submitting prior art in an *ex parte* context merely enables the applicant to strengthen the patent, while undermining the prior art on judicial review); Dickinson 10/25 at 170 (noting that litigators often advise against citing a competitor's best prior art to the PTO); Kahin 10/25 at 163, 167.

[142] Scherer 7/10 at 69; *see also* Lerner 2/20 at 191; Kesan 4/10 at 146-47; Merges, 14 BERKELEY TECH. L. J. at 614-15 ("We need to design a system that better taps into patent validity information, much of which is in private hands. Until we get better information in the system, the quality of patents will not improve.").

[143] *See* Dickinson 10/25 at 78 (estimating that increasing average examiner time per application costs $13-15 million per hour); Taylor 10/25 at 51.

[144] *See, e.g.,* Udell 2/28 at 568 (small percentage of patents actually reaches the market); Linck 4/9 at 30 (only a fraction of one percent of patents are actually litigated); Taylor 10/25 at 51-52; Kieff (stmt) 3-4.

[145] *See, e.g.,* Linck 4/9 at 30-31; Parkhurst 4/10 at 186. Stuart J. H. Graham et al., *Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 74, 114 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) (finding that in European oppositions "more valuable or technologically important patents . . . are more likely to trigger challenges"), *available at* http://books.nap.edu/books/0309086361/html/114.html (hereinafter *Patent Quality Control*). This analysis builds on the insights expressed by Mark Lemley in his journal article, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1495 (2001). Professor Lemley argues that "it is much cheaper for society to make detailed validity determinations in those few cases [in which patents are asserted against competitors] than to invest additional resources examining patents that will never be heard from again." "In short," he continues, "the PTO doesn't do a very detailed job of examining patents, but we probably don't want it to. It is 'rationally ignorant' of the objective validity of patents . . . ." *Id.* at 1497. Although the thrust of Professor Lemley's approach is to leave careful patent validity determinations to the courts, he observes that "an opposition system might be consistent with the insight of this article, if one believes that applications that are opposed tend to be the ones that are later litigated (or at

2. Timely Resolution of Uncertainty

Post-grant review offers an opportunity for timely resolution of uncertainty regarding patent validity. Such uncertainty harms competition and innovation by distorting business planning, increasing costs and risks, and interfering with the raising of capital and the negotiation of licenses.[146] Hearing testimony expressed concern with waiting for final judicial resolution of validity challenges, because this can come long after the damage has been incurred.[147] As panelist Robert Blackburn explained, "There certainly are areas of research that Chiron would have done, or would have pursued a little bit longer than it had if there had been an effective, cheap, quick way of testing the validity of a third-party patent."[148] Prompt administrative resolution of uncertainty through post-grant review would cut the delay and reduce the social harms.[149]

Significantly, if uncertainty regarding validity cannot be resolved through a relatively timely and less expensive administrative process, it may never be eliminated through litigation. Several panelists explained that incentives to challenge patents may be inadequate. Because the costs of a challenge are borne by the challenger, but the benefits of invalidation spill over to other potential licensees and to consumers, the private incentives to launch a challenge are less than would be warranted by the social return.[150] Procedures that reduce the private costs of challenging validity – such as administrative alternatives to full-blown litigation – are likely to better align private and social returns and thus to encourage efficient responses to patent quality issues.[151]

3. Offering Sufficient Value Without Duplicating Litigation

No post-grant procedure will be successful unless it is used. The virtually disregarded *inter partes* reexamination experience provides a case in point. Panelists noted the tension between keeping costs sufficiently low and outcomes sufficiently speedy, while simultaneously providing a scope and level of inquiry sufficiently high, to ensure broad use;

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least licensed)." *Id*. at 1525 (discussing, specifically, pre-grant oppositions).

[146] *See supra* Ch. 5(I).

[147] *See, e.g.,* Kirschner 2/26 at 244-45, 308-09 (noting the undesirable choice between "avoiding an area that otherwise you may have worked on and innovated within" and waiting until "you've spent your $800 million and 10 years in product development" to find out if you were right or wrong); *cf*. Nydegger 4/11 at 139 (describing value of administrative proceeding "to remedy the possible issuance of overly broad patents in a timely fashion"); J. Levin 10/25 at 93 (one of main economic benefits of an opposition is "to resolve uncertainties sooner").

[148] Blackburn 2/26 at 309.

[149] *See, e.g.,* R. Levin 2/6 at 103-04; Rai 4/10 at 196; Kesan 4/10 at 187-88 (oppositions in Germany provide early, clear signals to the marketplace of a patent's value), 196.

[150] *See, e.g.,* Gilbert 2/6 at 94-95; Thomas 2/8 (Patent Session) at 23; Farrell 2/28 at 603 and 11/6 at 181-82; Merges 2/28 at 590 ("no individual may have an incentive to invalidate it, even though we would all be better off if they did"). When multiple patents are involved, coordination problems may also abound. *See* Gilbert 2/6 at 95.

[151] *See, e.g.,* Kesan 4/10 at 174. In addition to the cost-related effects noted in the text, an administrative alternative to litigation may facilitate patent validity challenges currently delayed or barred by the standing requirement for bringing declaratory judgment actions. *See infra* Ch. 5(III)(C)(4).

careful balancing may be required.[152]

Panelists generally urged extending reviewable subject matter beyond the novelty and nonobviousness issues currently allowed.[153] Most favored extending the scope to include enablement and written description.[154] Some would include utility and patentable subject matter.[155] Indeed, the PTO's Strategic Plan recommends subjecting all issues of patent validity to its proposed post-grant review procedure.[156] In light of their potential competitive significance and their apparent susceptibility to administrative determination, the record as a whole suggests good basis for including at least nonobviousness, enablement, written description, and utility (in addition to novelty) as eligible subject matter in any post-grant review.

An administrative alternative to court litigation may well require a more thorough probing of the issues than is available through reexamination processes. The PTO's 21st Century Strategic Plan calls for documentary presentation of the case-in-chief followed by live cross-examination.[157] It also permits discovery "for good cause shown."[158] Cross-examination and an opportunity for appropriate discovery are likely to be needed if a review proceeding is to test an applicant's assertions and expert evidence on issues that extend beyond straightforward application of printed prior art,[159] particularly if the mandatory

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[152] *Compare* J. Levin 10/25 at 92-93 (noting need for careful "trade-off of keeping costs down versus providing a more thorough system") *and* Janis 4/10 at 184 (urging that a middle course involving post-grant oppositions be sought) *with* Thomas 4/11 at 143-44 (questioning whether oppositions less extensive than court litigation will work) *and* Gambrell 10/25 at 107 (questioning utility of reexamination/opposition efforts that may prove either too expensive or too cosmetic).

[153] *See, e.g.,* R. Levin 2/6 at 103; Janis 4/10 at 184; Parkhurst 4/10 at 186 ("open it up to all attacks").

[154] *See* Janis 4/10 at 184; Nydegger 4/11 at 138-40; Linck 10/25 at 96; Kushan 10/25 at 99-101. Substantial objections, however, were lodged against including challenges based on the "best mode" requirement, in view of the subjective nature of the inquiry, what some saw as the PTO's relative lack of expertise in dealing with such issues, and the costs and complexity that including best mode issues might introduce. *See, e.g.,* Linck 10/25 at 83, 96; Kushan 10/25 at 100. *See generally* Pooley 10/30 at 122 (best mode "interjects issues of state of mind"). On the other hand, the PTO already deals with best mode issues in the context of interference proceedings and consequently has some experience in resolving such issues. *See* 21st Century Plan, *Post-Grant Review of Patent Claims* at 6-7.

[155] *See* Nydegger 4/11 at 140; *but cf.* Kushan 10/25 at 101 (suggesting that "most of the utility issues that are going to be impacting on the claim scope are going to be properly raised under 112").

[156] 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 6-7 (allowing "any and all grounds that may be brought in a district court to challenge patent validity, but not to challenge patent enforceability" and explaining that this would allow the PTO "to use its expertise to check the quality of the patents and allow the district courts to use their expertise to determine issues such as fraud and inequitable conduct").

[157] 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 15.

[158] *Id*. at 12-14. The Strategic Plan also contemplates receipt of authority to impose sanctions "for failure to make disclosure or cooperate in discovery." *Id*. at 13-14.

[159] *See, e.g.,* Burchfiel 4/11 at 146 ("any re-examination worth doing would have to give the opponent a chance to cross examine and submit the depositions"); Kushan 10/25 at 105-06 (finding cross-examination needed to probe certain testimony, but favoring *inter partes* reexamination rather than post-grant opposition); Taylor 10/25 at 116-17 (indicating, as an example, that applicants sometimes conduct post-filing experiments that might have "enormous relevance" to enablement, but describing the discovery necessary to unearth that information as beyond his vision of PTO activity); *see also* Jonathan Levin & Richard Levin, *Benefits and Costs of an Opposition*

disclosure requirements initially sought by the PTO are withdrawn.[160]

Administrative review will also require a set of decision makers competent to handle the broader array of procedural and substantive issues that will flow from a fact-finding proceeding such as that outlined above.[161] Panelists indicated that the PTO is institutionally capable of providing this type of review, as demonstrated by its handling of *inter partes* interference proceedings.[162] Similar arrangements would be needed for post-grant review, and the PTO's 21st Century Strategic Plan would assign such review proceedings to administrative patent judges.[163] Reliance on independent judges would obviate many of the concerns expressed by some panelists with "post-decisional cognitive dissonance" arising from asking the PTO's corps of examiners to review its own decisions of record.[164]

4. Protecting Patentees from Harassment and Undue Delay

The record reveals substantial concerns that post-grant review proceedings could become very time consuming and might be used as vehicles for harassing patentees.[165] Although such concerns

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Process, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY at 120, 141 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) (recommending opportunity for cross-examination, but cautioning against "extensive" pre-hearing discovery), *available at* http://books.nap.edu/books/0309086361/html/141.html#pagetop; *cf.* Janis 4/11 at 147 ("we may end up with something that's administratively complex and not all that cheap, but we still may be better off than not having an effective system at all").

[160] *See supra* Ch. 5(II)(C).

[161] *See*, *e.g.,* Thomas 4/11 at 143; Janis 4/11 at 146, 154; Stoll 4/11 at 147; Linck 10/25 at 83; Kushan 10/25 at 101; Kesan 10/25 at 121-22.

[162] *See, e.g.*, Burchfiel 4/11 at 145; Stoll 4/11 at 147 ("we would be able to set up a system where we do cross examination, where we could do discovery"); Dickinson 10/25 at 90; *cf.* Linck 10/25 at 97 (noting that "the interference ALJs" believe that they can handle post-grant oppositions).

[163] 21st Century Strategic Plan*, Post-Grant Review of Patent Claims* at 2.

[164] *See, e.g.,* Kesan 10/25 at 86; Lerner 2/20 at 195-96; *cf.* Dickinson 10/25 at 167-68 (reexaminations no longer conducted by the initial examiner); Maebius 4/11 at 133 (same). Of course, *inter partes* reexamination would continue to play an important role of its own during the interim while a fully functioning post-grant review procedure is being put into place. Indeed, some panelists recommend retention of *inter partes* reexamination even after any post-grant review system is in operation. *See* Linck 10/25 at 96-97; Mossinghoff & Kuo, 85 J. PAT. & TRADEMARK OFF. SOC'Y at 253-54 (urging retention of current reexamination proceedings in addition to post-grant review). The PTO, in contrast, recommends eliminating *inter partes* reexamination upon implementation of post-grant review to make the most efficient use of its available examiners. S*ee* 21st Century Strategic Plan*, Post-Grant Review of Patent Claims* at 2, 20 (April 2, 2003) (noting that eliminating *inter partes* reexamination would "free examiners to examine applications and reduce pendency thereof"). PTO's concerns regarding the resource costs of offering two separate review procedures with third-party participation warrant considerable weight.

[165] *See, e.g.,* Linck 4/9 at 68 ("[o]ppositions go on for years and years and years") and 10/25 at 80-81; Dickinson 10/25 at 88 (reciting concerns of independent inventor community); J. Levin 10/25 at 92-93 (European oppositions cause 3-year delay); Merrill 10/25 at 94-95 (citing study showing that "length of time" is a "very significant problem" for European oppositions); Kushan 10/25 at 103-04 (absent a required threshold showing for initiating an opposition, "you can have people harassing you constantly"); Kesan 10/25 at 121 (warning against "a whole lot of discovery hearings and so on"); *but cf.* Maebius 4/11 at 150 (Japan has now increased the pace of opposition proceedings); Merrill 10/25 at 94 (study commissioned by the National Academy of Sciences shows that "the European opposition system has not been subject to the fears or concerns of the independent inventor community . . . . small entities have fared as well as large entities in European oppositions"); Graham *et al.*, *Patent Quality Control* at 108-09 (presenting regression results "suggestive that patents held by independent inventors are

warrant careful attention, several protections are available. Conducting review on a post-grant basis limits the effects of any harassment strategies.[166] Threshold showings may be required,[167] and time limits may be imposed on seeking post-grant review.[168] The former would ensure that reviews do not go forward on clearly spurious grounds, and the latter would contribute to administrative finality and protect against ongoing harassment of patentees. Once initiated, the post-grant review can be conducted under a defined time schedule,[169] and the availability and extent of discovery can be controlled.[170] Although standing requirements for seeking review might add further protection, the Hearing record suggests that such requirements have impeded early resolution of uncertainty through declaratory judgment challenges to patent validity in federal court and may not fit well with the goals of post-grant review.[171]

5. Recommendation

The Commission supports the PTO's efforts to establish a procedure for post-grant review of patent claims. Post-grant review offers greater value to challengers and a more thorough probing of the issues than *inter partes* reexamination, with less opportunity for delay and harassment than pre-grant opposition. The Commission recommends that (i) Congress enact legislation providing for post-grant review of patentability determinations including, at

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no more likely to be opposed [in a European opposition proceeding] than other patents, other things being equal.")

[166] *Cf.* Kunin 7/10 at 133 (foreign experience revealed *pre-grant* opposition as "a form of applicant harassment").

[167] For example, the current threshold for triggering an *inter partes* reexamination is "a substantial new question of patentability affecting a claim of a patent. . . ." 35 U.S.C. § 313. An alternative suggested by one panelist would be "something . . . like the prima facie standard for obviousness." Kushan 10/25 at 104. The PTO's 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 12, would allow the Director to issue a regulation specifying a time by which a petitioner must file its supporting information, after which the petition would be dismissed "if the showing is insufficient to justify proceeding."

[168] 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 5-6 (requiring that a petition for review be filed either within 12 months of the issuance of any claim challenged or within four months after the review petitioner is placed in "substantial apprehension" of being sued for infringement). Portions of the Hearings testimony suggested that a rigid, one-year limit might be inadequate, *see* Linck 10/25 at 83 ("Oftentimes you aren't even aware that a patent is a problem until much longer after the patent issues."); Kesan 10/25 at 85 (a one or two year limit "can be problematic"); Kushan 10/25 at 99-100, 105 (favoring *inter partes* reexamination allowing open-ended treatment of prior art issues but imposing a 2-3 year limit for challenges based on enablement or written description), but that some form of limit might have benefits. *See* J. Levin 10/25 at 93 (noting that a time limit would motivate early resolution of uncertainty regarding a patent's validity).

[169] Thus, the PTO envisions a post-grant review procedure designed to be completed in one year, pursuant to a statutorily-specified goal and regulations designed to meet it. 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 2, 17-18. Similarly, the Federal Trade Commission conducts certain adjudicatory proceedings under a time schedule specified by regulation. *See* 16 C.F.R. § 3.11A.

[170] *See* 21st Century Strategic Plan, *Post-Grant Review of Patent Claims* at 12-14 (proposing to allow discovery "for good cause shown," thereby permitting the PTO "to determine whether the discovery is appropriate, and restrict its nature and volume").

[171] *See* Blackburn 2/26 at 294-96 ("you cannot begin a D.J. action and challenge the validity of a patent unless you've been threatened with litigation by the patent owner. And usually people are not dumb enough to do that . . . there are these bad patents that sit out there and you can't touch them."); Nydegger 4/11 at 149 (absence of a standing requirement is consistent with the goal of inducing the public to proactively challenge invalid patents before problems develop).

a minimum, issues regarding novelty, nonobviousness, written description, enablement, and utility; (ii) such a review proceeding be initiated or allowed to be maintained only upon a suitable threshold showing by the review petitioner; (iii) an administrative patent judge preside over the review proceeding; (iv) the review proceeding allow cross-examination of witnesses and appropriate, carefully circumscribed discovery; (v) the review proceeding be conducted within defined time limits and under sanctions authority necessary to control proceedings of this nature; (vi) limitations be established to protect against undue delay in requesting post-grant review and against harassment through repetitive petitions for review; (vii) settlement agreements (including collateral agreements referred to therein) resolving post-grant review proceedings be filed with the PTO and made available, on written request, to other government agencies under terms comparable to those currently applicable to settlements of interferences;[172] and (viii) such a post-grant review proceeding be declared a delegation of authority permitting the ensuing PTO conclusions of law to carry the force of law.[173]

[172] *See* 21st Century Strategic Plan*, Post-Grant Review of Patent Claims* at 21-22 (recommending that post-grant review settlement agreements be filed with the PTO); 35 U.S.C. § 135(c) (governing filing of and access to interference settlement agreements); 37 C.F.R. § 1.666 (same).

[173] According to the Supreme Court's recent opinion in *United States v. Mead Corp.*, 533 U.S. 218 (2001),

> administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.

533 U.S. at 226-27 (*citing Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)). "It is fair to assume generally," the Court continued, "that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *Id.* at 230. Commentators have expressed uncertainty as to whether existing examination/reexamination procedures would constitute the "relatively formal administrative procedure[s]" that would trigger *Chevron* deference under *Mead*. *See* ROBERT MERGES & JOHN DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1167-68 (3d ed. 2002). Whatever the status of existing procedures, the Commission's recommendation is intended to confer such deference regarding conclusions of law reached in post-grant review proceedings. Both panelists and a prior patent reform commission have urged similar measures. S*ee* Rai 4/10 at 42 (urging greater judicial deference to PTO's application of substantive patentability criteria); *see also* Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J. L. & POL'Y 199 (2000); *cf.* Kunin 4/10 at 45-49 (urging that the PTO be granted substantive rulemaking authority in order to qualify for *Chevron* deference); 1966 REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM at 26 (Recommendation XIII: "A Patent Office decision refusing a claim shall be given a presumption of correctness, and shall not be reversed unless clearly erroneous."); *but cf.* Duffy 7/10 at 123 (cautioning that judicial "tweak[ing]" of deference standard may not greatly affect Federal Circuit practices).

IV. PATENT LITIGATION

A. General Trends

Testimony revealed that patent litigation, like the number of patents issued, has increased greatly in recent years, tripling between 1981 and 2000.[174] Some perceived more suits by large firms against smaller firms and entrants; more suits by niche rivals against each other; and more suits by

[174] *See, e.g.,* Lerner 2/20 at 157-58 and Lerner 2/20 Presentation at 6.

organizations not active in the market.[175] Several panelists voiced concern that the high cost of litigation may work to the disadvantage of small firms, pressuring them to settle when accused and discouraging them from asserting their own patent rights.[176]

A number of panelists cited data suggesting overall trends favorable to patentees since creation of the Federal Circuit in 1982.[177] Yet, the situation today is probably more complex. Considerable testimony indicated that with the advent of the Federal Circuit, patents typically have become easier to get, but more difficult to infringe, *i.e.,* we are seeing more, but narrower, patents.[178] Recent statistical data back both trends.[179] In particular, panelists cited trends toward easing the nonobviousness requirement but tightening breadth-determining factors such as the doctrine of equivalents and, at least in biotech cases, written description.[180] In view of this conflation of opposing trends, a number of panelists concluded that the

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[175] *See* Lerner 2/20 at 158-61; Ziedonis 3/20 at 70-71.

[176] *See, e.g.,* Lerner 2/20 at 159-60; Arora 2/25 at 73; Barton 2/26 at 213; Kahin 3/19 at 89-90; Cohen 10/30 at 78.

[177] *See, e.g,* Lerner 2/20 at 156-57 and Lerner 2/20 Presentation at 5 (percentage of appellate rulings upholding infringement rose markedly during the Federal Circuit's first eight years); Katsh 4/10 at 179 (percentage of patents invalidated fell dramatically following formation of the Federal Circuit); Scherer 7/10 at 33 (percentage of litigated patents determined to be either invalid or not infringed declined substantially following formation of the Federal Circuit).

[178] *See, e.g.,* Lunney 7/10 at 31, 91; Duffy 7/10 at 184-85; Dreyfuss 7/10 at 196-97 and 7/11 at 174; Quillen 7/11 at 156 (finding lower standards for patentability); Myrick 3/19 at 46 (citing trend against finding infringement). Software patents, however, were identified as a possible exception. *See, e.g.,* Burk 7/10 at 187.

[179] Thus, with regard to validity, data showed that 54% of final, published district court and appellate decisions during the 1989-96 period found patents valid, compared to only about 42% and 34%, at the district court and court of appeals levels, respectively, during the 1953-78 period prior to the formation of the Federal Circuit. *See* Allison & Lemley, 26 AIPLA Q. J. at 205 (studying 1989-96 period); GLORIA K. KOENIG, PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS 4-18 to 4-19, 4-21 to 4-23 (1980) (studying the 1953-78 period). The studies also revealed a second relationship that may better account for any self-selection bias in the nature of cases filed: in the 1989-96 period, district court determinations of patent invalidity were reversed 23% of the time, but district court determinations of validity were reversed only 10% of the time. Allison & Lemley, 26 AIPLA Q. J. at 241-42. "[I]n stark contrast," *id*. at 242, during the 1953-78 period, district court validity holdings were reversed substantially more often than district court invalidity rulings. *See* KOENIG, PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS at 4-34 to 4-41. The data suggest that the courts, particularly at the appellate level, may have grown more willing over the years to find patents valid. One further study, focused just on appellate rulings pre- and post-formation of the Federal Circuit, again showed a higher percentage of invalidity determinations during the earlier period (56% versus 49%), but the difference was not statistically significant. *See* Lunney 7/10 at 92-93.

In contrast, with regard to infringement, the data suggests that the Federal Circuit has not been supportive of patentees. *See* Myrick 3/19 at 46 (stating that in 2000 "[p]atent owners won only 12 decisions in the literal infringement area, while accused infringers won 47" and that under the doctrine of equivalents "patentees won five, while accused infringers won 44), *citing* Paul M. Janicke, *To Be or Not To Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit (1887 - 1982)*, 69 ANTITRUST L. J. 645, 665 n.117 (2002).

[180] *See, e.g.,* R. Levin 2/6 at 102-03 (discussing obviousness); Duffy 7/10 at 184 (discussing written description and doctrine of equivalents); Taylor 7/11 at 137 (discussing written description); American Bar Association Section of Intellectual Property Law, *Statement of Robert P. Taylor on Behalf of Section of Intellectual Property Law American Bar Association on Competition and Intellectual Property Law and Policy In the Knowledge-Based Economy* (7/11/02) 8 (discussing written description), *at* http://www.ftc.gov/opp/intellect/020711robertptaylor.pdf.

overall picture cannot simply be portrayed as pro-patent.[181]

Nonetheless, the trends in validity rulings, coupled with the strong competitive concerns implicated by the quality of patents, direct attention to the nature of validity litigation. The evidentiary burdens that govern this process are the focus of the next section.

B. Presumption of Validity/Clear and Convincing Evidence

The Hearings focused attention on the significance attached in litigation to the issuance of a patent. The issue has two aspects. First, the Patent Act creates a presumption of validity applicable when a patent is challenged in federal court: "A patent shall be presumed valid."[182] Second, the Federal Circuit has interpreted this requirement to impose a clear and convincing evidence standard on those who challenge validity.[183] Both the presumption and the clear and convincing evidence standard apply even when a patent is challenged on the basis of prior art that the PTO never saw, although, in such circumstances, the new evidence may "carry more weight and go further toward sustaining the attacker's unchanging burden."[184] The combination of the presumption and standard of proof drew considerable attention from the panelists.

Critics questioned whether that combination can be justified. Some noted the disparity between directing the PTO to issue patents based on an assessment of a mere preponderance of the evidence and subjecting third parties who challenge those patents to a higher standard of proof.[185] Others questioned whether there was a logical basis for extending the presumption or standard to challenges based on prior art that the PTO had never considered.[186] Several of the panelists took a pragmatic perspective, questioning whether the limited examination possible in terms of hours available and ability to probe behind applicants' assertions justified the

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[181] *See, e.g.,* Kitch 2/20 at 67-68; Myrick 3/19 at 46; Duffy 7/10 at 184; Wamsley 7/10 at 194; *cf.* ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 161 (5th ed. 2002 Supp.) (concluding that the "patent enforcement pendulum is swinging toward a more neutral position" than one in which the enforcement climate under the Federal Circuit had "strongly favor[ed] the patentee").

[182] 35 U.S.C. § 282.

[183] *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir.), *cert. denied,* 469 U.S. 821 (1984); *SSIH Equipment S.A. v. United States Int'l Trade Comm.*, 718 F.2d 365 (Fed. Cir. 1983). Both cases relied upon the Supreme Court's opinion in *Radio Corp. of America v. Radio Engineering Laboratories*, 293 U.S. 1 (1934), which, spoke in terms of "more than a dubious preponderance" of evidence, "clear and satisfactory evidence," and evidence sufficient "to evoke a clear conviction," *id*. at 8-10, but did not expressly establish a clear and convincing evidence standard. Panelists generally attributed the clear and convincing evidence standard to the Federal Circuit. *See*, *e.g.*, Weinstein 2/27 at 533-34; Kesan 4/10 at 148.

[184] *See, e.g., American Hoist & Derrick*, 725 F.2d at 1360; Duffy 7/10 at 118, 120.

[185] *See, e.g.,* T.S. Ellis 7/11 at 118-19; Thomas 10/25 at 137-38; Gambrell 10/25 at 148.

[186] *See, e.g.,* Duffy 7/10 at 121 and John F. Duffy, *Nonobviousness: The Economics and Legal Process of the Doctrine* (7/10/02) (slides) at 17, *at* http://www.ftc.gov/opp/intellect/020710johnfduffy.pdf (hereinafter Duffy Presentation); Kushan 10/25 at 142; Gambrell 10/25 at 148.

presumption or the high standard of proof.[187]

Defenders of the presumption and standard urged that a finding of validity by a neutral government agency using a knowledgeable examiner justifies placing a heavy burden on challengers.[188] Some observed that the Federal Circuit has recognized that the challenger's burden is partially discharged when new, material prior art is presented, and argued that any remaining advantages flowing from the presumption and high standard of proof have little, or only a measured, practical effect.[189] Others, in contrast, asserted that the presumption and standard can have compelling effects on both judges and juries.[190] District Judge Ellis worried that the clear and convincing evidence burden may work to undermine the role contemplated by the patent system for court challenges to weed out faulty patents.[191]

Panelists put forward an array of possible changes. Some called for eliminating the presumption of validity,[192] at least in cases involving new, material prior art.[193] Other testimony focused instead on the standard of proof, urging that it be reduced from clear and convincing evidence to preponderance of the evidence.[194] Still other testimony suggested that the presumption of validity and/or the clear and convincing evidence standard might be applied only when a patent has undergone examination under a heightened disclosure requirement or has survived an *inter partes* reexamination or some form of opposition proceeding.[195]

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[187] *See. e.g.,* T.S. Ellis 7/11 at 118-19; Kirschner 2/26 at 289-90; Weinstein 2/27 at 533; Kesan 10/25 at 146; *cf.* Langenfeld 2/20 at 17 (deference to issued patents presumes high accuracy in examination process); Linck 4/9 at 67-68 (time pressures limit what practicably can be expected from examinations).

[188] *See* Garner 10/25 at 136, 163-64.

[189] *See, e.g.,* Garner 10/25 at 136; Linck 10/25 at 151-53; Taylor 10/25 at 158-60.

[190] *See, e.g.,* Seide 3/19 at 219 (because of the presumption of validity, the standard to invalidate a patent in court is "much higher" than the standard during examination); Gambrell 10/25 at 39-40 (the presumption of validity and clear and convincing evidence standard tell a jury that "unless we find something devastating[ly] effective against it, we're going to affirm it"), 150-51 (jurors "see the seal on the patent, they hear clear and convincing evidence, and their likelihood of going for the defendant is much slighter than it is for the patentee"), 153-54.

[191] *See* T.S. Ellis 7/11 at 119-20; *see also* Sung 2/8 (Patent Session) at 141-42 (noting possible *in terrorem* effect of presumption of validity and clear and convincing evidence standard against challenging invalid patents).

[192] *See, e.g.,* Friedman 2/27 at 357; Kieff 4/10 at 162 (decrease or eliminate presumption of validity).

[193] *See, e.g.,* Duffy 7/10 at 121 and Duffy Presentation at 17; Gambrell 10/25 at 148, 150-51. One panelist suggested that the presumption might be retained, but with a delayed effective date. Dickinson 10/25 at 91 (analogizing to incontestability of certain trademarks after five years).

[194] *See* Thomas 10/25 at 138; Gambrell 10/25 at 150-51; *see also* Lemley, 95 Nw. U. L. REV. at 1528-29; *cf.* Kunin 7/10 at 138 (preponderance of the evidence standard "perhaps being, let's say, a little bit more realistic from the standpoint of permitting the presumption to be rebutted").

[195] *See* Kesan 4/10 at 148-49, 10/25 at 62, 145-46; T.S. Ellis 7/11 at 126 (tying clear and convincing evidence standard to meeting enhanced disclosure requirements a good idea); *see also* Kesan, 17 BERKELEY TECH. L. J. at 773-75. *But see* Kushan 10/25 at 143 (unfair to withhold presumption of validity from a patent whose validity was never even questioned).

Analysis

As a simple matter of burden assignment, the presumption of validity is not objectionable. The patent has been examined and found valid by the PTO. If the patent subsequently is challenged, the burden of persuasion rests with the party seeking to overturn the PTO's ruling.[196]

But there is no persuasive reason why the level of that burden should be clear and convincing evidence.[197] As panelists underscored, the PTO's determinations supporting issuance of patents are based only on a preponderance of the evidence. Perhaps even more telling, those determinations are reached under tight time constraints and on an *ex parte* basis allowing minimal opportunity to hear a third party's opposing views. All the failings of *ex parte* examination discussed *supra* in Ch. 5(II) – limited examiner time, the limited nature of applicants' disclosure obligations, limited access to potentially vital prior art and third-party expertise, the need for examiners to accept applicant's positions on point after point under presumption after presumption – have profound implications given that the burden rests on the PTO to demonstrate that patents should not issue. Rather than suggesting a basis for weighting judicial review in the patentee's favor, these factors state a compelling case against imposing a heightened evidentiary standard on those challenging patent validity.[198]

Recommendation. To the extent that the clear and convincing evidence standard distorts the litigation process, as some of the panelists indicate, it is a matter for particular concern. Litigation is a mechanism for focusing enhanced attention on those patents that are most likely to hold commercial significance and for weeding out from this group those patents that should not have been granted.[199] If these market-selected inquiries cannot be conducted on a level playing field, there is serious potential for judicially confirming unnecessary, potentially competition-threatening rights to exclude.[200] Accordingly, the Commission recommends that legislation be enacted specifying that challenges to the validity of a patent be determined based on a preponderance of the evidence.

C. Willfulness/Treble Damages

A second aspect of litigation that drew substantial discussion was willful infringement. Pursuant to 35 U.S.C. § 284,

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[196] *See* Thomas 10/25 at 138 ("The burden is probably properly upon an accused infringer"); Linck 10/25 at 151-52 ("The presumption . . . is really a burden shifting device to put the burden on the challenger.").

[197] It is not expressed in the Patent Act. As one commentator, analogizing to a tennis match, observes, "§ 282 [stating the presumption of validity] determines who will serve first, but does not regulate the height of the net." Charles E. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 FED. CIR. BAR J. 143, 148 (2000).

[198] Any benefit from enhanced certainty resulting from the heightened, "clear and convincing" evidentiary standard thus carries the potential harm of reduced accuracy and increased costs of error.

[199] *See* Kieff (stmt) 4. As noted *supra* in Ch. 5(III), post-grant review procedures would fill a similar role.

[200] *See* Lemley, 95 Nw. U. L. REV. at 1529 (relying on in-depth litigation to eliminate examination errors in the cases that really matter will not work if validity litigation "defers to the cursory review already conducted. Based on what we know of patent examinations, deference is not appropriate.").

a court may award up to three times the amount of damages found or assessed. This authority may be exercised when the defendant has willfully infringed a valid patent – that is, the defendant knew about the patent but nevertheless went ahead with the infringing conduct without a reasonable basis for so doing.[201]

Panelists expressed considerable dissatisfaction with a state of affairs that in effect exposes firms to greater potential damages for trying to learn if they are infringing any patents than if they keep themselves blissfully ignorant.[202] A number of panelists stated that the exposure to willfulness charges in fact discourages firms from determining what patents they might be infringing, although some observed that the dangers of going forward with eyes closed sometimes are too great.[203] Other panelists raised a separate problem: fear of willfulness charges discourages inventors from reading others' patents, thereby undermining the disclosure function of the patent system.[204] Other testimony indicated that when troublesome patents are identified, firms frequently seek to show due care and dissipate willfulness concerns by securing opinion letters regarding invalidity or non-infringement from outside counsel.[205] Some testimony questioned the value of that practice and noted that attempts to inquire about or pierce the surface of opinion letters can raise thorny disputes over attorney-client privilege.[206]

The current state of the willfulness doctrine drew few defenders.[207] One panelist noted that enhanced damages make sense when violations are likely to go undetected or unpunished, but believed that the number of instances when infringement

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[201] *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428 (Fed. Cir. 1988) ("The test is whether, under all the circumstances, a reasonable person would prudently conduct himself with any confidence that a court might hold the patent invalid or not infringed."); *see also Central Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1577 (Fed. Cir. 1983).

[202] *See, e.g.,* Pooley 2/27 at 380 and 10/30 at 122 (willfulness doctrine generates "universal concern").

[203] *Compare* Greenhall 2/27 at 420-21 (stating that until recently, when he was required to sign warrants, "I simply didn't look at any patents . . . and if anybody mentioned a patent I burned it as quickly as possible"); Lemley 4/18 at 46-47 ("a number of companies actually try very hard to avoid doing patent searches at all because they don't want to learn anything that might alarm them"); Barr 2/28 at 677 and 10/30 at 81 (willfulness doctrine dissuades firms from performing clearance searches); and Pooley 10/30 at 87 (companies "specifically avoid looking at patents") *with* Myrick 10/30 at 82-83 ("every product that gets sent out the door gets checked, and avoidance is a prerequisite"), 126 (emphasizing risk of infringing out of ignorance, while acknowledging that there is also risk under the willfulness doctrine).

[204] *See, e.g.,* Thomas 10/25 at 139; Kahin 10/30 at 76; Myrick 10/30 at 125; *see also* Edwin H. Taylor & Glenn E. Von Tersch, *A Proposal to Shore Up the Foundations of Patent Law that the Underwater Line Eroded*, 20 HASTINGS COMM. & ENT. L. J. 721, 737 (1998) (many firms discourage employees from reading patents out of fear of willful infringement).

[205] *See* Sung 2/8 (Patent Session) at 147 (a competent, independent legal opinion, even if incorrect, will usually help to rebut an allegation of willful infringement).

[206] *See, e.g,* Thomas 10/25 at 155 (rather than getting "quality advice from counsel . . . we're getting sort of pats on the back that, you might as well continue and here's your shield from triple damages"), 177-78 (not suggesting that patent bar will "cynically dish out any kind of opinion"); Gambrell 10/25 at 169; Taylor 10/25 at 160.

[207] A solicitation at one roundtable for any defenders of the willfulness requirement drew no takers. *See* Hearing Transcript 10/30 at 127.

will not be remedied is relatively small.[208] Another worried that without a willfulness rule large companies may make conscious decisions to violate small firms' patents, but also shared the concerns expressed about current willfulness practices.[209] Some expressed concern that legal expenses might eat up single-damage awards, but others noted that a separate statutory provision permits recovery of attorney fees.[210] Still others stressed that treble damages are rarely actually awarded,[211] but panelists nonetheless testified to a disproportionately large *in terrorem* effect.[212]

Analysis

Viewed from a competition perspective, two attributes of the willfulness doctrine stand out. First, fear of willfulness charges works to undermine the patent system's disclosure goals by discouraging third parties from reading patents. As one panelist put it, "[I]t is perverse to make it less desirable that people read what it is the public's paying for."[213] Second, panelists amply testified that willfulness considerations may significantly interfere with gaining the knowledge of others' patents necessary for planning a noninfringing business or research strategy.[214] This introduces unnecessary uncertainty, raises risks, and reduces efficiency. In light of the many concerns it raises, some of the panelists called for abolishing the willfulness doctrine.[215] Nonetheless, the record also reveals that the doctrine serves some use, such as when one

[208] *See* Duffy 10/30 at 131-32. Another panelist added that the possibility of injunctive relief enhances deterrence. *See* Banner 10/30 at 130-31.

[209] *See* Taylor 10/25 at 160-61.

[210] *Compare* Armbrecht 3/19 at 106 (noting potential inadequacy of single-damage remedy) *with* Myrick 3/19 at 106 (stressing potential to recover attorney fees) and 10/30 at 139 (same) *and* Gambrell 10/25 at 149 (awarding attorney fees is preferable to awarding treble damages, which are unrelated to actual costs). Pursuant to 35 U.S.C. § 285, attorney fees may be awarded to the prevailing party "in exceptional cases." One panelist suggested a possible lowering of the hurdle for recovering attorney fees if the willfulness doctrine is abandoned. *See* Pooley 10/30 at 131.

[211] *See, e.g.,* Chambers 10/25 at 146-47 (willfulness really only requires defendants to seek out a good opinion of counsel showing invalidity or noninfringement); Gambrell 10/25 at 148-49. Recent data, however, suggest that courts enhance damages in a significant percentage of decisions that find infringement. *See* Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 11 FED. CIR. B.J. 209 (2001). Professor Moore's data, culled from the records of all patent cases tried from 1983 through 1999, show a finding of willfulness in 39% of the 888 decisions that found infringement and enhanced damage awards in 70% of the 219 cases in which judges considered enhancement issues. *Id*. at 237, 241.

[212] *See* Banner 10/30 at 127-28; Pooley 10/30 at 128 (willfulness promotes "a fear that animates decisions").

[213] Myrick 10/30 at 125 (finding the willfulness doctrine "a terrible deterrent to the use of the patent system to its full extent"); *see also* Taylor & Von Tersch, 20 HASTINGS COMM. & ENT. L. J. at 737 ("By placing potential infringers on notice for simply reading a patent, the Federal Circuit puts the patent owner's rights to exclude ahead of the public interest in disclosure . . . . this defeats the basic purpose of the patent[] laws, dissemination of information."); William C. Rooklidge & Robert O. Bolan, *The Official Gazette and Willful Patent Infringement: Stryker Corp. v. Intermedics Orthopedics, Inc.*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 605, 606-07 (1997) ("The specter of penalties for willful patent infringement could discourage corporations from using the Official Gazette and the patent information the Official Gazette identifies. This information is the very technical information that the patent system encourages inventors to disclose as part of the bargain between the inventor and the public.").

[214] *See supra* note 203.

[215] *See, e.g.,* Myrick 10/30 at 127 ("Getting rid of willfulness is goodness because it helps to disseminate the information."); Mossinghoff 10/30 at 134 ("I fully support the abolition of willfulness").

firm knowingly and deliberately uses another's patented invention because the likelihood that the patentee can afford to bring suit, and the expected value of single damages, are low. Given difficulties in recovering attorney fees, some infringers can profit from this strategy.

Recommendation. A solution that raises the threshold for finding willfulness in a way that (i) permits firms to read patents for their disclosure value and to survey the patent landscape to learn about potential infringement pitfalls, yet (ii) retains a viable willfulness doctrine in other settings could protect both competition and wronged patentees. The Commission recommends that legislation be enacted requiring either actual, written notice of infringement from the patentee or deliberate copying of the patentee's invention, knowing it to be patented, as a predicate for willful infringement. Under such a system, so long as the defendant creates its own invention, it would not be harmed by knowledge gained through reading patents; the patent system's disclosure function would be protected, and firms could conduct searches to determine their potential exposure to infringement claims.[216] Yet an infringer could not just ignore a patentee's notice and dare a plaintiff to fund, bring, and win a single-damage court suit, without risking treble damages. A plaintiff would continue to benefit from treble damage possibilities from the time of giving actual notice.[217] To avoid generating a spate of spurious demand letters, the requisite notice would need to take a form sufficient to endow the recipient with standing to challenge the patent's validity.[218] The price for creating an opportunity to seek treble damages, consequently, would be creating a corresponding opportunity to extinguish the patent if it can be shown to be invalid.

V. CONCLUSION

The procedures through which patents are examined, reexamined, and litigated are fundamental determinants of patent system quality. Issuance of patents of questionable validity may affect competition and innovation by discouraging entry and research efforts, inducing unnecessary licenses and royalty payments, and imposing litigation costs. Uncertainty and delay in resolving validity questions add to each problem. Other concerns are raised by procedures and doctrines that maintain secrecy of some pending applications and interfere with the patent system's disclosure function. Hearing testimony regarding

[216] *See* Barr 10/30 at 135 (changing the willfulness standard to require notification "does help the problem of patent clearances, wanting to do patent clearances and patent searches"); Taylor & Von Tersch, 20 HASTINGS COMM. & ENT. L. J. at 741 (proposing to limit willful infringement to cases of literal infringement involving either (i) actual notice with a reasonable time to study the patent prior to litigation or (ii) clear and convincing evidence of copying of a marked product). *But cf.* Pooley 10/30 at 130-31 (arguing that most of the costs of the willfulness doctrine would remain even with a notice system).

[217] Concerns that treble damages generally would be unavailable for periods in which a third party knowingly infringes in secret appear, on balance, less compelling than gains from securing the benefits of patent disclosures and avoiding the costs of determining willfulness under current practices.

[218] Standing to bring a declaratory judgment action challenging the validity of a patent requires "a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity." ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 8.1(a)(iii) at 447 (5th ed. 2001). For discussion regarding the difficulty potential declaratory judgment plaintiffs sometimes experience in establishing such standing, *see* Blackburn 2/26 at 294-96; Nydegger 4/11 at 149.

examination, reexamination/post-grant review, and litigation suggested changes that could better address competition concerns.

The examination process could be strengthened by enabling examiners to take better advantage of the information and knowledge possessed by applicants. Specifically, the Commission recommends that the PTO require applicants, upon request of the examiner, to submit statements of relevance regarding their prior art references and that it remove impediments to greater use of examiner inquiries. Moreover, the Commission urges that, to reduce business uncertainty, public notice of patent applications be expanded by legislation eliminating the opportunity for some applicants to opt out of the 18-month publication requirement.

Establishment of a post-grant review procedure would offer important opportunities to draw upon the prior art and expertise of third parties most familiar with a patented invention's technology. It could enhance patent quality and resolve business uncertainty more rapidly than litigation. It could direct finite agency resources for improving patent quality toward those patents that the market finds both commercially significant and in need of further review. The Commission supports the PTO's efforts to establish a procedure for post-grant review of patent claims and suggests ways to ensure that the procedure offers sufficient value to be used, without imposing the costs and delays of litigation, and without exposing patentees to third-party harassment.

Finally, the Commission offers two recommendations for upgrading the patent litigation process. Absent a viable *inter partes* reexamination/post-grant review procedure, litigation is essentially the public's one line of defense against improvidently granted patents and the potential harms to competition and innovation that they may cause. Yet, under current rules, the ability to challenge patents is hamstrung by a clear and convincing evidence standard incommensurate with the nature and realities of the *ex parte* examination process. The Commission recommends that legislation be enacted specifying that challenges to patent validity be determined based on a preponderance of the evidence. Moreover, under current application of the willfulness doctrine, a third party who reads a patent to learn from its technology disclosures or to make informed decisions regarding the infringement risks of a course of research or marketing is exposed to potential treble damage liability for infringement. The Commission recommends that legislation be enacted limiting treble damages for willful infringement to circumstances when the patentee gives written notice or the infringer deliberately and knowingly copies a patented invention. Such a change would preserve treble damage liability in appropriate cases, while boosting competition and innovation through unhindered use of patent disclosures.

CHAPTER 6 COMPETITION AND PATENT POLICY CAN AND SHOULD WORK TOGETHER

CHAPTER 6 COMPETITION AND PATENT POLICY CAN AND SHOULD WORK TOGETHER

Introduction. Competition and patent policy generally work together to promote consumer welfare over time. The substantive standards and procedural rules of each policy accordingly should account for values that underlie both policies. For example, competition policy, as implemented by antitrust enforcement, should take into account how antitrust can affect patents and the role of patents in promoting consumer welfare. Similarly, patent policy should take into account how it can affect competition and the role of competition in promoting consumer welfare. Mechanisms that allow each doctrine to take the other's values into account will help achieve the proper balance between them as means to promote consumer welfare over time.

This chapter examines a variety of perspectives on how competition and patent policy can work together. Section I considers some of the ways in which each legal doctrine can and should take account of its relationship with the other. Section II discusses the Federal Circuit, one of the points at which competition, antitrust, and patent policy most directly intersect, in terms of the scope of its role and the trends that some perceive in its case law. Section III concludes with recommendations for the PTO and the Antitrust Agencies on how to improve consideration of and coordination with each other's policies.

I. ANTITRUST AND PATENT LAW AND POLICY

A. Antitrust Law and Policy Can and Should Take Patent Policy into Account to Promote Consumer Welfare Over Time

Antitrust law focuses on promoting consumer welfare, not only in the short term, but in the long term as well. It recognizes and takes account of the importance of dynamic competition to generate new and improved goods and services through technological progress, as well as the importance of static competition, with its emphasis on price and output levels of goods and services provided by existing technology. This broad focus necessarily leads to the consideration of issues such as how antitrust enforcement should take into account the need to prevent free riding and to allow efficient combinations of assets, for example. That antitrust law develops largely through case law gives it the flexibility to incorporate the goals of patent law into the antitrust analysis of conduct with respect to patents.

The joint FTC/DOJ report (forthcoming) will discuss the antitrust analysis of business conduct with respect to patents. This section highlights a few of the basic concepts.

1. Incentives to Innovate

Patent laws provide "incentives for innovation . . . by establishing enforceable property rights for the creators of new and

useful products [and] more efficient processes. . . ."[1] The importance of incentives to innovate resonates in antitrust law, which, by protecting competition, also can spur innovation.[2] In the IP Guidelines, the Agencies recognized how patents can spur innovation by providing "incentives for innovation and its dissemination and commercialization" and by avoiding rapid imitation that could "erode incentives to invest, ultimately to the detriment of consumers."[3]

Both antitrust and patent law must consider their effects on initial and follow-on innovation in cumulative technology industries. For example, when follow-on patents are obtained by independent follow-on innovators, grantbacks can "provide a means for the licensee and the licensor to share risks and reward the licensor for making possible further innovation based on or informed by the licensed technology."[4] Antitrust enforcement now recognizes this as a procompetitive benefit from grantbacks.[5]

[1] U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property §1.0 (Apr. 6, 1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm (hereinafter IP Guidelines).

[2] "It is the possibility of success in the marketplace, attributable to superior performance, that provides the incentives on which the proper functioning of our competitive economy rests." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2nd Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980).

[3] IP Guidelines § 1.0.

[4] *Id*. at § 5.6.

[5] *Id*.

2. The Reduction of Free Riding

By conferring a right to exclude others from making, using, or selling an invention, patent law reduces the ability of rivals to free ride on a firm's investments in innovation. Antitrust law is also concerned with the prevention of free riding. For example, in holding that antitrust law does not obligate firms to predisclose technological innovations to competitors, the Second Circuit stated as follows: "[i]f a firm that has engaged in the risks and expenses of research and development were required in all circumstances to share with its rivals the benefits of those endeavors, this incentive would very likely be vitiated."[6] Similarly, the Supreme Court has upheld restrictions on competition that prevented competitors from "free riding" on a firm's promotional efforts.[7]

3. The Generation of Efficiencies by Combining Complementary Factors of Production

The IP Guidelines also signaled the Agencies' increased appreciation of the efficiencies generated through cross-licensing and other licensing practices. In particular, the Agencies recognized that "intellectual property licensing allows firms to combine complementary factors of production and is generally

[6] *See Berkey*, 603 F.2d at 281.

[7] *Continental T.V., Inc. v. GTE Sylvania Inc.,* 433 U.S. 36, 54-55 (1977). *See also* IP Guidelines § 2.3 (the IP Guidelines note that "various forms of exclusivity" can give a licensee the incentive to invest in commercializing and distributing products that embody the intellectual property by "protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor.").

procompetitive."[8] Licensing can, for example, promote the coordinated development of technologies when the use of an independent follow-on innovator's patent is blocked by a patent on first-generation technology.

4. The Reduction of Transaction Costs

Patent rights render innovation a tradeable commodity by reducing transaction costs and enabling licensing negotiations.[9] In cumulative technology industries where downstream innovation can depend on access to upstream patents held by many different owners, the transaction costs of access can be substantial. By acknowledging the potential for patent pools and cross licenses to facilitate the commercialization of innovation in cumulative technology industries, antitrust analysis can be sensitive to the implications of transaction costs for innovation.[10]

B. Patent Law and Policy Can and Should Take Competition Policy into Account to Promote Consumer Welfare Over Time

1. Patent Law Takes Competition Policy into Account to Promote Consumer Welfare Over Time

Concern for public benefits also animates patent law, from its earliest predicates in the U.S. Constitution through its embodiment in the basic substantive standards of the Patent Act. The courts on occasion have fully discussed and considered the impact on public benefit in reaching conclusions about the proper interpretation of patent law.[11]

The Constitution authorizes Congress to implement a patent system for a clearly specified purpose. Pursuant to Article 1, Section 8, "[t]he Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The Supreme Court has characterized this clause as "both a grant of power and a limitation."[12] The authority extends only to promoting the progress of science and useful arts, and it must be implemented accordingly:

> The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the *innovation, advancement or social benefit* gained thereby.[13]

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[8] IP Guidelines § 2.0.

[9] *See supra* Ch. 2(I)(A)(2).

[10] *See* Second Report (forthcoming).

[11] *See, e.g., supra* Ch. 1(III)(A)(2)(b) (discussing the Federal Circuit's attentiveness to notice function of patents), Ch. 4(II)(C)(2) (discussing Supreme Court's attention, in *Festo*, to effects of doctrine of equivalents on competition).

[12] *Graham v. John Deere Co.,* 383 U.S. 1, 5 (1966).

[13] *Id.* at 5-6 (emphasis added).

In economic terms, policies chosen with "regard to the innovation, advancement or social benefit gained thereby" are policies that contribute to consumer welfare over time. That is, patent policy is for the benefit of the public, not patent holders. The ultimate point of granting a patent is not to reward inventors, but rather to create incentives for actions – invention, disclosure, and commercial development – that will further the public interest and thus benefit consumers over time. Patent institutions, however, have not always brought this goal to the forefront in interpreting and applying the underlying policies. Sharper focus at both the administrative and judicial levels on the consequences of policy choices and the relationship of those choices to the patent system's consumer welfare function could yield substantial public benefit.

In crafting the substantive standards of the Patent Act, Congress specified the mechanisms through which the PTO and the courts can pursue this fundamental goal. Each of the key substantive standards for granting or interpreting patents discussed in Chapter 4 – nonobviousness, enablement, written description, the doctrine of equivalents, and utility – rests on a foundation of principles chosen to advance innovation and provide public benefit.

a. Nonobviousness

The nonobviousness requirement arises out of the principle that the patent system does not promote innovation if it grants exclusive rights on inventions that are already, or could be soon, in the public domain.[14] As the Supreme Court's *Graham* opinion states,

> Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.[15]

Similarly, as the Federal Circuit explains,

> That is the real meaning of "prior art" in legal theory – it is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art. Society, speaking through Congress and the courts, has said, "thou shalt not take it away."[16]

Granting a right to exclude based on "knowledge that is available, including what would be obvious from it," upsets the balance between property protection and competition that the Supreme Court in *Bonito Boats* found so basic.[17] It risks conferring market power without receiving something innovative in return and conflicts

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[14] Of course, the novelty standard raises similar considerations.

[15] *Graham,* 383 U.S. at 6.

[16] *Kimberley-Clark Corp. v. Johnson & Johnson,* 745 F.2d 1437, 1453-54 (Fed. Cir. 1984).

[17] *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) ("From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy."). For additional discussion of *Bonito Boats*, *see supra* Ch. 1.

with "the underlying policy of the patent system that [the public benefits] must outweigh the restrictive effect of the limited patent monopoly."[18] How the line demarcating nonobvious inventions is drawn, therefore, implicates the "careful balance" that sanctions patents only under the general circumstances that make them likely to benefit society.

b. Enablement and Written Description

The enablement standard secures the patent system's disclosure goals. Disclosure is the *quid pro quo* for conferring patent rights,[19] and enablement ensures that the patent applicant has upheld his or her end of the bargain. Moreover, the standard is a basic element in determining patent breadth. A patent's coverage reaches no farther than what its disclosures enable, so the more follow-on developments that a patent's disclosures enable without undue experimentation, the broader its claims may be.[20] Patent breadth, in turn, affects the division of rewards between initial and independent follow-on innovators.[21] A patent broader than what actually has been enabled thus risks damaging follow-on innovation competition without providing the requisite public benefit. Again, drawing the line demarcating what has been enabled goes to the heart of *Bonito Boats'* patent/competition bargain.

The written description requirement derives in part from similar considerations of patent breadth. By requiring patent applicants to provide a description sufficient to show that they are in possession of the invention, the requirement protects against overbroad claim amendments.[22] Indeed, the Federal Circuit has described one "policy-based rationale" for the description requirement as follows:

> Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.[23]

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[18] *Graham*, 383 U.S. at 10-11; *see also Bonito Boats*, 489 U.S. at 150 ("Taken together, the novelty and nonobviousness requirements express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public or that which may be readily discerned from publicly available material.").

[19] *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, James Rogan Testimony Feb. 6, 2002*, at page 21 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)); *see also Bonito Boats*, 489 U.S. at 151 ("In consideration of its disclosure and the consequent benefit to the community, the patent is granted.").

[20] *See* Merges 2/26 at 154-55; *see also supra* Ch. 4 (II)(B)(1).

[21] *See* Scotchmer 2/26 at 130-35; *see also supra* Ch. 4(II)(B)(2).

[22] As discussed *supra* in Ch. 4(II)(B)(1), an applicant cannot broaden claims beyond the scope of the written description and still take advantage of the original filing date.

[23] *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1561 (Fed. Cir. 1991) (*quoting Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551 (3d Cir.), *cert. denied,* 454 U.S. 1055 (1981)). The court noted that another rationale, to give public notice of a patent's scope, may have had greater bearing previously, *before* the patent statutes required that applications contain separately identified claims. *Id.* at 1560-61.

The written description requirement's roots thus trace, at least in part, from concern with potential competitive harms from after-the-fact "overreaching" beyond an applicant's actual invention, and the requirement plays its own role in shaping the competition/right-to-exclude interface.

c. Doctrine of Equivalents

The doctrine of equivalents brings the need for delicate balance to the fore. As the Supreme Court recognized in its *Festo* opinion, the doctrine raises issues of claim transparency that affect the public: "This clarity [of patent boundaries] is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not."[24] The doctrine of equivalents, however, "renders the scope of patents less certain. . . . If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures."[25] The Federal Circuit in *Festo* gave these considerations precedence, emphasizing the notice value of claims in finding a complete bar to application of the doctrine of equivalents to claim elements narrowed during the course of a prosecution.[26] The Supreme Court ultimately softened the appellate court's ruling, however, making the bar a matter of rebuttable presumption.[27] The key point, however, is not the outcome in the particular case, but rather that the parameters of debate again evolved in *Bonito Boats* terms, seeking the right balance between protection of the patentee and impact on outside competition.[28]

d. Utility

The utility requirement reveals yet another element of the patent system's "careful balance" of rights to exclude with competitive concerns. The Supreme Court's *Brenner* opinion addressed this balance at some length:

> [A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. . . . Such a patent may confer power to block off whole areas of

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[24] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 730-31 (2002).

[25] *Id.* at 732.

[26] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 574-78 (Fed. Cir. 2000) (emphasizing the notice function of claims).

[27] *Festo,* 535 U.S. at 737-41. The Court reasoned that a complete bar in these circumstances would exceed the inferences that courts reasonably can draw from a narrowing amendment and would "disrupt the settled expectations of the inventing community." *Id*. at 737-39. It sought to strike the appropriate balance by placing the burden of proof on the patentee to show why an amendment does not surrender the particular equivalent in question. *Id.* at 739-41.

[28] Indeed, similar considerations lie at the heart of another recent Federal Circuit ruling regarding a different aspect of the doctrine of equivalents. *See Johnson & Johnston Assoc. v. R.E. Service Co*., 285 F.3d 1046, 1052-54 (Fed. Cir. 2002) (*en banc)* (prohibiting use of the doctrine of equivalents to cover subject matter disclosed in the specification but not included in the patent's claims, on grounds that this would conflict with the "primacy of the claims" in defining the scope of the patent rights and providing notice on which the public is entitled to rely).

> scientific development without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[29]

Thus, concerns with patenting too close to the laboratory bench and with blocking off scientific development and follow-on research are part and parcel of the utility inquiry. Once again, the patentability standard is crafted, interpreted, and justified in terms of harmonizing with competition and providing public benefit.

2. Patent Institutions Should Expand their Consideration of Competition Policy Concerns in Decision Making

Despite these very substantial connections between the standards of patentability and consumer welfare goals, neither the PTO nor the Federal Circuit has consistently kept those goals at the forefront of its policymaking. To the contrary, several panelists observed that both the agency and the court generally were unreceptive to policy considerations and that both, to some extent, regarded policy issues as beyond the scope of their charters.

Some suggested that the PTO merely carries out the dictates of the Patent Act, as enacted by Congress and interpreted by the courts, and consequently has little role in considering policy. For example, the PTO's John Love stated:

> [T]he amount of discretion that the PTO has is very limited. . . . [W]e are constrained quite a bit, in the first place [by] a statute, 35 U.S.C., of course, that explains very specifically the conditions of patentability and, in addition to novelty and non-obviousness, patentable subject matter – 101 is a considerable restriction. We are also constrained by the way the CAFC interprets those provisions. . . . and we cannot go outside the constraints of the law, which state that, "A patent shall be granted unless . . .," I mean, there is your discretion.[30]

In addition, Stephen Kunin, the PTO's Deputy Commissioner for Examination Policy, explained that the Federal Circuit has stated that the PTO rulemaking authority[31] is interpretive in nature and does not entail the authority to issue substantive rules entitled to deference from the courts.[32]

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[29] *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

[30] John Love 2/28 at 626-27; *see also* Chen 2/28 at 629.

[31] *See* 35 U.S.C. § 2(b)(2) (providing that the PTO "may establish regulations, not inconsistent with law, which (A) shall govern the conduct of proceedings in the Office . . . .").

[32] *See* Kunin 4/10 at 46 (citing *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996)). The Federal Circuit in *Merck* determined that Congress had not vested the PTO "with any general substantive rulemaking power," and consequently held that "the rule of controlling deference set forth in *Chevron* does not apply." *Merck*, 80

Some agreed with this narrow role for the agency,[33] but others saw value in a broader role for the PTO[34] or raised concerns with recent trends.[35] One of the panelists cited the PTO's 2001 revisions to its Utility Examination Guidelines[36] as an example of how "the PTO, absent the courts, . . . can exercise a fair bit of latitude with important consequences for innovation and economic welfare."[37] As noted *supra* in Chapter 4, those revisions generally have been well-received, but a review of the informal notice-and-comment process arguably suggests that in some instances the PTO may have taken a constrained view of its role in working – within the interstices of existing law – toward policies that maximize welfare.[38]

At the same time, several panelists suggested that litigants do not perceive the Federal Circuit as receptive to economic arguments or attuned to the overall economic consequences of its decisions. Panelists testified that the Federal Circuit does not "think[] in economic ways"[39] and does not often receive briefs or write opinions citing to economic journals or law

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F.3d at 1550 (referring to *Chevron, USA, Inc. v. National Resources Defense Council*, 467 U.S. 837 (1984)). *See also United States v. Mead Corp.*, 533 U.S. 218, 229-30 (2001) (framing the deference inquiry in terms of whether Congress "provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement" with "the effect of law").

[33] *See, e.g.,* Bendekgey 2/26 at 303-05 (PTO "shouldn't be raising and lowering standards" but does "have to apply the law to technology"); Mossinghoff 10/30 at 10; Pooley 10/30 at 13-14; Banner 10/30 at 15-16 (any "fixes to be made" should come from Congress, "most definitely not" from the PTO). *But cf.* Myrick 10/30 at 24 (PTO and the courts, "in their respective areas of relevance, should be making policy-like decisions, but the fundamental policy rests with the Congress").

[34] *See, e.g.,* Rai 4/10 at 42 (acknowledging "the apparent lack of power of the PTO from an administrative law standard," but nonetheless arguing that the PTO is "the appropriate place to place the sort of power of determining how these particular substantive [patentability] criteria should be applied"); Katsh 4/10 at 58-59; Kunin 7/10 at 190-91 ("it's important for us [the PTO] to be able to have a very strong role in the norm setting process").

[35] *See* Merrill 10/25 at 186 (the environment of receptivity to policy arguments at the PTO has "deteriorated" and the PTO's in-house analytical capability has declined).

[36] United States Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (2001).

[37] Cohen 10/30 at 30.

[38] For example, the PTO noted that "[s]everal comments stated that DNA should be freely available for research," that "patents are not necessary to encourage additional discovery and sequencing of genes," and that "patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA." *Utility Examination Guidelines*, 66 Fed. Reg. at 1095. Granting that such subject matter is patentable, such comments nevertheless raise significant issues relating to where the line should be drawn in finding basic genetic research sufficiently ripe to meet the statutory utility requirement. Yet the PTO dismissed these issues with a five-sentence response that (i) noted that patentable subject matter and patentability standards are set by statute; (ii) quoted the statute; (iii) observed that "Congress creates the law and the Federal judiciary interprets the law;" (iv) pointed out that "[t]he USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them;" and (v) concluded that "when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term." *Id*. At least on its face, this approach avoids any policy consideration of *when* the statutory utility requirement is met, which the Utility Guidelines serve to explain. Such an approach arguably reflects a very limited view of agency responsibility for working with the statute's terms and the governing judicial interpretations to administer the Patent Act for the public benefit.

[39] *See* Rai 4/10 at 116; *see also* Merrill 10/25 at 186-87 (judicial receptivity to economic analysis has deteriorated).

review analyses.[40] One indicated that the courts do not see the implications of their decisions for progress and innovation as "their first order mission."[41] Moreover, as two panelists phrased it, the Federal Circuit has not seen patent law "as part of a whole panoply of tools that are used to promote innovation"[42] and does not "give due credit to competition as a driver of innovation."[43]

Yet, as we saw in Chapter 4 and in Section I.B.1 above, the Supreme Court has made clear that there is room for policy-oriented interpretation of the patent laws. The statute, although more explicit than the antitrust laws, is still far from detailed. The basic nonobviousness standard requires two sentences,[44] and the enablement, written description, and best mode requirements all fit within the same, one-sentence text.[45] The entire utility requirement consists of the words "useful," "use," and "using."[46] The doctrine of equivalents does not even appear in the statute. Under these circumstances, interstices are inevitable, and there is room for thought and choice in how they are filled.[47] As Professor Wesley Cohen explained, "there's an enormous amount of latitude, and where you come down in that domain of flexibility can have enormous consequences for the pace of innovation and for economics, either considered narrowly or broadly."[48]

II. THE FEDERAL CIRCUIT: GOALS, JURISDICTION, CHOICE OF LAW, AND CASE LAW TRENDS

Nowhere is the intersection between institutional design and substantive outcomes more pronounced than within the context of the United States Court of Appeals for the Federal Circuit. Congress established the Federal Circuit in 1982 through merging two specialized courts of limited subject matter, but nationwide, jurisdiction – the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals. The Federal Circuit was an "experiment" designed to increase patent

[40] *See* Dreyfuss 7/10 at 75-76 ("from time to time the Federal Circuit Judges have said that they don't understand why people cite this material. . . . They're not making policy . . . ."); Wamsley 7/10 at 76 (Federal Circuit makes few citations to economic journals or law review articles); Lunney 7/10 at 85 (Federal Circuit regards discussion of the economic literature as "the last refuge of the desperate"); Duffy 10/30 at 33; *cf.* Pooley 10/30 at 14 (noting that some judges would like more information in briefing, but asking how a broad enough array of economic input could be submitted to make it useful, rather than dangerous).

[41] *See* Cohen 10/30 at 12.

[42] Dreyfuss 7/10 at 47.

[43] Quillen 7/11 at 161.

[44] *See* 35 U.S.C. § 103(a).

[45] *See id.* at § 112, ¶ 1.

[46] *See id.* at §§ 101, 112.

[47] Professor John Duffy, for example, pointed out that even following the Supreme Court's *Graham v. John Deere* opinion, the primary factors in nonobviousness analysis "leave you off at the very point you think the analysis should start . . . you've identified a gap between what's in the prior art and this invention . . . . And *Graham* . . . doesn't tell you how to judge whether the gap is sufficient for a patent." Duffy 7/10 at 116-17. *See also* Rai 4/10 at 83-84 (patent law should be grounded in innovation policy and economic policy considerations); Stoner 10/30 at 37 (urging implementation of the patent system in ways that take account of economic goals).

[48] Cohen 10/30 at 30.

law uniformity.[49] Not surprisingly, the debates that occurred during its formation retain salience today. This section briefly discusses how aspects of the Federal Circuit relate to the balance between competition, antitrust, and patent policy.

A. The Federal Circuit and Its Intended Effect on the Law

1. Patent Law

Congress created the Federal Circuit "to bring about uniformity of decisions in certain critical areas of the law without the need for Supreme Court review to resolve conflicts between circuits. To this end, the Federal Circuit was given exclusive jurisdiction over appeals from all district courts in cases which arise under the patent laws. . . . A particular need was seen in the field of patents where instability in the law was having a detrimental effect on an important segment of our society, the industrial and business community."[50] As Judge Newman observed, creation of the Federal Circuit was "a dramatic move for the purpose of adding stability to the patent law."[51] Prior to creation of the Federal Circuit, in the most extreme cases, "different courts dealing with the same patent reached different conclusions."[52] The Federal Circuit was to provide clearer and more consistent application of patent law, which in turn would increase the predictability of patents and, thus, their value as means to promote innovation.[53]

2. Antitrust Law

Another important consideration was how the Federal Circuit would treat antitrust issues that may arise in conjunction with patent claims. As the then-Chairman of the ABA Antitrust Section observed at the Hearings, Congress specifically contemplated that the Federal Circuit would have a role in development of antitrust law, but Congress also expected the Federal

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[49] THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT – A HISTORY (1982-1990), at xi (1991). This history was written by the Court of Appeals for the Federal Circuit and published by authorization of the U.S. Judicial Conference Committee on the Bicentennial of the Constitution of the United States.

[50] *Id.* at xii. *See also* Rogan 2/6 at 25 (observing that Congress created the Federal Circuit to promote a more stable patent system through the reduction of jurisdictional splits).

[51] Newman 2/6 at 37.

[52] Taylor 7/11 at 22 (emphasis added). *See generally* S. REP. No. 97-275, at 5 (1981). At the time, not all agreed that circuit splits required creation of the Federal Circuit. *See, e.g.,* Paul Janicke, *To Be or Not To Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit (1887-1982)*, 69 ANTITRUST L.J. 645, 646, n.5 (2002) and accompanying text. Disagreement about this fundamental issue remains. *Cf.* American Bar Association Section of Intellectual Property Law, *Statement of Robert P. Taylor on Behalf of Section of Intellectual Property Law American Bar Association on Competition and Intellectual Property Law and Policy In the Knowledge-Based Economy* (7/11/02) 2-3 (noting that there had been a particular problem with the existence of several pockets of "anti-patent" judicial sentiment), *at* http://www.ftc.gov/opp/intellect/020711robertptaylor.pdf (hereinafter ABA IP Section (stmt)). *Compare* Taylor 7/11 at 22 (statistics demonstrate general disparity between circuits) *with* Quillen 7/11 at 52 (questioning the extent of the circuit splits prior to the Federal Circuit and whether any differences that did in fact exist between circuits had any statistical relevance) *and* Katsh 4/10 at 31 ("I don't think the venue, the forum shopping argument, had any merit.").

[53] *See generally* American Bar Association Section of Antitrust Law, *Report on the United States Court of Appeals for the Federal Circuit* (Public Comment) 8-14, *at* http://www.ftc.gov/opp/intellect/0207salabarpt.pdf (hereinafter ABA Antitrust Section, *Federal Circuit Report*).

Circuit to "zealously guard against the expansion of that role beyond areas implicating the development of patent law."[54] Congress appears to have been "persuaded that the Federal Circuit would strictly construe its own jurisdiction and that its jurisdiction could not easily be manipulated."[55] The manner in which the Federal Circuit has interpreted its jurisdiction will be addressed below.

B. Jurisdiction and Choice of Law Issues at the Federal Circuit

Two legal filters – jurisdiction and choice of law – affect the cases that the Federal Circuit decides and the law that the Federal Circuit applies in reaching its decisions. Jurisdiction is "the legal right by which judges exercise their authority. . . . It exists when [a] court has cognizance of class of cases involved, proper parties are present, and [the] point to be decided is within the powers of the court."[56] Choice of law refers to the determination of what law should govern when a conflict in law arises.[57] When the Federal Circuit evaluates what cases it will hear and what law it will apply, the value of patent law uniformity is explicitly and implicitly at issue.

1. Jurisdictional Standards

"Determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system."[58] The Federal Circuit's interpretations of its subject matter jurisdiction similarly have required such sensitive judgments.

a. Arising Under Jurisdiction

Title 28, Section 1295 of the U.S. Code establishes Federal Circuit jurisdiction. The Federal Circuit has exclusive jurisdiction over appeals from final decisions of district courts, if the district court jurisdiction was "based, in whole or in part, on section 1338."[59] Section 1338(a) provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . ."[60] Historically, Federal Circuit jurisdiction has encompassed antitrust claims through their inclusion in a complaint, through joinder or consolidation of an antitrust claim with a pre-existing patent claim,[61] or through the presence of a counterclaim.

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[54] Busey 7/11 at 17; *see also* ABA Antitrust Section, *Federal Circuit Report* at 16-22.

[55] Ronald S. Katz & Adam J. Safer, *Should One Patent Court be Making Antitrust Law for the Whole Country?*, 69 ANTITRUST L.J. 687, 691 (2002).

[56] BLACK'S LAW DICTIONARY 853 (6th ed. 1990).

[57] *Id.* at 241.

[58] *Christianson v. Colt*, 486 U.S. 800, 809 n. 2 (1988) (discussing jurisdiction of Federal Circuit).

[59] 28 U.S.C. § 1295(a)(1).

[60] *Id*. at § 1338(a).

[61] Nonetheless, Congress stated that "mere joinder of a patent claim in a case whose gravamen is antitrust should not be permitted to avail a plaintiff of the jurisdiction of the Federal Circuit in avoidance of the traditional jurisdiction and governing legal interpretation of a regional court of appeals. . . ." S. REP. No. 97-275, at APP. 21-30 (1981). This statement suggests that Congress intended the Federal Circuit to prevent such efforts to use joinder to gerrymander Federal Circuit jurisdiction.

Most recently, the Supreme Court addressed what constitutes "arising under" jurisdiction when the plaintiff does not allege a patent law claim, but the defendant files a compulsory patent counterclaim.[62] The Federal Circuit had ruled such compulsory counterclaims were sufficient to establish the Federal Circuit's jurisdiction.[63] Nonetheless, in *Holmes v. Vornado*, the Supreme Court ruled they were not. The Court applied the "well-pleaded-complaint rule" as governing "arising under" jurisdiction for purposes of § 1338.[64] The Court held that, where a well-pleaded complaint does not assert any claim arising under federal patent law, the Federal Circuit cannot assert jurisdiction based solely upon a patent counterclaim.[65]

Panelists' reaction to the Supreme Court ruling in *Holmes* was mixed. One practitioner opined that *Holmes* will narrow Federal Circuit jurisdiction, although to what extent is unclear.[66] Along similar lines, another panelist predicted "occasional races to the courthouse," because antitrust plaintiffs who want to avoid the Federal Circuit will file their cases as an antitrust action, before defendants attempt to secure Federal Circuit jurisdiction.[67] This alone would not necessarily avoid Federal Circuit jurisdiction, however, since antitrust plaintiffs seeking regional circuit review also would have to plead in a manner to avoid *Christianson,* which we discuss next.[68]

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[62] *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002).

[63] *Holmes Group, Inc. v. Vornado Air Circulation Sys*., 13 Fed. Appx. 961 (2001); *see also Aerojet-General Corp. v. Machine Tool Works*, 895 F.2d 736, 741-42 (Fed. Cir. 1990).

[64] *Holmes*, 535 U.S. at 829 (citing *Christianson v. Colt*, 486 U.S. 800 (1988)). The "well-pleaded complaint rule" provides that a federal district court's jurisdiction extends over "only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law. . . ." *Christianson*, 486 U.S. at 808. The Supreme Court further held that "linguistic consistency" requires that § 1338(a) jurisdiction likewise extends only to those cases in which "patent law is a necessary element of [a] . . . well-pleaded claim[ ]." *Id*. at 808-9. The Supreme Court's invocation of the well-pleaded-complaint rule in *Holmes* implicitly raises additional issues. For example, the "well-pleaded complaint" rule typically applies to complaints as filed. Could Federal Circuit jurisdiction change depending upon the disposal of patent issues after filing but prior to appeal, such as through voluntary withdrawal, dismissal with prejudice, or severance followed by partial final judgments? For a discussion of such issues, *see generally* Gordon 7/10 at 44, 65-66; ABA Antitrust Section, *Federal Circuit Report* at 36-43.

[65] *Holmes*, 535 U.S. at 833-34. *See generally* ABA Antitrust Section, *Federal Circuit Report* at 33-35; ABA IP Section (stmt) 4.

[66] Baker 7/11 at 39.

[67] Kobak 7/11 at 128; *see also* ABA Antitrust Section, *Federal Circuit Report* at 36.

[68] Kobak 7/11 at 130 (for example, such a party would not want to ask for a declaratory judgment of invalidity, which would provide a basis for Federal Circuit jurisdiction under *Christianson*, even though declaratory judgments frequently were sought before *Holmes*). Another question *Holmes* raises is whether "a patent claim [may] be filed as a separate action in federal court while a separate antitrust action is pending, or must the patent claim be dismissed for nonjoinder." ABA IP Section (stmt) 5. The American Bar Association's Section of Intellectual Property Law further noted that to the extent regional and Federal Circuit interpretations of patent law differ, incentives will exist for "plaintiffs to race to file in order to engage in . . . forum shopping." *Id.*

b. Substantial Question of Patent Law

In *Christianson v. Colt*, the Supreme Court held that the Federal Circuit also has jurisdiction over those cases in which "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law."[69] One panelist characterized the substantial question threshold in the following manner: "[d]o [the] claims require proof of [a] patent's scope, validity, and/or infringement?"[70] The Federal Circuit itself has characterized *Christianson* as "set[ting] a lenient standard for jurisdiction under 28 U.S.C. § 1338(a)."[71]

c. The Breadth of Federal Circuit Jurisdiction

Panelists expressed varied assessments regarding the Federal Circuit's jurisdictional interpretations. One panelist saw general agreement that the Federal Circuit has expanded its authority over the years.[72] Another did not see the Federal Circuit expanding its jurisdiction through changing its precedent, but rather applying that precedent to new situations.[73] Still another saw Federal Circuit jurisdiction as fairly stable over the years.[74] No consensus emerged.

2. Choice of Law

To understand better the full effect of these jurisdictional matters, we look to choice of law issues. As the American Bar Association Intellectual Property Section noted, "jurisdiction and choice of law are inextricably intertwined as a practical matter, but should be examined independently for clarity."[75]

When Federal Circuit cases involve only patent issues, the Federal Circuit applies its own law, because it is the only court of appeals with jurisdiction over such cases. When cases involve both patent and other legal issues, however, choice of law issues necessarily arise. The Federal Circuit must decide whether to apply its own law with respect to the non-patent issues or to apply to those non-patent issues the law of the regional circuit in which the case would have been heard, absent the patent issues.[76]

The intersection of antitrust and patents obviously raises choice of law issues for the Federal Circuit. From its inception, the Federal Circuit has generally interpreted choice of law in a manner to permit the infusion of its own ideas regarding the

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[69] *Christianson*, 486 U.S. at 809; *see also* Gordon 7/11 at 43.

[70] George G. Gordon, *The Implications of Federal Circuit Jurisdiction for the Development of Antitrust Law* (7/11/02) (slides) at 7, *at* http://www.ftc.gov/opp/intellect/020711georgegordon.pdf (hereinafter Gordon Presentation).

[71] *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000).

[72] Dreyfuss 7/11 at 170.

[73] Gordon 7/11 at 100 (noting, however, a possible exception to this trend in breach of contract cases).

[74] Taylor 7/11 at 101.

[75] ABA IP Section (stmt) 2; *see also* Weil 7/11 at 69; Dreyfuss 7/11 at 99.

[76] As one commentator has aptly noted, a "fundamental choice of law problem faced by the Federal Circuit arises from its limited subject matter jurisdiction." ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 18.3 at 1086 (5th ed. 2001).

relationship between patents and antitrust.[77] This implicit trend became concrete relatively recently in *Nobelpharma v. Implant Innovations,* when the Federal Circuit held that:

> As a general proposition, when reviewing a district court's judgment involving federal antitrust law, we are guided by the law of the regional circuit in which that district court sits. . . . However, we apply our own law, not regional circuit law, to resolve issues that clearly involve our exclusive jurisdiction.[78]

In *Nobelpharma*, a patent assignee brought an action for infringement, and the alleged infringer counterclaimed for antitrust violations. The Federal Circuit held that whether conduct in the prosecution or enforcement of a patent is sufficient to overcome any antitrust immunity arising under the principles of *Eastern R.R. President's Conference v. Noerr Motor Freight, Inc.*[79] and related cases, falls within its exclusive jurisdiction.[80] The court reasoned that most antitrust claims involving these issues will be filed as counterclaims by defendants in patent infringement suits and that, as a consequence, most cases involving these issues will be appealed to the Federal Circuit. The Federal Circuit eschewed reliance on various regional precedents, because such reliance could endanger the court's efforts "to create a uniform body of federal law on this subject."[81] Nonetheless, the Federal Circuit cited issues involving the "elements of antitrust law such as relevant market, market power, damages, etc." as areas where it will continue to apply regional circuit law.[82]

During the Hearings, some supported the *Nobelpharma* reasoning as in accord with the purpose of the Federal Circuit to bring consistency to patent law.[83] One panelist argued that the same rationale supporting the need for a uniform appellate review of patent matters also supports a need for uniform appellate review of the patent/antitrust interface.[84] In contrast, another argued that the Federal Circuit should not be the only circuit deciding patent/antitrust interface issues, and determining "how patent law fits into the wider mosaic of rights and obligations in our

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[77] *See generally* ABA Antitrust Section, *Federal Circuit Report* at 52-71.

[78] 141 F.3d 1059, 1067 (Fed. Cir.), *cert. denied*, 525 U.S. 876 (1998). In so doing, the Federal Circuit overruled *Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153 (Fed. Cir. 1996), and two other cases, to the extent they held otherwise. *Nobelpharma,* 141 F.3d at 1068 (citing cases).

[79] 365 U.S. 127 (1961).

[80] *Nobelpharma,* 141 F.3d at 1067.

[81] *Id*. at 1067-68.

[82] *Id*. at 1068.

[83] *See, e.g.*, American Intellectual Property Law Association (AIPLA), *AIPLA Testimony* (Public Comment) 15, *at* http://www.ftc.gov/os/comments/intelpropertycomments/aipla.pdf (hereinafter AIPLA (stmt)); Intellectual Property Owners Association, *Comments on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Public Comment) 7-8, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipo.pdf (hereinafter IPO (stmt)). *See generally* ABA IP Section (stmt) 6-7 (indicating that recent experience with the interface of patents and antitrust law lies with the Federal Circuit).

[84] Baker 7/11 at 38.

legal system."[85] One patent practitioner maintained that the value of enhanced uniformity in patent/antitrust rulings does not alone justify unchecked expansion into "the development of antitrust law [where], as in other areas, competition can be a good thing."[86] Similarly, an antitrust practitioner stated that antitrust jurisprudence benefits from the percolation and development of ideas that jurisdiction in several courts of appeal affords.[87]

C. Trends in the Law of the Federal Circuit

1. Patent Law Trends

Congress's primary goal for the Federal Circuit was to increase the uniformity of patent law.[88] Many panelists stated that the Federal Circuit's patent jurisprudence has increased patent law certainty and consistency.[89] The Federal Circuit has brought stability and increased predictability to various elements of patent law, thus reducing legal uncertainty and facilitating business planning. Nonetheless, some questioned the extent to which the Federal Circuit has succeeded in achieving this goal,[90] and others raised concerns that certain Federal Circuit opinions had conformed patent law, but in unhelpful ways.[91] Chapter 4 discusses the issues that panelists raised most frequently as sources of concern.[92]

Some have expressed concern that the Supreme Court's decision in *Holmes v.*

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[85] Gordon 7/11 at 49.

[86] Matthew F. Weil, *Statement* (7/11/02) 15, *at* http://www.ftc.gov/opp/intellect/020711weilmatthewf.pdf.

[87] Busey 7/11 at 74.

[88] *See supra* Ch. 6(II)(A)(1).

[89] *See, e.g.*, Mossinghoff 2/6 at 76-78; Myrick 3/19 at 17. Industrial Research Institute (IRI) members had been polled decades ago, prior to the advent of the Federal Circuit, and had supported centralizing patent appeals in a single court. *See generally* S. REP. No. 97-275, at 5 (1981). Its current President, Ross Armbrecht, testified at the FTC/DOJ Hearings that his own informal poll of IRI members indicated that the Federal Circuit brought greater stability and predictability to patent process across all industries. Armbrecht 3/19 at 54-55.

[90] *See, e.g.*, Quillen 7/11 at 156 (arguing that the Federal Circuit has introduced additional uncertainty into valuation of patents and determination of validity); Katsh 4/10 at 31 ("I think the Federal Circuit frankly has not been the success that it was intended."); Weil 7/11 at 142-44 (Federal Circuit's sometimes "rough treatment of precedent" has "created or exaggerated conflicts" among its decisions), at 144-45 (Federal Circuit's tendency "to reach beyond" its appellate role and function as a "mini-trial" court undermines goal of certainty in decision making), at 145 (noting Federal Circuit's reluctance to use *en banc* review to resolve intra-circuit conflicts), at 145-46 (observing that some of the problems identified have improved in recent years). *But see* Weil 7/11 at 151 (noting that the Federal Circuit has done "an incredibly good job" of bringing consistency to many areas of patent law).

[91] Banner 10/30 at 182-83.

[92] District courts also play an important role in impacting patent law uniformity. Professor Kimberly Moore has empirically studied patent enforcement in district courts and concluded "despite the creation of the Federal Circuit, choice of forum continues to play a critical role in the outcome of patent litigation." Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 892 (2001). According to Professor Moore, forum variation among district courts "increases the unpredictability of the law and its application" and, as a consequence, it "undermines the innovation incentive underlying patents." *Id*. at 927. "Even with the Federal Circuit dispensing binding substantive legal pronouncements, district court outcomes vary procedurally and substantively in ways that the appellate court cannot regulate." *Id*. at 932. Moore proposes two possibilities for limiting forum shopping: creation of a specialized trial court or statutory reform to tighten venue requirements. *Id*. at 934.

Vornado will operate to undermine the consistency of patent law. Federal Circuit Chief Judge H. Robert Mayer has been quoted as saying that "*Holmes* is likely to limit the availability of Federal Circuit review and permit forum shopping, and both results may return the state of patent law to that existing before the Federal Circuit's creation, a situation in which the diversity in the application of the patent laws reduced the value of patents."[93] Others, such as a study group created by the Board of Governors of the Federal Circuit Bar Association, have voiced similar concerns.[94] Some panelists saw a virtue in allowing other courts of appeal to challenge Federal Circuit interpretations of Supreme Court patent law, citing the Federal Circuit's treatment of obviousness under *Graham v. Deere* as one issue that could benefit from alternative interpretations.[95] Another panelist questioned the extent to which regional courts of appeal would disagree with Federal Circuit precedent, stating that "regardless of appellate forum, even after [*Holmes*]," it is clear that "Federal Circuit precedents [regarding patent law] are likely to carry significant weight with many of the courts in which the agencies litigate."[96]

Others disagreed that *Holmes* might adversely affect patent law uniformity. For example, one panelist argued that Federal Circuit jurisdiction under *Christianson*, which recognizes Federal Circuit jurisdiction when a "substantial question" of patent law is involved, would prevent the Federal Circuit's docket from being substantially reduced.[97]

2. Antitrust Law Trends

The discussion of the Federal Circuit's interpretations of antitrust law distinguished between the Federal Circuit's holdings and how it articulates antitrust principles. There was general agreement that, in terms of its holdings, the Federal Circuit did not engage in any significant deviations from mainstream antitrust analysis.[98] Indeed, to the extent that Federal Circuit holdings differed from mainstream antitrust, it was to uphold verdicts in *Nobelpharma* and *Bard* on antitrust theories

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[93] Anne M. Maher, *The "Holmes" Decision*, NAT'L L. J., July 8, 2002, at B11 (Col. 1).

[94] *See Report of the Ad Hoc Committee to Study Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 12 Fed. Cir. B.J. 713 (2002) (arguing that the state of the law following *Holmes* "compromises the uniformity of patent law" and recommending legislative action that would effectively reverse *Holmes* by extending Federal Circuit jurisdiction to appeals of cases in which patent claims are raised only in responsive pleadings).

[95] Quillen 7/11 at 136, 159-60 (arguing this diversity would be a beneficial check on Federal Circuit patent law interpretations); *see also* Taylor 7/11 at 137 (agreeing that the opportunity to argue that the Federal Circuit misinterprets Supreme Court patent law precedents is more likely to exist under *Holmes*); *supra* Ch. 4(II)(A)(3).

[96] Gordon 7/11 at 50; Gordon Presentation at 15. "The level of unpredictability in patent law may largely depend on whether the regional circuits apply Federal Circuit precedent or choose to apply their own law to the cases before them." Edward G. Poplawski, *Patent Litigation After Vornado*, 725 PLI/PAT 407, 420 (2002).

[97] Baker 7/11 at 39-40. That same panelist also noted, however, that "*Holmes* may introduce conflicts in substantive law at the patent/antitrust interface that the public thought the Federal Circuit had settled." Charles P. Baker, *Statement* (7/11/02) 14, *at* http://www.ftc.gov/opp/intellect/020711charlesbaker.pdf.

[98] *See*, *e.g.*, Busey 7/11 at 18; Gordon 7/11 at 48; ABA Antitrust Section, *Federal Circuit Report* at 70, 77; ABA IP Section (stmt) 2, 5.

that typically failed in other circuits.[99]

Nonetheless, observers commented that there are "some sweeping very unnuanced dicta" in certain cases.[100] Some panelists cited *CSU* [101] and *Intergraph*[102] as sources of overbroad dicta that, some analysts have suggested, lower courts have arguably misapplied, as in *Townshend v. Rockwell Int'l Corp.*[103] and *Minebea Co. v. Papst*.[104] One commentator expressed concern that the Federal Circuit could "skew or have adverse effect" on antitrust law development that is disproportionately large.[105]

Overall, the Hearings revealed ongoing challenges in balancing the value of accuracy obtained from diversity in development and the value of certainty derived from uniform application of the law. As stressed in Chapter 5, uncertainty interferes with efficient business activity, and the value of uniformity in the application of patent law is clear. At the same time, diversity of approach and the incremental development of case law have benefitted antitrust law greatly, increasing its accuracy by double-checking its doctrines. FTC General Counsel William Kovacic observed that "a uniquely remarkable feature of the U.S. antitrust system" is its heavy reliance, unprecedented in the field of economic regulation in the U.S., upon judicial elaboration of standards over time.[106] Panelist and antitrust practitioner George Gordon described "a concentration of decision-making authority in the Federal Circuit," and argued that the current system "deprives regional circuits of the opportunity to develop views and express views" and "deprives the system of the benefit of getting a multiplicity of views."[107] While recognizing the value of certainty to participants in the patent system, the Commission views *Holmes* as a potentially salutary development from an antitrust perspective, in light of the importance of "a

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[99] Gordon 7/11 at 48 (referring to *C.R. Bard v. M3 Systems,* 157 F.3d 1340 (Fed. Cir. 1998), *cert. denied,* 526 U.S. 1130 (1999)).

[100] Kobak 7/11 at 132.

[101] *CSU v. Xerox Corp*., 203 F.3d 1322 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001). *See, e.g.,* Pitofsky 2/6 at 30-31 (criticizing *CSU* dictum); Whitener 5/1 at 232 (same); Kobak 7/11 at 132-33 (same). Under *Holmes*, the Federal Circuit would not have had jurisdiction over the *CSU* case.

[102] *Intergraph Corp. v. Intel Corp.,* 195 F.3d 1346 (1999). *See* Kobak 7/11 at 132-33.

[103] *Townshend v. Rockwell Int'l Corp.,* 2000-1 Trade Cas. (CCH) 72,890 (N.D. Cal. 2000). *See generally* Gordon 7/11 at 48; ABA Antitrust Section, *Federal Circuit Report* at 84-85; R. Hewitt Pate, *Refusals to Deal and Intellectual Property Rights*, 10 GEO. MASON L. REV. 429, 435-36 (2002).

[104] *Minebea Co. v. Papst*, 229 F. Supp. 2d 1 (D.D.C. 2002). *See generally* Gordon 7/11 at 48; ABA Antitrust Section, *Federal Circuit Report* at 84-85.

[105] Gordon 7/11 at 48. *But see* ABA IP Section (stmt) 7, n.12 (concern that the Supreme Court cannot review most Federal Circuit cases because of absence of circuit splits is not accurate; the Supreme Court has been motivated by powerful Federal Circuit dissents to review cases).

[106] Kovacic 2/8 (Antitrust Session) at 16. (Stating that in drafting the crucial antitrust statutes, Congress essentially said, "We want to give the statute[s] a consciously, deliberately evolutionary scheme so that [they] can be adapted through judicial interpretation over time to account for new developments in relevant social science disciplines such as economics and to adjust and adapt to new understandings of business behavior." *Id*. at 15.).

[107] Gordon 7/11 at 69-70. Gordon further stated that these concerns have been expressed by many in industry. *Id*.

multiplicity of views" to the development of antitrust law.

III. INSTITUTIONAL CONSIDERATIONS FOR THE ANTITRUST ENFORCEMENT AGENCIES AND THE PTO

A. Recommendations Relating to the PTO

1. Provide Adequate Funding for the PTO

The Commission strongly recommends that Congress increase the PTO's funding so that it can improve the quality of its determinations on patentability. The current Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, James E. Rogan, observed in the Hearings that "[f]or a number of years, the USPTO has been engaged in what sometimes seems to be an epic struggle to muster sufficient resources to provide the timely and quality service our customers need."[108] Other heads of the PTO have agreed, noting that the quality of the PTO's work depends on adequate funding.[109] Similarly, many participants noted that the PTO lacks the funding necessary consistently to make high-quality determinations as to whether patent applications deserve to be granted.[110] Some pointed out that inadequate funding makes it difficult for the PTO to hire enough staff to examine patent applications carefully and

[108] Rogan 2/6 at 26. Funding issues arise notwithstanding the PTO's considerable efforts to meet its challenges by increasing operational efficiency through modernization and reorganization of its systems. For PTO's recent analysis of these issues, s*ee* United States Patent and Trademark Office, The 21st Century Strategic Plan (April 2, 2003), *at* http://www.uspto.gov/web/offices/com/strat21/index.htm.

[109] *See, e.g.,* Mossinghoff 2/6 at 75 (arguing that fiscal restraints compromise the PTO's ability to "do its job properly," notably by slowing the implementation of e-government support); Dickinson 2/6 at 64-65 ("if the quality is to be further improved, resources have to be found"); *Commerce Secretary Wants to End Fee Diversion*, 65 PATENT, TRADEMARK & COPYRIGHT J. 430 (2003) (reporting that Secretary of Commerce Donald Evans testified on March 6, 2003 before the House Appropriations Committee that "[m]aking more fees available sooner will enable the agency to increase the quality of patents and trademarks issued"), *available at* http://subscript.bna.com/SAMPLES/ptc.nsf/0/2bc4d8546b850c5d85256ce8008396d3?OpenDocument; *Written Statement on the Commerce Department's FY 2002 Budget*: *Hearing Before the House Appropriations Subcomm. on Commerce, Justice, State and the Judiciary,* 108th Cong. (2003) (statement of Commerce Secretary Donald L. Evans) (linking measures to improve funding to the PTO's strategic plan to improve the quality of its output), *available at* http://www.ogc.doc.gov/ogc/legreg/testimon/108f/evans0306.htm. One PTO official attending the Hearings made a similar point. *See* Chen 2/26 at 299 (noting that statistical reviews have found that examination quality is improving and that correlation exists between resources and quality).

[110] *See, e.g.,* Bendekgey 2/26 at 230 (observing that allocating more resources to the PTO can improve the quality of its examinations); Levin 2/6 at 102 (recognizing steps taken by PTO to improve the quality of its review in emerging technology areas and its database, but maintaining that more resources may be necessary); Alderucci 4/9 at 12, 14-15 (stating that lack of funding hinders "timely and quality examinations of patent applications" and contributes to the issue of overly broad patents, but noting that "a mere increase in funding, without . . . substantial operational changes, rarely results in significant improvement of any organization"); Musacchia 4/9 at 28 (observing that full funding would improve quality of PTO's work); IPO (stmt) 5 ("Many of the 'competitive' problems that have been cited in the course of these proceedings are symptoms of inadequate funding of the USPTO and an inability of the USPTO to keep pace with the quantity and complexity of the patent applications it receives.").

efficiently.[111] Another panelist noted how hard it is to hire and retain talented staff in emerging technologies, where the private sector offers substantially higher salaries than the PTO.[112]

Patent review committees have long made this point. In 1979, the Advisory Committee on Industrial Innovation recommended that Congress give the PTO sufficient funding for the agency to hire more examiners, expand its database, and improve quality control.[113] In 1992, the Advisory Committee on Patent Law Reform similarly recommended that PTO funding be maintained at a level sufficient to ensure timely and high-quality patent examination.[114] As recently as 2002, the Patent Public Advisory Committee stated that the PTO faces "a crisis in funding that will adversely and seriously impact . . . the quality of . . . issued patents."[115] The Commission thus strongly believes that Congress should allocate sufficient funds to allow the PTO to ensure quality patent review.

2. Expand PTO's "Second-Pair-of-Eyes" Review to Selected Areas

The Commission endorses the PTO's recommendation that it expand its "second-pair-of-eyes" review to selected areas.[116] The PTO began its second-pair-of-eyes review in March 2000, to allow a reviewer to examine each business method patent allowance and "to quickly flag issues that need further attention by the examiner or the examiner's supervisor."[117]

The Commission believes that expanding this program to cover such fields as semiconductors, software, and biotechnology would help boost the quality of patent review in areas where it will make

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[111] *See, e.g.*, Katsh 4/10 at 29-30 (arguing that underfunding hurts the PTO's ability to employ enough expert examiners); Gable 3/20 at 122 (observing that the PTO's funding structure, especially as it relates to user fees, makes it difficult to hire the number of examiners necessary to do its job).

[112] *See* Lerner 2/20 at 161-62 (pointing to the importance of adequate funding to recruiting and retaining examiners in emerging fields where the private sector offers substantially higher pay). Several participants criticized Congress's diversion of PTO user fees to other government programs, arguing that it undermines the PTO's ability to conduct timely, high-quality patent examinations. *See*, *e.g.*, Dickinson 2/6 at 64; Earp 2/26 at 326; Webbink 3/20 at 171; Delrahim 3/19 at 76-77; Mossinghoff 2/6 at 75; Misener 2/27 at 396; Udell 2/28 at 566-67; Frankel 4/10 at 11-12; Myrick 3/19 at 74; Armitage 3/19 at 214; AIPLA (stmt) 18; IPO (stmt) 5-6.

[113] *See* FINAL REPORT OF ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION 153-54 (1979) (comparing PTO's funding unfavorably with that of the European Patent Office). The report also recommended that Congress return user fees to the PTO. *See id.* at 154.

[114] *See* THE ADVISORY COMMISSION ON PATENT LAW REFORM, REPORT TO THE SECRETARY OF COMMERCE 191-92 (Aug. 1992) (proposing that PTO receive enough funding for it to review patent applications within 18 months without compromising examination quality), *available at* http://world.std.com/obi/USG/Patents/overview.

[115] PATENT PUBLIC ADVISORY COMMITTEE, ANNUAL REPORT 6 (Nov. 29, 2002), *at* http://www.uspto.gov/web/offices/com/advisory/acrobat/ppacannual12-05-02.pdf.

[116] United States Patent and Trademark Office, The 21st Century Strategic Plan at Item 29 (April 2, 2003) ("Expansion of the Second-Pair-of-Eyes Review"), *at* http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm (hereinafter 21st Century Strategic Plan at Item 29).

[117] *Id.*

the most difference.[118] The PTO's decision to target specific areas for enhanced review makes sense. Additional PTO review can be expensive, and such costs may well outweigh the benefits of universally expanding second-pair-of-eyes review.[119]

In industries such as semiconductors and software in which unwarranted upstream patents can hinder critical downstream innovation, however, additional review may well be worthwhile.[120] Second-pair-of-eyes review in such areas can protect downstream innovation by preventing issuance of unnecessary rights to exclude covering upstream intellectual property. Likewise, in emerging areas such as biotechnology, second-pair-of-eyes review can significantly help improve the quality of patent application review, since in emerging areas, examiners necessarily lack experience reviewing the new industry's patent applications, and the body of prior art is slim.[121] As new technologies continue to emerge, the PTO ought to remain alert to possible additional needs for this program. The PTO also recommends evaluating whether second-pair-of-eyes review will prove effective earlier in the examination process, an option the Commission agrees merits exploration.[122]

In short, the Commission recognizes the PTO's selective expansion of the second-pair-of-eyes process as part of its larger effort to "bolster confidence in the quality of U.S. patents,"[123] and the Commission endorses both that effort and its specific implementation here.

3. Continue to Implement the Recognition that the PTO Balances the Public's Interest in Intellectual Property and Individuals' Interests in Their Patents

The Commission also endorses the PTO's current recognition that its role is not solely to help applicants receive patents. Thus, while the PTO's 2002 Corporate Plan states that the "Under Secretary and Director champions intellectual property rights," it expressly recognizes that he also "forges a balance between the public's interest in intellectual property and each customer's interest in his/her patent and trademark."[124] This balance is crucial: in serving the

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[118] *Cf. id*. (recommending expanding second-pair-of-eyes review to "such advanced fields as semiconductors, telecommunications, and biotechnology.").

[119] *See, e.g.,* Dickinson 10/25 at 78 (noting that "get[ting] examiners additional time" costs "13 to 15 million dollars per hour").

[120] *See supra* at Ch. 3(IV) and (V); *see also* Levin 2/6 at 102.

[121] *See supra* at Ch. 3(III); *cf.* PATENT PUBLIC ADVISORY COMMITTEE, ANNUAL REPORT at 8 (recommending additional review of patent applications to "identify errors that may crop up in examination, particularly in new technologies").

[122] 21st Century Strategic Plan at Item 29 (April 2, 2003).

[123] *See Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary*, 107th Cong. (2003) (statement of James Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office), *available at* http://www.uspto.gov/web/offices/com/speeches/stratplan2003apr03rogan.htm. *Cf.* Chambers 10/25 at 207 (citing second-pair-of-eyes process as an example of PTO's efforts to take into account the economic effects of patent grants).

[124] *See* United States Patent and Trademark Office, *FY2002 Corporate Plan* 28 (2001), *at* http://www.uspto.gov/web/offices/com/corpplan/fy2002/index.html.

objective of enhancing consumer welfare over time, the PTO functions as a steward of the public interest, not a servant of the patent applicants. Notwithstanding that the PTO should provide timely and high quality service to patent applicants, its core mission is to serve the public interest. Thus, the PTO must protect the public against the issuance of invalid patents that add unnecessary transaction costs and may confer market power, just as it should issue valid patents to encourage invention, disclosure, and commercial development.

Past PTO statements describing patent applicants as the PTO's customers, however, could suggest that the agency's mission is to promote the welfare of patentees or patent applicants, not the public. For example, the PTO's Corporate Plan for fiscal year 2001 stated bluntly, "[t]he Patent Business is one of the PTO's three core businesses. The primary mission of the Patent Business is to help customers get patents."[125] Such thinking may be more than surface deep; one prior PTO examiner/Associate Solicitor testified:

> I don't know that the examiners view their role as protecting the public anymore. I think more often than not they view their role as protecting the customer. And the customer, according to the patent office, is the individual filing for a patent.[126]

As noted, the PTO has now rephrased some of the descriptions of its role, introducing a sense of "balance between the interests of patentees and the interests of the public,"[127] and this may be a reflection of a potentially very beneficial trend.

B. The FTC Will Pursue Steps to Increase Communication between Antitrust Agencies and Patent Institutions

1. The FTC Will Increase its Competition Advocacy Role through Filing Amicus Briefs in Appropriate Circumstances

The Commission will renew its commitment to the filing of amicus briefs in important patent cases that can affect competition, as well as in cases at the intersection of patent and antitrust law. When such cases have high stakes for the public, the Commission can serve the public interest by filing amicus briefs to present its perspectives regarding their implications for consumer welfare.[128] Some suggested that

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[125] United States Patent and Trademark Office, *FY2001 Corporate Plan*, *at* http://www.uspto.gov/web/offices/com/corpplan/. Panelists criticized this type of view. *See, e.g.*, Myrick 3/19 at 108-09 (noting that the Patent Public Advisory Committee had criticized a PTO mission statement as "inappropriate with regard to the public interest"), 10/30 at 40; Kahin 3/19 at 85-86 and Brian Kahin, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (3/19/02) (slides) at 3 (criticizing the PTO for describing its mission in terms of helping customers get patents), *at* http://www.ftc.gov/opp/intellect/020319briankahin.pdf; James Love 3/19 at 114; Bhaskar 10/25 at 113, 183.

[126] Chambers 10/25 at 31.

[127] Myrick 3/19 at 109 (citing the Fiscal Year 2002 Corporate Plan); *see also* Kahin 3/19 at 85.

[128] Fox 2/28 at 696-697 (suggesting that the Agencies file amicus briefs to "present their perspectives on issues of patent law with significant competition implications"). Moreover, just as the Agencies helped courts develop coherent rules for market definition, they might, through the filing of amicus briefs, guide courts to

guidance is especially needed on issues such as licensee estoppel; patent misuse; prosecution laches and late claiming; the proper role of juries in patent cases; and intellectual property bundling.[129] Panelists suggested that amicus briefs would be helpful not just in the Supreme Court, but in the lower courts (including the Federal Circuit) as well.[130]

2. In Appropriate Circumstances, the FTC Will Ask the PTO Director to Reexamine Questionable Patents that Raise Competitive Concerns

The Commission intends to play a more active, though still selective, role in asking the PTO Director to reexamine patents that raise competitive concerns when a substantial new question of patentability exists.[131] As one panelist suggested, a "collective action problem" frustrates industry challenges to questionable patents: instead of challenging a patent's validity, many firms may simply license it, since no single firm has the incentive to finance the expensive legal challenge.[132] An enforcement agency, however, can take account of the cost of the questionable patent to the entire industry, solving the coordination problem.[133] The FTC has done something similar at least once in the past,[134] and, in appropriate circumstances, it intends to be more active in this area in the future.

3. The FTC Will Encourage Increased Communication between Patent Institutions and the Antitrust Agencies

Increased coordination among the three federal agencies – the FTC, the DOJ and the PTO – that set the broad terms for competition and innovation involving inventions covered by patents is key to ensuring a better balance between intellectual property and competition policy. The three agencies have always communicated with each other, to be sure, but some panelists recommended that the communication become "continual and not occasional."[135] As former PTO Director Dickinson noted, such communication "can head off problems . . . and is always, always beneficial."[136]

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the use of "sensible" rules governing the interaction of intellectual property and antitrust law. *See* Mackie-Mason 5/1 at 182-83.

[129] *See* Fox 2/28 at 697 (outlining the need for helpful intervention by the Agencies at "points of conflict" between intellectual property and antitrust law); Jacobson 5/14 at 34 (suggesting that the Agencies "actively seek out" cases involving intellectual property bundling in particular).

[130] *See, e.g.,* Fox 2/28 at 697; Jacobson 5/14 at 34.

[131] *See* Myrick 3/19 at 50 (proposing this).

[132] *See* Kesan 4/10 at 154.

[133] *See Id.* Some panelists debated whether the Agencies should sue to clarify the validity of questionable patents. *Compare* Gambrell 10/25 at 197 (suggesting that the Agencies "have to have a standing to sue and clarify the validity or invalidity for patents") *with* Dickinson 10/25 at 213 (criticizing idea); Kahin 10/25 at 211 (same).

[134] In 1992, the FTC informed the PTO that FTC staff had reason to question the allowability of certain claims of a particular patent. *See* Letter from Janet Steiger, Chairman, Federal Trade Commission, to Douglas Comer, Commissioner of Patents and Trademarks, Patent and Trademark Office (Sept. 15, 1992).

[135] Kahin 3/19 at 90; *see also* Dickinson 10/25 at 188 (recommending that "effective dialogue" between the Agencies and the PTO become "more routine[]").

[136] Dickinson 10/25 at 188-89.

Moreover, as another panelist noted, interagency communication can allow the Agencies to bring to bear their "broad expertise . . . [to] help provide an economic understanding of innovation."[137] Agency insights would help illuminate variations in innovation depending upon, among other factors, the technology, industry, and nature of the developmental process.[138] Such communication can also allow the Agencies to benefit from the PTO's patent expertise.[139] An increasing number of the FTC's competition matters require the application of antitrust law to conduct relating to intellectual property, and there is need for the best understanding possible of the nature and scope of patents. A closer working relationship with the PTO can only help in this regard. In short, antitrust enforcers and the PTO need to talk to each other regularly and often.

One means of improving interagency communication is the establishment of a Liaison Panel between the Antitrust Enforcement Agencies and the PTO. The Liaison Panel would be composed of individuals from the FTC, the DOJ's Antitrust Division, and the PTO. It would meet regularly and make periodic public reports on current issues and activities involving intellectual property and competition policy. This Liaison Panel would function primarily as a practical, policy-oriented group designed to permit the exchange of views on important new issues as they arise. An additional project for this panel could be the formulation of an empirical research agenda on the relationship between competition and intellectual property law, an agenda that economists, academics, and others can pursue.[140]

Another means of fostering interagency dialogue would be through the founding of an Office of Competition Advocacy within the PTO.[141] Such an office could, when appropriate, advise PTO policymakers about the competitive impact of its policy decisions, helping the PTO to serve the objectives of promoting consumer welfare over time. For example, the office could provide PTO policymakers with some economic analysis of the "downstream effects of their work."[142]

A final means of encouraging communication among the agencies is to request that Congress amend the membership categories of the Patent Public Advisory Committee (P-PAC). Congress created the P-PAC in 1999 to review the PTO's patent "policies, goals, performance, budget and user fees" and to make annual reports on those

[137] Kahin 3/19 at 90 (noting that this, in turn, "must be based on a deeper understanding of how patents work in practice, and how the costs of evaluating and negotiating patents play out.").

[138] *See id.*

[139] The PTO's statutory charter provides that it "shall advise Federal departments and agencies on matters of intellectual property policy . . . ." 35 U.S.C. § 2(b)(9).

[140] One panelist suggested that the Agencies set forth such a "research agenda." Kahin 3/19 at 91.

[141] *See, e.g.,* James Love 3/19 at 114-15 (arguing for the establishment of "some kind of office of advocacy" at the PTO that would be attuned to the competitive consequences of patent grants).

[142] Myrick 3/19 at 107.

issues.[143] Congress has provided that P-PAC's voting members "represent the interests of diverse users," represent "small and large entity applicants," and have "substantial background and achievement in finance, management, labor relations, science, technology, and office automation."[144] By expanding the P-PAC's membership to include competition experts and economists, Congress could allow the P-PAC to advise the PTO on competition issues generally.

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The Commission looks forward to working closely with the PTO and other patent organizations to increase communication and include all parties in discussion and implementation of the FTC's recommendations.

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[143] 35 U.S.C. § 5(d). One panelist who served on the P-PAC noted that it advises the PTO on policy and budget matters, and that after it criticized the PTO's mission statement, the PTO provided more balanced descriptions of its role. *See* Myrick 3/19 at 108-09; *see also* Myrick 10/30 at 40.

[144] 35 U.S.C. § 5(b). Certain labor organization representatives are nonvoting members. *Id*.

APPENDIX A:
Contributors to FTC/DOJ Hearings

Name	Affiliation	Date
Greg **Aharonian**	Editor, Internet Patent News Service	2/27/02
Dean **Alderucci**	Chief Counsel of Intellectual Property, Walker Digital	4/9/02
Peter **Alexiadis**	Partner, Squire, Sanders & Dempsey, LLP	5/22/02
Gwillym **Allen**	Senior Economist and Strategic Policy Advisor, Competition Policy Branch, Canadian Competition Bureau	5/22/02
Lynn J. **Alstadt**	Shareholder, Buchanan Ingersoll; Adjunct Professor, Duquesne University	3/19/02
American Bar Association Section of Antitrust Law	The ABA Antitrust Section is a leading forum for ongoing analysis of policies and developments affecting competition and consumer protection law.	Public Comment
American Bar Association Section of Intellectual Property Law	The ABA Intellectual Property Law Section is a leading forum for ongoing analysis of policies and developments affecting Intellectual Property.	Public Comment

Name	Affiliation	Date
American Intellectual Property Law Association	AIPLA represents a diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright and unfair competition law, as well as other fields of law affecting intellectual property. Members represent both owners and users of intellectual property.	Public Comment
American National Standards Institute (ANSI)	ANSI is the primary organization for fostering the development of technology standards in the U.S.	Public Comment
Steven D. **Anderman**	Professor of Law, Essex University	5/22/02
Michael **Antalics**	Partner, O'Melveny & Myers, LLP	4/18/02
F.M. Ross **Armbrecht**, Jr.	President, Industrial Research Institute	3/19/02
Robert A. **Armitage**	Vice President and General Patent Counsel, Eli Lilly and Company	3/19/02
Ashisha **Arora**	Visiting Associate Professor of Economics, Stanford University; Associate Professor of Economics and Public Policy, Carnegie Mellon University	2/25/02; 5/1/02
Kenneth **Arrow**	Nobel Memorial Prize and Joan Kenney Professor of Economics Emeritus, and Professor of Operations Research Emeritus, Stanford University	2/25/02
Aventis Pharmaceuticals, Inc.	Aventis Pharmaceuticals is the U.S. pharmaceuticals business of Aventis, a world leader in pharmaceuticals and human vaccines.	Public Comment

Name	Affiliation	Date
Charles P. **Baker**	Partner, Fitzpatrick, Cella, Harper & Scinto	7/11/02
David **Balto**	Partner, White & Case, LLP	Public Comment
Mark T. **Banner**	Banner & Witcoff, Ltd; Chair, ABA Intellectual Property Law Section	10/30/02
Thomas O. **Barnett**	Partner, Covington & Burling	5/2/02
E. Bruce **Barnes**	Comments regarding Competition and Intellectual Property, April 15, 2002	Public Comment
Robert **Barr**	Vice President, Worldwide Patent Counsel, Cisco Systems, Inc.	2/28/02; 10/30/02
John H. **Barton**	George E. Osborne Professor of Law, Stanford University Law School	2/26/02; Public Comment
Garrard R. **Beeney**	Partner, Sullivan & Cromwell	4/17/02
David W. **Beier**	Partner, Hogan & Hartson, LLP; Counsel to Biotechnology Industry Organization	2/26/02
Lee **Bendekgey**	General Counsel and Executive Vice President, Incyte Genomics	2/26/02
Stanley M. **Besen**	Vice President, Charles River Associates	4/18/02
James **Bessen**	Research on Innovation, Massachusetts Institute of Technology	Public Comment
R. **Bhaskar**	Senior Research Fellow, Harvard Business School	7/11/02; 10/25/02
Edward J. **Black**	President and CEO, Computer & Communications Industry Association	3/20/02
Robert **Blackburn**	Vice President, Chief Patent Counsel, Chiron Corp.	2/26/02

Name	Affiliation	Date
Molly S. **Boast**	Partner, Debevoise and Plimpton	5/14/02
Margaret A. **Boulware**	Shareholder, Jenkens & Gilchrist, PC; Past President and Fellow, American Intellectual Property Law Association	10/30/02
John R. **Boyce**	Professor, Department of Economics, University of Calgary	Public Comment
Joseph F. **Brodley**	Professor, Boston University School of Law	5/2/02
Monte R. **Browder**	Senior Intellectual Property Counsel, Ivax Corporation	3/19/02
George B. **Brunt**	Senior Vice-President, General Counsel and Secretary, Alcatel USA	3/20/02
Eric **Buddington**	Semi-Professional Programmer/Free Software	Public Comment
Kenneth J. **Burchfiel**	Partner, Sughrue Mion, PLLC	4/11/02
Dan L. **Burk**	Julius E. Davis Professor of Law, University of Minnesota Law School	3/20/02; 7/10/02
Michelle **Burtis**	LECG, Inc.	11/6/02
Roxane C. **Busey**	Partner, Gardner Carton & Douglas; Chair, ABA Section of Antitrust Law	7/11/01
Carl **Cargill**	Director Corporate Standards, Sun Microsystems, Inc.	4/18/02
Fiona **Carlin**	Partner, European Law Center, Baker & McKenzie	5/22/02
Michael A. **Carrier**	Assistant Professor, Rutgers University School of Law	Public Comment
George S. **Cary**	Partner, Cleary, Gottlieb, Steen & Hamilton	5/2/02
Gregory John **Casamento**	Software Engineer	Public Comment

Name	Affiliation	Date
Timothy D. **Casey**	Partner, Fried, Frank, Harris, Shriver & Jacobson	4/9/02
Barbara **Caulfield**	Executive Vice President and General Counsel, Affymetrix, Inc	3/19/02
Yar R. **Chaikovsky**	General Counsel, Zaplet, Inc.	2/27/02
Scott A. **Chambers**	Adjunct Faculty Member at Georgetown Law Center and The George Washington University School of Law; Associate, Arnold and Porter	2/8/02 (Patent Law for Antitrust Lawyers); 10/25/02
Yee Wah **Chin**	Senior Counsel, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.	5/22/02
David **Coffin-Beach**	President, Torpharm, Inc	3/19/02
Wesley M. **Cohen**	Professor of Economics and Management, Fuqua School of Business, Duke University	2/20/02; 10/30/02
Robert N. **Cook**	Partner, Drinker, Biddle & Reath, LLP	5/2/02
James A. **Craft**	Attorney, Gammage & Burnham, PLC	Public Comment
Dan **Crouse**	Deputy General Counsel, Microsoft Corporation	Public Comment
Makan **Delrahim**	Republican Chief Counsel, Senate Committee on the Judiciary	3/19/02
Peter N. **Detkin**	Vice President, Legal and Government Affairs and Assistant General Counsel, Intel Corporation	2/28/02
Donald R. **Deutsch**	Vice President, Standards Strategy and Architecture, Oracle Corp.	4/18/02
Rebecca P. **Dick**	Counsel, Swidler Berlin Shereff Friedman, LLP	5/14/02

Name	Affiliation	Date
Q. Todd **Dickinson**	Partner, Howrey, Simon, Arnold & White, LLP; former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office	2/6/02; 10/25/02
Maurits **Dolmans**	Partner, Cleary, Gottlieb, Steen & Hamilton	5/22/02
Rochelle C. **Dreyfuss**	Pauline Newman Professor of Law, New York University School of Law	7/10/02; 7/11/02
John F. **Duffy**	Associate Professor of Law, William and Mary School of Law	7/10/02; 10/30/02
David J. **Earp**	Vice President, Intellectual Property, Geron Corp.	2/26/02
James J. **Egan**	Senior Vice President, Business and Corporate Development, Novirio Pharmaceuticals	5/2/02
Richard **Eichmann**	Research Associate, Cornerstone Research	Public Comment
The Honorable T. S. **Ellis**, III	U.S. District Court for the Eastern District of Virginia	7/11/02
Mark **Ellis**	Comments regarding Competition and Intellectual Property	Public Comment
Henry **Ergas**	Managing Director, Network Economics Consulting Group	5/22/02; 5/23/02
Robert E. **Evenson**	Professor of Economics, Yale University	2/20/02
Joseph **Farrell**	Professor of Economics and Chair, Competition Policy Center, University of California, Berkeley	2/28/02; 5/14/02; 11/6/02
Richard A. **Feinstein**	Partner, Boies, Schiller & Flexner, LLP	5/2/02
Frank **Fine**	Partner, DLA	Public Comment

Name	Affiliation	Date
Ian **Forrester**	Executive Partner, White & Case, LLP	5/22/02
Stephen P. **Fox**	Associate General Counsel and Director, Intellectual Property, Hewlett-Packard Company	2/28/02
Kenneth M. **Frankel**	Partner, Finnegan, Henderson, Farabow, Garrett & Dunner	4/10/02
Bradford L. **Friedman**	Director of Intellectual Property, Cadence Design Systems, Inc.	2/27/02
Jeffery **Fromm**	Former Senior Managing Counsel, Hewlett-Packard Company	4/17/02; 11/6/02
Baryn **Futa**	Manager and Chief Executive Officer, MPEG LA	4/17/02
James B. **Gambrell**	Visiting Professor, The University of Texas School of Law	10/25/02
R. Lewis **Gable**	Partner, Cowan, Liebowitz & Latman, P.C.	3/20/02
Melvin C. **Garner**	Partner, Darby & Darby; Second Vice President, American Intellectual Property Law Association	10/25/02
Ernest **Gellhorn**	Professor, George Mason University School of Law	4/18/02
Daniel J. **Gifford**	Robins, Kaplan, Miller & Ciresi Professor of Law, University of Minnesota School of Law	4/18/02
Richard J. **Gilbert**	Professor of Economics, University of California Berkeley; former Deputy Assistant Attorney General for Antitrust, Department of Justice	2/6/02; 2/25/02
Jonathan **Gleklen**	Partner, Arnold & Porter	5/1/02

Name	Affiliation	Date
Gregory J. **Glover**	Partner, Ropes & Gray; Counsel to Pharmaceutical Research and Manufacturers of America	3/19/02
George G. **Gordon**	Partner, Dechert	7/11/02
R. Jordan **Greenhall**	Co-founder and Chief Executive Officer, DivX Networks	2/27/02
Shane Mitchell **Greenstein**	Elinor and Wendall Hobbs Professor of Management and Strategy, Kellogg School of Management, Northwestern University	2/20/02
Peter **Grindley**	Senior Managing Economist, LECG, Ltd.	4/17/02; 4/18/02
Margaret E. **Guerin-Calvert**	Principal, Economists, Inc.	2/20/02
Bronwyn H. **Hall**	Professor of Economics, University of California, Berkeley	2/26/02; 2/28/02
H. Stephen **Harris**, Jr.	Partner, Alston & Bird, LLP	5/23/02
Les **Hart**	Vice President of Intellectual Property, Harris Corporation	4/9/02
Joanne M. **Hayes-Rines**	Vice President, United Inventors Association	3/19/02
Robert J. **Hoerner**	Former Partner, Jones, Day, Reavis & Pogue	7/11/02
Richard **Holleman**	Industry Standards Consultant	4/18/02; Public Comment
Aidan **Hollis**	Associate Professor, Department of Economics, University of Calgary	Public Comment
Thomas J. **Horton**	Partner, Orrick, Herrington & Sutcliffe, LLP	Public Comment
James W. **Hughes**	Associate Professor, Economics Department, Bates College	Public Comment

Name	Affiliation	Date
Justin **Hughes**	Visiting Professor of Law, University of California, Los Angeles	2/28/02
David W. **Hull**	Partner, Covington & Burling	5/22/02
Robert M. **Hunt**	Economist, Research Department, Federal Reserve Bank of Philadelphia	Public Comment
Institute of Electrical and Electronics Engineers (IEEE)	IEEE is a non-profit, technical professional association. Through its members, it is a leading authority in technical areas ranging from computer engineering, biomedical technology and telecommunications, to electric power, aerospace and consumer electronics, among others.	Public Comment
Intellectual Property Owners Association (IPO)	IPO is a trade association that represents companies and individuals who own patents, trademarks, copyrights, and trade secrets.	Public Comment
Jonathan M. **Jacobson**	Partner, Akin, Gump, Strauss, Hauer & Feld, LLP	5/14/02
Charles **James**	Assistant Attorney General for Antitrust, Department of Justice	2/6/02
Mark D. **Janis**	Professor of Law, University of Iowa College of Law	4/10/02; 4/11//02; 5/22/02;
Japan Fair Trade Commission	2002 Study Group on "Patents in New Areas and Competition Policy"	5/23/02
Karl F. **Jorda**	David Rines Professor of Intellectual Property Law and Industrial Innovation, Franklin Pierce Law Center	5/23/02
Brian **Kahin**	Visiting Professor and Director, Center for Information Policy, University of Maryland	3/19/02; 4/11/02; 10/25/02; 10/30/02; Public Comment

Name	Affiliation	Date
David A. **Kantor**	President, Victory Wholesale Grocers	Public Comment
Joshua **Kaplan**	President and Chief Executive Officer, Intouch Group, Inc.	2/27/02
Salem M. **Katsh**	Partner, Shearman & Sterling	4/10/02; 5/14/02
Joseph **Kattan**	Partner, Gibson, Dunn & Crutcher, LLP	5/14/02; 11/6/02
Ronald S. **Katz**	Partner, Manatt, Phelps & Phillips, LLP	Public Comment
Christopher J. **Kelly**	Special Counsel, Kaye Scholer, LLP	4/17/02
Jay P. **Kesan**	Assistant Professor of Law, University of Illinois College of Law	4/10/02; 10/25/02
F. Scott **Kieff**	John M. Olin Senior Research Fellow in Law, Economics, and Business, Harvard Law School; Associate Professor, Washington University School of Law	4/10/02; Public Comment
Byungbae **Kim**	Competition Policy Counselor/Director General, Korean Fair Trade Commission	5/23/02
Paul **Kirsch**	Partner, Townsend, Townsend and Crew, LLP	5/1/02
Michael K. **Kirschner**	Vice President Intellectual Property, Immunex Corp.	2/26/02
Edmund W. **Kitch**	Joseph M. Hartfield Professor of Law, University of Virginia School of Law	2/20/02; 10/30/02
Benjamin **Klein**	Professor of Economics, University of California, Los Angeles	5/1/02
James B. **Kobak**, Jr.	Partner, Hughes Hubbard & Reed, LLP	7/11/02

Name	Affiliation	Date
Robert H. **Kohn**	Vice Chairman, Borland Software Corp.	2/27/02
Zoe **Konovalov**	The Economics of Open Source Software	Public Comment
William E. **Kovacic**	General Counsel, Federal Trade Commission	2/8/02 (Antitrust Law for Patent Lawyers)
Masayuki **Koyanagi**	Director, Institute of Intellectual Property	5/23/02
Jeffrey R. **Kuester**	Partner, Thomas, Kayden, Horstemeyer & Risley	4/11/02; Public Comment
James **Kulbaski**	Partner, Oblon Spivak McClelland Maier & Neustadt, P.C.	4/17/02; Public Comment
Stephen G. **Kunin**	Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office	4/10/02; 7/10/02; 7/11/02
Jeffrey P. **Kushan**	Partner, Sidley Austin Brown & Wood, LLP	4/11/02; 10/25/02
John Temple **Lang**	Counsel, Cleary, Gottlieb, Steen & Hamilton	5/22/02
James A. **Langenfeld**	Director, LECG, LLC	2/20/02
League for Programming Freedom	Organization of software programmers and users opposing software patents and interface copyrights	Public Comment
James **Leavy**	Member, Serra, Leavy & Cazals	5/22/02
Rusty **Lee**	Small business owner and professional software developer	Public Comment
Nick **Leggett**	Independent inventor holding two U.S. Patents	Public Comment

Name	Affiliation	Date
Mark **Lemley**	Professor of Law, and Director, Berkeley Center for Law and Technology, University of California, Berkeley	2/25/02; 4/18/02
Hans **Lennros**	Question regarding Competition and Intellectual Property, January 12, 2002	Public Comment
Joshua **Lerner**	Jacob H. Schiff Professor of Investment Banking, Harvard Business School	2/20/02; 4/17/02 Public Comment
Jonathan D. **Levin**	Assistant Professor of Economics, Stanford University	10/25/02
Richard C. **Levin**	President, Yale University	2/6/02; Public Comment
Stan **Liebowitz**	Professor of Managerial Economics, School of Management, The University of Texas at Dallas	2/20/02
Nancy J. **Linck**	Senior Vice President, General Counsel and Secretary, Guilford Pharmaceuticals; former Solicitor for the U.S. Patent and Trademark Office	3/19/02; 4/9/02; 10/25/02
Abbott **Lipsky**, Jr.	Partner, Latham & Watkins	5/14/02; 5/23/02
Arthur D. Little, Inc.	Arthur D. Little, Inc. is a premier consulting firm working at the interface of business and the technologies that drive innovation and growth.	Public Comment
Dr. Len-Yu **Liu**	Commissioner, Taiwan Fair Trade Commission	5/23/02
Allen M. **Lo**	Director of Intellectual Property, Juniper Networks, Inc.	4/18/02

Name	Affiliation	Date
John **Love**	Director, Technology Center 2100, United States Patent and Trademark Office	2/27/02; 2/28/02
James **Love**	Director, Consumer Project on Technology	3/19/02
Glynn S. **Lunney**, Jr.	Professor of Law, Tulane Law School	7/10/02
Jeff **MacKie-Mason**	Arthur W. Burks Professor of Information and Computer Science and Professor of Economics and Public Policy, University of Michigan	5/1/02
Stephen B**. Maebius**	Partner, Foley & Lardner	4/11/02
Amy A. **Marasco**	Vice President and General Counsel, American National Standards Institute	4/18/02
Eric **Maskin**	Harvard University and Massachusetts Institute of Technology	Public Comment
Julie **Mar-Spinola**	Chief Litigation and Intellectual Property Counsel, Atmel Corporation	2/28/02
Daniel **McCurdy**	President and Chief Executive Officer, ThinkFire	3/20/02
Michael **McFalls**	Associate, Jones, Day, Reavis & Pogue	11/6/02
Barbara M. **McGarey**	Deputy Associate General Counsel, National Institutes of Health	11/6/02
David **McGowan**	Associate Professor of Law, University of Minnesota School of Law	4/17/02
Kirtikumar **Mehta**	Director, DG COMP/A, European Commission	5/22/02

Name	Affiliation	Date
Luis **Mejia**	Senior Associate, Office of Technology Licensing, Stanford University	2/27/02
A. Douglas **Melamed**	Partner, Wilmer, Cutler & Pickering	5/1/02; 5/14/02
Robert P. **Merges**	Wilson Sonsini Goodrich & Rosati Distinguished Professor of Law and Technology and Director, Berkeley Center for Law and Technology, University of California, Berkeley	2/26/02; 2/28/02
Stephen A. **Merrill**	Executive Director, Board on Science Technology and Economic Policy, National Research Council/National Academy of Sciences	10/25/02; 10/30/02
Joseph Scott **Miller**	Assistant Professor, Lewis & Clark Law School	5/14/02
Paul **Misener**	Vice President, Global Public Policy, Amazon.com	2/27/02
John T. **Mitchell**	Partner, Seyfarth Shaw Fairweather and Geraldson Public comment on behalf of the the Video Software Dealers Association (VSDA) which is the international trade association representing the home video industry and video stores across the nation.	Public Comment
M.J. **Moltenbrey**	Former Director of Civil Non-Merger Enforcement, U.S. Department of Justice, Antitrust Division	5/14/02
Michael J. **Moore**	Bank of America Research Professor of Business Administration, Darden School, University of Virginia	Public Comment
Jeremiah T. **Moree**	PC Xperience	Public Comment

Name	Affiliation	Date
Paul F. **Morgan**	Personal Comments regarding Competition and Intellectual Property	Public Comment
M. Howard **Morse**	Partner, Drinker, Biddle & Reath, LLP	4/17/02
Gerald **Mossinghoff**	Senior Counsel, Oblon, Spivak, McClelland, Maier & Neustadt; former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks	2/6/02; 10/30/02; Public Comment
David C. **Mowery**	Milton W. Terrill Professor of Business, University of California, Berkeley	2/27/02
Timothy **Muris**	Chairman, Federal Trade Commission	2/6/02
Mary U. **Musacchia**	Counsel to the President/CEO and Director, Government Relations & Public Policy, SAS Institute	4/9/02; Public Comment
Ronald E. **Myrick**	Chief Patent Counsel, General Electric; President-Elect, American Intellectual Property Law Association	3/19/02; 10/30/02
Philip B. **Nelson**	Principal, Economists, Inc	2/20/02
Joshua **Newberg**	Assistant Professor, Robert H. Smith School of Business, University of Maryland	4/17/02; 5/23/02
The Honorable Pauline **Newman**	U.S. Court of Appeals for the Federal Circuit	2/6/02
Rick D. **Nydegger**	Shareholder, Workman, Nydegger & Seeley	2/27/02; 4/11/02
Vincent E. **O'Brien**	Director, LECG, LLC	Public Comment
Ross **Oehler**	Vice President, U.S. Patent Operations, Aventis Pharmaceuticals Inc.	2/26/02

Name	Affiliation	Date
DonPaul **Olshove**	Comments regarding Competition and Intellectual Property, April 25, 2002	Public Comment
Open GIS Consortium (OGC)	OGC is an industry consortium aimed at growing interoperability for technologies involving spatial information and location.	Public Comment
Janusz **Ordover**	Professor of Economics, New York University	2/20/02; 11/6/02
Maureen A. **O'Rourke**	Professor of Law, Boston University School of Law	2/20/02
Roger W. **Parkhurst**	Partner, Parkhurst & Wendel, LLP; President, American Intellectual Property Law Association	4/10/02
Mark R. **Patterson**	Associate Professor of Law, Fordham University School of Law	4/18/02
Scott K. **Peterson**	Corporate Counsel, Hewlett-Packard Company	4/18/02; 11/6/02
Pharmaceutical Research and Manufacturers of America (PhRMA)	PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies.	Public Comment
Robert **Pitofsky**	Professor of Law, Georgetown University Law Center; former Chairman of the Federal Trade Commission	2/6/02; Public Comment
John **Place**	Executive Director, Center for Internet and Society, Stanford University Law School	2/27/02
James **Pooley**	Partner, Milbank, Tweed, Hadley & McCoy	2/27/02; 10/30/02
Joel **Poppen**	Director, Patent Litigation and Licensing, Micron Technology, Inc.	2/28/02

Name	Affiliation	Date
Robert **Potter**	Chief, Legal Policy Section, Antitrust Division	4/17/02
Thomas **Pritchard**, Sr.	Digital Video Yellow Pages	Public Comment
Phillip A. **Proger**	Partner, Jones, Day, Reavis & Pogue	5/2/02
Daniel I. **Prywes**	Partner, Pepper Hamilton, LLP	Public Comment
Jonathan **Putnam**	Assistant Professor of the Law and Economics of Intellectual Property, University of Toronto School of Law	4/17/02
Cecil D. **Quillen**, Jr.	Senior Advisor, Cornerstone Research	3/19/02; 7/11/02; Public Comments
Arti K. **Rai**	Assistant Professor of Law, University of Pennsylvania Law School	4/10/02
Richard T. **Rapp**	President, National Economic Research Associates	4/18/02; Public Comment
Patrick **Rey**	Professor of Economics, University of Toulouse; Research Director, Institut d'Economie Industrielle	5/22/02
Desi **Rhoden**	President and Chief Executive Officer, Advanced Memory International, Inc.	2/28/02
Sal **Ricciardi**	President, Pharmaceutical Distribution Association	Public Comment
Robert M. **Riches**	Former Senior Component Design Engineer and CAD Engineer, large semiconductor manufacturer	Public Comment
James **Rill**	Partner, Howrey Simon Arnold & White, LLP	5/23/02
James **Rogan**	Under Secretary of Commerce for Intellectual Property and Director of the U. S. Patent and Trademark Office	2/6/02; Public Comment

Name	Affiliation	Date
Daniel L. **Rubinfeld**	Robert L. Bridges Professor of Law, and Professor of Economics, University of California, Berkeley	2/25/02
Charles F. **Rule**	Partner, Fried, Frank, Harris, Shriver & Jacobson	11/6/02
Adam J. **Safer**	Miller & Wrubel P.C.	Public Comment
Scott **Sander**	President, Chief Executive Officer and Co-Founder, SightSound Technologies	3/20/02
Kurt M. **Saunders**	Assistant Professor of Business Law, California State University, Northridge	Public Comment
F. M. **Scherer**	Roy E. Larson Professor of Public Policy and Management, Harvard University	7/10/02
Suzanne Andersen **Scotchmer**	Professor of Economics and Public Policy, University of California, Berkeley	2/26/02; 4/10/02
Rochelle K. **Seide**	Partner, Baker Botts, LLP	3/19/02
Carl **Shapiro**	Transamerica Professor of Business Strategy and Professor of Economics, Haas School of Business; Director, Institute of Business and Economic Research, University of California, Berkeley	2/27/02; 5/1/02; 5/2/02; 11/6/02
Howard **Shelanski**	Acting Professor of Law, and Director, Berkeley Center for Law and Technology, University of California, Berkeley	2/25/02
David S. **Sibley**	John Michael Stuart Professor of Economics, University of Texas at Austin	5/14/02

Name	Affiliation	Date
J. Gregory **Sidak**	F.K. Weyerhaeuser Fellow in Law and Economics Emeritus, American Enterprise Institute	5/14/02
Edward A. **Snyder**	Dean and Professor of Economics, University of Chicago Graduate School of Business	3/19/02; Public Comment
Gerald **Sobel**	Partner, Kaye Scholer, LLP	7/10/02; Public Comment
Christopher J. **Sprigman**	Counsel, King & Spalding	5/1/02
Stephen A. **Stack**, Jr	Partner, Dechert	5/2/02
Richard **Stallman**	President, Free Software Foundation	4/9/02; Public Comment
Lauren J. **Stiroh**	Vice President, National Economic Research Associates	4/18/02; Public Comment
Robert **Stoll**	Administrator for External Affairs, United States Patent and Trademark Office	4/11/02
Robert D. **Stoner**	Vice President, Economists, Inc	2/26/02; 10/30/02
Daniel **Swanson**	Partner, Gibson, Dunn & Crutcher, LLP	4/18/02
Lawrence M. **Sung**	Assistant Professor, University of Maryland School of Law	2/8/02 (Patent Law for Antitrust Lawyers); 4/17/02
Toshiaki **Tada**	Associate, Weil, Gotshal & Manges, LLP	5/23/02
Robert P. **Taylor**	Partner, Howrey Simon Arnold & White, LLP	2/27/02; 7/11/02; 10/25/02
David J. **Teece**	Mitsubishi Bank Professor of International Business and Finance, University of California, Berkeley	2/26/02; 2/27/02; 4/18/02

Name	Affiliation	Date
Frederick J**. Telecky**, Jr.	Senior Vice President and General Patent Counsel, Texas Instruments	2/28/02; Public Comment
John R. **Thomas**	Professor of Law, Georgetown University Law Center	2/8/02 (Patent Law for Antitrust Lawyers); 4/10/02 4/11/02; 10/25/02; 10/30/02
Earle **Thompson**	Intellectual Asset Manager and Senior Counsel, Texas Instruments	11/6/02
Lawrence **Thompson**	Associate, Thomas, Kayden, Horstemeyer & Risley, LLP	Public Comment
Mozelle W. **Thompson**	Commissioner, Federal Trade Commission	2/25/02
Richard L. **Thurston**	Vice President and General Counsel, Taiwan Semiconductor Manufacturing Company, Ltd.	3/20/02
Willard K. **Tom**	Partner, Morgan Lewis & Bockius	2/8/02 (Antitrust Law for Patent Lawyers); 5/22/02
Lawrence J. **Udell**	Executive Director, Intellectual Property International, Ltd.	2/28/02
United States Council for International Business (USCIB)	Pro-trade, pro-market liberalization organization which promotes American business views and solutions on a wide range of issues – from telecommunications to e-commerce to labor relations – directly to U.S. and international policy makers.	Public Comment
Andrew **Updegrove**	Partner, Lucash, Gesmer & Updegrove, LLP	4/18/02

Name	Affiliation	Date
Hal R. **Varian**	Dean, School of Information Management and Systems; Professor, Haas School of Business and Department of Economics, University of California, Berkeley	2/25/02
James S. **Venit**	Partner, Skadden, Arps, Slate, Meagher & Flom, LLP	5/22/02
Paul **Vishny**	Member, D'Ancona & Pflaum LLC; General Counsel, Telecommunications Industry Association	11/6/02
Gregory **Vistnes**	Vice President, Charles River Associates	5/14/02
Herbert C. **Wamsley**	Executive Director, Intellectual Property Owners Association	7/10/02
Mark **Webbink**	Senior Vice President and General Counsel, Red Hat, Inc.	3/20/02; Public Comment
Ogden H. **Webster**	Former Assistant General Counsel, Eastman Kodak Company	Public Comment
Matthew **Weil**	Partner, McDermott, Will & Emery	7/11/02
Les J. **Weinstein**	Partner, Squire, Sanders, & Dempsey	2/27/02
Daniel **Weitzner**	Director of Technology and Society Activities, World Wide Web Consortium	4/18/02; Pubic Comment
Charles D. **Weller**	Law Offices of Charles D. Weller	Public Comment
Lawrence **White**	Arthur E. Imperatore Professor of Economics, Leonard N. Stern School of Business, New York University	2/20/02
Mark **Whitener**	Antitrust and General Counsel, General Electric	5/1/02

Name	Affiliation	Date
Alik **Widge**	Comments regarding Competition & Intellectual Property, February 9, 2002	Public Comment
John Shepard **Wiley**, Jr.	Professor of Law, University of California, Los Angeles	5/1/02
George T. **Willingmyre**, P.E.	President, GTW Associates	Public Comment
Harry **Wolin**	Vice President of Intellectual Property, Advanced Micro Devices, Inc.	3/20/02
Dennis **A. Yao**	Associate Professor of Business and Public Policy and Management, The Wharton School, University of Pennsylvania	4/18/02
Robert **Young**	Chairman, Red Hat, Inc.; Chairman, Center for Public Domain	4/11/02
Gary **Zanfagna**	Associate General Counsel for Antitrust, Honeywell International	3/20/02
Rosemarie **Ziedonis**	Assistant Professor of Management, The Wharton School of the University of Pennsylvania	3/20/02

APPENDIX B:
Public Comments

Name	Title of Comments
American Bar Association Section of Antitrust Law	• *Comments Re: U.S. Department of Justice Antitrust Division and Federal Trade Commission Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, June 28, 2002* • *Report on the United States Court of Appeals for the Federal Circuit* • *The Economics of Innovation: A Survey*
American Bar Association Section of Intellectual Property Law	• *Statement of Robert P. Taylor on Behalf of Section of Intellectual Property Law American Bar Association on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, July 11, 2002*
American Intellectual Property Law Association	• *AIPLA Testimony Before Federal Trade Commission and Antitrust Division on Antitrust and Intellectual Property Issues, April 10, 2002*
American National Standards Institute (ANSI)	• *Comments Re: FTC/DOJ Hearings on the Implications of Competition and Patent Law and Policy, November 14, 2002*
Aventis Pharmaceuticals, Inc.	• *Comments, Dr. Nahed Ahmed, Vice President, Productivity, Portfolio & Project Management Drug Innovation & Approval, Aventis Pharmaceuticals Inc., July 15, 2002*
David **Balto** and Daniel I. **Prywes**	• *Standard-Setting Disputes: The Need for Guidelines*
Bruce E. **Barnes**	• *Comments Regarding Competition & Intellectual Property, April 15, 2002*
John H. **Barton**	• *International Patent-Antitrust Principles: The United States-European Balances, Statement for DOJ/FTC Joint Hearings, May 22, 2002* • *Reforming the Patent System*
Jim **Bessen** and Eric **Maskin**	• *Sequential Innovation, Patents, and Imitation*
John R. **Boyce** and Aidan **Hollis**	• *Innovation, Imitation & Preliminary Injunctions in Patents*
Eric **Buddington**	• *Comments Regarding Competition & Intellectual Property, November 29, 2001*
Michael A. **Carrier**	• *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation* • *Unraveling the Patent-Antitrust Paradox*
Gregory John **Casamento**	• *Comments Regarding Competition & Intellectual Property, February 20, 2002*
James A. **Craft**	• *Patent Pools and Cross-Licensing: When Do They Promote or Harm Competition?, April 25, 2002*
Mark **Ellis**	• *Comments Regarding Competition & Intellectual Property*

Frank **Fine**	• *NDC/IMS: A Logical Application of Essential Facilities Doctrine*
Richard J. **Holleman**	• *A Response: Government Guidelines Should Not Be Issued in Connection with Standards Setting*
Thomas J. **Horton**	• *Patenting Our Lives and Our Genes: Where Does Congress Stand in the Coming Clash?*
Robert M. **Hunt**	• *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* • *Patentability, Industry Structure, and Innovation* • *Patent Reform: A Mixed Blessing For the U.S. Economy?* • *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the New Economy?*
Institute of Electrical and Electronics Engineers (IEEE)	• *Comments Regarding Competition & Intellectual Property, April 17, 2002*
Intellectual Property Owners Association (IPO)	• *Comments Regarding Competition & Intellectual Property, Nov. 15, 2002*
Brian **Kahin**	• *A Possible Higher Standard of Nonobviousness* • *Comments Submitted by Brian Kahin, University of Maryland, Concerning Discussion of Institutional Roles During October 25 Roundtable* • *The Expansion of the Patent System: Politics and Political Economy*
David A. **Kantor** and Sal **Ricciardi**	• *Comments Regarding Competition & Intellectual Property, May 10, 2002*
Ronald S. **Katz** and Adam J. **Safer**	• *Why is One Patent Court Deciding Antitrust Law for the Whole Country?*
F. Scott **Kieff**	• *Summary of Proposed Testimony*
Zoe **Konovalov**	• *The Economics of Open Source Software*
Jeffrey R. **Kuester** and Lawrence E. **Thompson**	• *Risks Associated With Restricting Business Method and E-Commerce Patents*
James J. **Kulbaski**	• *Comments On Patent Pools and Standards For Federal Trade Commission Hearings Regarding Competition & Intellectual Property, January 2002*
League for Programming Freedom	• *Against Software Patents, February 28, 1991*
Rusty **Lee**	• *Comments Regarding Competition & Intellectual Property, March 24, 2002*
Nick **Leggett**	• *Comments Regarding Competition & Intellectual Property, February 13, 2002*
Hans **Lennros**	• *Question Regarding Competition & Intellectual Property, January 12, 2002*
Joshua **Lerner**	• *The Patent System and Competition*

Richard C. **Levin**	• *Testimony of Richard C. Levin, President, Yale University, February 6, 2002*
Arthur D. Little, Inc.	• *Arthur D. Little Bio-Pharmaceutical Study Finds Significant Link Between Innovation and Market-Based Drug Pricing* • *Executive Summary: Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation*
Microsoft Corporation	• *Statement of Dan Crouse, Deputy General Counsel, Microsoft Corporation*
John T. **Mitchell**	• *Retailers of Intellectual Property: The Competitive Voice of Consumers, Statement by John T. Mitchell on behalf of Video Software Dealers Association, July 2002*
Jeremiah T. **Moree**	• *Comments Regarding Competition & Intellectual Property, January 28, 2002*
Paul F. **Morgan**	• *Personal Comments for the Joint FTC and DOJ Public Hearings on Intellectual Property Law beginning February 6, 2002*
Gerald J. **Mossinghoff**	• *Statement of Hon. Gerald J. Mossinghoff, Senior Counsel, Oblon, Spivak, McClelland, Maier & Neustadt, February 6, 2002*
Mary U. **Musacchia**	• *Prepared Remarks of Mary U. Musacchia, Counsel to the President/CEO Director, Government Relations & Public Policy SAS Institute Inc., Cross Industry Perspectives on Patents, April 9, 2002*
Vincent E. **O'Brien**	• *Economics and Key Patent Damage Cases*
DonPaul **Olshove**	• *Comments Regarding Competition & Intellectual Property, April 25, 2002*
Open GIS Consortium (OGC)	• *Intellectual Property Rights Policy of Open GIS Consortium, Inc., May 9, 2002*
Pharmaceutical Research and Manufacturers of America (PhRMA)	• *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights (White Paper on the Intersection of Intellectual Property and Antitrust Law in the Pharmaceutical Industry)*
Robert **Pitofsky**	• *The Essential Facilities Doctrine Under United States Antitrust Law*
Thomas **Pritchard**, Sr.	• *Comments Regarding Competition & Intellectual Property Law, September 20, 2002*

Cecil D. **Quillen**, Jr.	• *Continuing Patent Applications and Performance of the U.S. Patent Office* (Cecil D. Quillen, Jr. and Ogden H. Webster) • *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office - Extended* (Cecil D. Quillen, Jr., Ogden H. Webster, and Richard Eichmann) • *Innovation and The United States Patent System Today* • *Innovators, Innovation, and the U.S. Patent System* • *Patent Standards and Innovation, The National Academies Board on Science, Technology and Economic Policy, Conference on Intellectual Property Rights: How Far Should They Be Extended? February 2-3, 2000* • *Proposal For the Simplification and Reform of the United States Patent System* • *Testimony of Cecil D. Quillen, Jr., Presented at the Public Hearing on the Standard of Nonobviousness at the United States Patent and Trademark Office on July 20, 1994* • *The U.S. Patent System: Is It Broke? And Who Can Fix It If It Is?*
Richard T. **Rapp** and Lauren J. **Stiroh**	• *Standard Setting and Market Power, April 18, 2002*
Sal **Ricciardi**	• *Comments Regarding Competition & Intellectual Property, April 5, 2002*
Robert M. **Riches** Jr.	• *Comments Regarding Competition & Intellectual Property*
James **Rogan**	• *Prepared Remarks of James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, February 6, 2002*
Kurt M. **Saunders**	• *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*
Edward A. **Snyder**, James W. **Hughes** & Michael J. **Moore**	• *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare*
Gerald **Sobel**	• *Patent Scope and Competition: Is The Federal Circuit's Approach Correct?*
Richard **Stallman**	• *The Danger of Software Patents, Speech by Richard Stallman at Cambridge University, March 25, 2002*
Frederick J. **Telecky**, Jr.	• *Statement of Frederick J. Telecky, Jr., Senior Vice President and General Counsel, Texas Instruments, June, 3, 2002*
United States Council for International Business (USCIB)	• *Comments of the United States Council for International Business on the Joint Hearings of the Federal Trade Commission and the Department of Justice Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, July 12, 2002*

Mark **Webbink** with Colin **Crossman**, Thomas **Griffin** and David **Silverstein**	• *Red Hat's Comments to the Joint FTC/DOJ Hearing on Competition and Intellectual Property Law, March 20, 2002*
Daniel **Weitzner**	• *Supplemental Comments, Standards and Intellectual Property: Antitrust Law and Patent Landscapes* • *W3C Patent Policy*
Chuck **Weller**	• *Daubert Sounds the Death Knell for Antitrust's Merger Presumption After Baby Foods* • *Harmonizing Antitrust Worldwide by Evolving to Michael Porter's Dynamic Productivity Growth Analysis* • *Patent Reform by Daubert Litigation*
Alik **Widge**	• *Comments Regarding Competition & Intellectual Property, February 9, 2002*
George T. **Willingmyre**, P.E.	• *Approaches to Influence the IPR Policies and Practices in US and Global Standards Setting, June 14, 2002* • *Comments Regarding Competition & Intellectual Property, GTW Associates, June 14, 2002* • *Considerations in Assessing a Standards Developing Organization's Intellectual Property Rights Policies in Advance of Participation, June 14, 2002* • *Intellectual Property Rights Policies of Selected Standards Developers, May 2002*

APPENDIX C:
Glossary of Patent Terms

Primary Source: United States Patent and Trademark Office Website: http://www.uspto.gov/main/glossary/index.html.

Term	Definition
Applicant	Inventor or joint inventors who are applying for a patent on their own invention, or the person mentioned in 37 C.F.R. 1.42, 1.43 or 1.47 who is applying for a patent in place of the inventor.
Continuation-in-Part (CIP)	An application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the earlier nonprovisional application.
Claims	Define the invention and are what are legally enforceable. The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery. The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.
Continuation	A second application for the same invention claimed in a prior nonprovisional application and filed before the first application becomes abandoned or patented.
Continuing Application	A continuation, divisional, or continuation-in-part patent application.
Copyrights	Protect works of authorship, such as writings, music, and works of art that have been tangibly expressed. The Library of Congress registers copyrights which last for the life of the author plus 70 years.
Disclosure	In return for a patent, the inventor gives as consideration a complete revelation or disclosure of the invention for which protection is sought.
Divisional Application	A later application for an independent or distinct invention disclosing and claiming (*only a portion of and*) only subject matter disclosed in the earlier or parent application.
Enforceability of Patent	The right of the patent owner to bring an infringement suit against a party who, without permission, makes, uses or sells the claimed invention. The period of enforceability of a patent is the length of the term of the patent plus the six years under the statute of limitations for bringing an infringement action.

Term	Definition
Interference	A proceeding, conducted before the Board of Patent Appeals and Interferences (Board), to determine priority of invention between a pending application and one or more pending applications and/or one or more unexpired patents.
Invention	Any art or process *(way of doing or making things)*, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.
Inventor	One who contributes to the conception of an invention. The patent laws of the United States require that the applicant in a patent application must be the inventor.
Manual of Patent Examining Procedure (MPEP)	The MPEP is published to provide U.S. Patent and Trademark Office patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the U.S. Patent and Trademark Office. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application.
Parent Application	The term "parent" is applied to an earlier application of the inventor disclosing a given invention.
Patent	A property right granted by the U.S. Government to an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited time in exchange for public disclosure of the invention when the patent is granted.
Patent Application	A nonprovisional utility patent application must include a specification, including a claim or claims; drawings, when necessary; an oath or declaration; and the prescribed filing fee.
Patent Application Publication	Pre-grant publication of patent application at 18 months from priority date.
Patentable	Suitable to be patented; entitled by law to be protected by the issuance of a patent.
Priority Claim	Claims under 35 U.S.C. 119(a)-(e) and 35 U.S.C. 120 for the benefit of the filing date of earlier filed applications.

Term	Definition
Reexamination Proceeding	At any time during the enforceability of the patent, any person may request reexamination by the Office of any claim of a patent on the basis of prior patents or printed publications cited under 37 C.F.R. 1.501. In order for the request for reexamination to be granted, a substantial new question of patentability must be present with regard to at least one patent claim. The request must be in writing and must be accompanied by payment of a reexamination request filing fee as set forth in 37 C.F.R. 1.20(c).
Reissue Application	An application for a patent to take the place of an unexpired patent that is defective in one or more particulars *(items or details)*.
Specification	A written description of the invention and the manner and process of making and using the same.
Technology Center (or TC, also referred to as a Group)	A unit of several Group Art Units* in the mechanical, electrical, chemical or design area, managed by one or more Group Directors. Formerly referred to as Groups. *Group Art Unit - a working unit responsible for a cluster of related patent art. Staffed by one supervisory patent examiner and a number of patent examiners who determine patentability on applications for a patent. Group Art Units are identified by a four digit number, i.e., 1642.
Trade Secret	Information that companies keep secret to give them an advantage over their competitors.
Utility Patent	May be granted to anyone who invents or discovers any new, useful, and nonobvious process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.

APPENDIX D:
Selected Federal Statutes

U.S. Patent Code

35 U.S.C. § 101
35 U.S.C. § 102
35 U.S.C. § 103
35 U.S.C. § 112
35 U.S.C. § 120
35 U.S.C. § 122(b)(1)(A)
35 U.S.C. § 122(b)(2)(B)(i)
35 U.S.C. § 271
35 U.S.C. § 273(a)(3)
35 U.S.C. § 273(b)(1)-(b)(3)(A)
35 U.S.C. § 282
35 U.S.C. § 284
35 U.S.C. § 301
35 U.S.C. § 302
35 U.S.C. § 303
35 U.S.C. § 304
35 U.S.C. § 305
35 U.S.C. § 306
35 U.S.C. § 311
35 U.S.C. § 312
35 U.S.C. § 313
35 U.S.C. § 314
35 U.S.C. § 315

Federal Trade Commission Act

15 U.S.C. § 41
15 U.S.C. § 44
15 U.S.C. § 45(a)
15 U.S.C. § 46(f)

Sherman Act

15 U.S.C. § 1
15 U.S.C. § 2
15 U.S.C. § 3

Clayton Act

15 U.S.C. § 18

U.S. Patent Code

35 U.S.C. § 101. Inventions patentable
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title [35 USCS §§ 1 et seq.].

35 U.S.C. § 102. Conditions for patentability; novelty and loss of right to patent
A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 103. Conditions for patentability; nonobvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b) (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if--

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)--

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means--

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to--

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 120. Benefit of earlier filing date in the United States

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

35 U.S.C. § 122(b)(1)(A). Confidentiality

Except as provided in subsection (b), applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of an Act of Congress or in such special circumstances as may be determined by the Director.

35 U.S.C. § 122(b)(2)(B)(i). Exceptions

If an applicant makes a request upon filing, certifying that the invention disclosed in the application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing, the application shall not be published as provided in paragraph (1).

35 U.S.C. § 271. Infringement of patent

(a) Except as otherwise provided in this title [35 USCS §§ 1 et seq.], whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e) (1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act [21 USCS § 360b] or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(f) (1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no

adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

35 U.S.C. § 273(a)(3). Defense to infringement based on earlier inventor: Definitions

The term "method" means a method of doing or conducting business . . . .

35 U.S.C. § 273(b)(1)-(b)(3)(A). Defense to infringement

(1) In general. – It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims for a method in the patent being asserted against a person, if such person had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.

(2) Exhaustion of right. – The sale or other disposition of a useful end product produced by a patented method, by a person entitled to assert a defense under this section with respect to that useful end result shall exhaust the patent owner's rights under the patent to the extent such rights would have been exhausted had such sale or other disposition been made by the patent owner.

(3) Limitations and qualifications of defense. – The defense to infringement under this section is subject to the following:

(A) Patent. – A person may not assert the defense under this section unless the invention for which the defense is asserted is for a method. . . .

35 U.S.C. § 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such

invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,
(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title [35 USCS §§ 100 et seq.] as a condition for patentability,
(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title.
(4) Any other fact or act made a defense by this title. . . .

35 U.S.C. § 284. Damages.

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court. When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title. The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

35 U.S.C. § 301. Citation of prior art

Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

35 U.S.C. § 302. Request for reexamination

Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301 of this title. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of section 41 of this title. The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Director promptly will send a copy of the request to the owner of record of the patent.

35 U.S.C. § 303. Determination of issue by Director

(a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and

publications discovered by him or cited under the provisions of section 301 of this title. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) A record of the Director's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting reexamination, if any.

(c) A determination by the Director pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and nonappealable. Upon such a determination, the Director may refund a portion of the reexamination fee required under section 302 of this title.

35 U.S.C. § 304. Reexamination order by Director

If, in a determination made under the provisions of subsection 303(a) of this title, the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and new claim or claims he may wish to propose, for consideration in the reexamination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested reexamination under the provisions of section 302 of this title. Within a period of two months from the date of service, that person may file and have considered in the reexamination a reply to any statement filed by the patent owner. That person promptly will serve on the patent owner a copy of any reply filed.

35 U.S.C. § 305. Conduct of reexamination proceedings

After the times for filing the statement and reply provided for by section 304 of this title have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133 of this title. In any reexamination proceeding under this chapter [35 USCS §§ 301 et seq.], the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter [35 USCS §§ 301 et seq.]. All reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, will be conducted with special dispatch within the Office.

35 U.S.C. § 306. Appeal

The patent owner involved in a reexamination proceeding under this chapter [35 USCS §§ 301 et seq.] may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

35 U.S.C. § 311. Request for inter partes reexamination

(a) In general. Any third-party requester at any time may file a request for inter partes reexamination by the Office of a patent on the basis of any prior art cited under the provisions of section 301.

(b) Requirements. The request shall--

(1) be in writing, include the identity of the real party in interest, and be accompanied by payment of an inter partes reexamination fee established by the Director under section 41; and
(2) set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested.

(c) Copy. The Director promptly shall send a copy of the request to the owner of record of the patent.

35 U.S.C. § 312. Determination of issue by Director

(a) Reexamination. Not later than 3 months after the filing of a request for inter partes reexamination under section 311, the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) Record. A record of the Director's determination under subsection (a) shall be placed in the official file of the patent, and a copy shall be promptly given or mailed to the owner of record of the patent and to the third-party requester.

(c) Final decision. A determination by the Director under subsection (a) shall be final and non-appealable. Upon a determination that no substantial new question of patentability has been raised, the Director may refund a portion of the inter partes reexamination fee required under section 311.

35 U.S.C. § 313. Inter partes reexamination order by Director

If, in a determination made under section 312(a), the Director finds that a substantial new question of patentability affecting a claim of a patent is raised, the determination shall include an order for inter partes reexamination of the patent for resolution of the question. The order may be accompanied by the initial action of the Patent and Trademark Office on the merits of the inter partes reexamination conducted in accordance with section 314.

35 U.S.C. § 314. Conduct of inter partes reexamination proceedings

(a) In general. Except as otherwise provided in this section, reexamination shall be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133. In any inter partes reexamination proceeding under this chapter [35 USCS §§ 311 et seq.], the patent owner shall be permitted to propose any amendment to the patent and a new claim or claims, except that no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted.

(b) Response.

(1) With the exception of the inter partes reexamination request, any document filed by either the patent owner or the third-party requester shall be served on the other party. In addition, the Office shall send to the third-party requester a copy of any communication sent by the Office to the patent owner concerning the patent subject to the inter partes reexamination proceeding.

(2) Each time that the patent owner files a response to an action on the merits from the Patent and Trademark Office, the third-party requester shall have one opportunity to file written comments addressing issues raised by the action of the Office or the patent owner's response thereto, if those written comments are received by the Office within 30 days after the date of service of the patent owner's response.

(3) [Redesignated]

(c) Special dispatch. Unless otherwise provided by the Director for good cause, all inter partes reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, shall be conducted with special dispatch within the Office.

35 U.S.C. § 315. Appeal

(a) Patent owner. The patent owner involved in an inter partes reexamination proceeding under this chapter [35 USCS §§ 311 et seq.]--

(1) may appeal under the provisions of section 134 and may appeal under the provisions of sections 141 through 144, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent; and

(2) may be a party to any appeal taken by a third-party requester under subsection (b).

(b) Third-party requester. A third-party requester--

(1) may appeal under the provisions of section 134, and may appeal under the provisions of sections 141 through 144, with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent; and

(2) may, subject to subsection (c), be a party to any appeal taken by the patent owner under the provisions of section 134 or sections 141 through 144.

(c) Civil action. A third-party requester whose request for an inter partes reexamination results in an order under section 313 is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the inter partes reexamination proceedings. This subsection does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third-party requester and the Patent and Trademark Office at the time of the inter partes reexamination proceedings.

Federal Trade Commission Act

15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade.

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 18(f)(3) [15 USCS § 57a(f)(3)], Federal credit unions described in section 18(f)(4) [15 USCS § 57a(f)(4)], common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to the Federal Aviation Act of 1958 [49 USCS §§ 40101 et seq.], and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 USCS §§ 181 et seq.], except as provided in section 406(b) of said Act [7 USCS § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless--

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect--

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States. . . .

15 U.S.C. § 46(f). Publication of information; reports.

To make public from time to time such portions of the information obtained by it hereunder as are in the public interest; and to make annual and special reports to the Congress and to submit therewith recommendations for additional legislation; and to provide for the publication of its reports and decisions in such form and manner as may be best adapted for public information and use: Provided, That the Commission shall not have any authority to make public any trade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential, except that the Commission may disclose such information to officers and employees of appropriate Federal law enforcement agencies or to any officer or employee of any State law enforcement agency upon the prior certification of an officer of any such Federal or State law enforcement agency that such information will be maintained in confidence and will be used only for official law enforcement purposes.

Sherman Act

15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2. Monopolization; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 3. Trusts in Territories or District of Columbia illegal; combination a felony

(a) Every contract, combination in form of trust or otherwise, or conspiracy, in restraint of trade or commerce in any Territory of the United States or of the District of Columbia, or in restraint of trade or commerce between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia and any State or States or foreign nations, is declared illegal. Every person who shall make any such contract or engage in any such combination or conspiracy, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

(b) Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce in any Territory of the United States or of the District of Columbia, or between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia, and any State or States or foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $ 350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

Clayton Act

15 U.S.C. § 18. Acquisition by one corporation of stock of another

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition, of such stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially to lessen competition, or to tend to create a monopoly.

This section shall not apply to persons purchasing such stock solely for investment and not using the same by voting or otherwise to bring about, or in attempting to bring about, the substantial lessening of competition. Nor shall anything contained in this section prevent a corporation engaged in commerce or in any activity affecting commerce from causing the formation of subsidiary corporations for the actual carrying on of their immediate lawful business, or the natural and legitimate branches or extensions thereof, or from owning and holding all or a part of the stock of such subsidiary corporations, when the effect of such formation is not to substantially lessen competition.

Nor shall anything herein contained be construed to prohibit any common carrier subject to the laws to regulate commerce from aiding in the construction of branches or short lines so located as to become feeders to the main line of the company so aiding in such construction or from acquiring or owning all or any part of the stock of such branch lines, nor to prevent any such common carrier from acquiring and owning all or any part of the stock of a branch or short line constructed by an independent company where there is no substantial competition between the company owning the branch line so constructed and the company owning the main line acquiring the property or an interest therein, nor to prevent such common carrier from extending any of its lines through the medium of the acquisition of stock or otherwise of any other common carrier where there is no substantial competition between the company extending its lines and the company whose stock, property, or an interest therein is so acquired.

Nothing contained in this section shall be held to affect or impair any right heretofore legally acquired: Provided, That nothing in this section shall be held or construed to authorize or make lawful anything heretofore prohibited or made illegal by the antitrust laws, nor to exempt any person from the penal provisions thereof or the civil remedies therein provided.

Nothing contained in this section shall apply to transactions duly consummated pursuant to authority given by the Secretary of Transportation, Federal Power Commission, Surface Transportation Board, the Securities and Exchange Commission in the exercise of its jurisdiction under section 10 of the Public Utility Holding Company Act of 1935 [15 USCS § 79j], the United States Maritime Commission, or the Secretary of Agriculture under any statutory provision vesting such power in such Commission, Board, or Secretary.

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