

"A GOVERNMENT PERSPECTIVE ON IP AND ANTITRUST LAW"

REMARKS OF

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I am pleased to have the opportunity to provide a perspective on the intersection of intellectual property ("IP") and antitrust law and enforcement.

The title of this conference, "The IP Grab: the Struggle Between Intellectual Property Rights and Antitrust" is certainly evocative. But to examine effectively the topic, it is important to recognize that the two bodies of law are complementary, with both playing an essential role in promoting innovation, which provides vast and continuing benefits for consumers. Antitrust and IP contribute to that effort in ways that are different, but not entirely separate.

To most effectively foster progress and enhance economic welfare, both must function

¹ The views stated here are my own and do not necessarily reflect the views of the Commission or any other Commissioner.

according to sound economic principles. Any errors or systematic biases in how one body of law is interpreted and applied can harm the other's effectiveness.

If a patent is properly granted under appropriate standards of patentability, the incentives and other advantages it provides typically outweigh possible market power concerns. Indeed, the FTC's 2003 Report on competition and patent law policy ("FTC's IP Report")² strongly endorsed a properly functioning patent system. If, however, a patent should not have been granted – as a result either of a flawed standard of patentability or of examiner error – any ensuing harm to competition would be unwarranted. The FTC has advocated the passage of legislation that would reform certain aspects of the patent system to eliminate or reduce the harm to competition that results from the granting of questionable patents.³

An examination of the economic effects of various patent rules, both legislative and judicial, can enhance the process of making and applying the patent laws. Legal rules do not exist in a vacuum, and their likely effect on competition is often relevant in determining which legal and policy choices to make.⁴

²Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy* (Oct. 2003) (*IP Report*), *at* http://www.ftc.gov/opa/2003/10/ipreport.htm. The transcripts of the hearings underlying the report and materials submitted by participants are available at http://www.ftc.gov/opp/intellect/index.htm.

³The Subcommittee on Courts, the Internet, and Intellectual Property of the Committee on the Judiciary for the House of Representatives has held several hearings relevant to H.R. 2795, the "Patent Reform Act." On June 15, 2006, the Subcommittee conducted its seventh hearing on patent reform in the 109th Congress by examining the issue of "patent trolls." The Hon. Lamar Smith, Opening Statement, "Patent Trolls: Fact or Fiction?" (June 15, 2006), at http://judiciary.house.gov/oversight.aspx?ID=245.

⁴For that reason, the FTC Report recommended that patent policy expand its consideration of economic learning and competition policy concerns. *IP Report*, Executive Summary at 17.

Similarly, antitrust law and enforcement must function properly, which means basing them on market facts and accepted economic principles. Thus, in *Illinois Tool Works v*. *Independent Ink*,⁵ the FTC with the Department of Justice recommended that the Supreme Court reject the presumption that patents confer market power on their owners in tying cases. Our reason was simple: patents often do not confer market power. The Court did, in fact, hold that this presumption is no longer appropriate, consistent with the analytical developments that favor market analysis over rigid rules.

Perhaps the same type of analytical developments that have occurred in antitrust litigation for the past 20 or so years are emerging in cases at the intersection of antitrust and IP: that is, the reduction of presumptions in favor of more fact-based inquiries of market effects.

A. eBay

The Supreme Court's recent decision in *eBay, Inc. v. MercExchange LLC*⁶ is illustrative. While that decision, at a glance, may look simply like a clarification of the legal standard for issuing injunctions in patent cases, in fact, the case may be important from a competition perspective. The Court addressed whether patent holders seeking permanent injunctions against patent infringers are required to satisfy the traditional four-factor test historically applied by courts of equity. The test is a familiar one: a plaintiff must show that (1) it suffered an irreparable injury; (2) remedies at law are inadequate to compensate for that injury; (3) an injunction is warranted in light of the balance of hardships between the plaintiff and the defendant; and (4) the public interest would not be disserved by a permanent injunction.

⁵Illinois Tool Works v. Independent Ink, Inc., 126 S. Ct. 1281 (2006).

⁶eBay, Inc. v. MercExchange L.L.C., 126 S. Ct. 1837 (2006).

The United States (with support from the FTC staff) weighed in on the issue, advocating use of the four-part test.⁷ The Court agreed that the test should be used -- a decision that conflicts with years of prevailing practice by lower courts which have granted such injunctions almost automatically. While lower courts probably will continue to issue injunctions as remedies for patent infringement in most cases, the Court's decision allows the lower courts to tailor this remedy in circumstances in which an injunction would allow a patent holder to appropriate more than the full value of its invention, to the detriment of competition and innovation.

In the case, MercExchange sued eBay and Half.com alleging, among other things, infringement of a business method patent on systems that allow individuals to sell goods to other individuals through an electronic network. A jury upheld the validity of the patents, and awarded \$35 million in damages to MercExchange. MercExchange also sought an order permanently enjoining eBay and Half.com from infringing the patent, but the district court denied the request. The district court applied the four-factor test. On appeal, the Federal Circuit reversed the denial of the injunction, applying its general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.

⁷Brief for the United States as *Amicus Curiae* Supporting Respondent, eBay Inc. v. MercExchange, L.L.C., No. 05-130 (S. Ct.), 2006 WL 622120 (Mar. 10, 2006). The government filed its brief in support of MercExchange because it reasoned that applying the four-factor equitable analysis to the facts at issue leads to the same conclusion reached by the court of appeals: that an injunction should not issue in this particular case.

⁸See MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 710-716 (E.D. Va. 2003).

⁹ MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323 (Fed. Cir. 2005).

In a unanimous opinion, the Supreme Court acknowledged that the Patent Act provides patent holders with the right to exclude others from "making, using, . . . or selling" the patented invention. But the Court rejected the argument that this right alone justifies a general rule in favor of permanent injunctive relief and vacated and remanded the case for further proceedings. The full Court declined to provide further guidance as to when an injunction would be appropriate for patent infringement. A four-Justice concurrence, however, suggested that competitive considerations could bear upon whether to grant an injunction, drawing substantially from the FTC's IP Report and the government's *amicus* brief. 12

The concurring Justices noted that an injunction may at times give a patent holder more leverage than is appropriate for the public interest. The Justices specifically mentioned circumstances in which some non-practicing entities try to extract high rents from small patented improvements incorporated into complex systems. Referring to the FTC's IP report, the concurrence noted that for these firms, an injunction can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. The Justices stated that "when the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest." ¹³

¹⁰eBay, 126 S.Ct. at 1840; see 35 U.S.C. § 154(a)(1).

¹¹*Id.* at 1840.

¹²*Id.* at 1842 (Kennedy, J., Stevens, J., Souter, J., and Breyer, J., concurring).

 $^{^{13}}$ *Id*.

The examination of the traditional four equitable factors is, at its core, an examination of the economic landscape faced by the parties. A review of the economic relationship of the parties to each other, and to the patent, necessarily implicates competition. It is likely that, in the majority of cases, an evaluation of the equities will continue to support granting an injunction. In most instances, the patent owner's ability to maintain control over its invention by obtaining an injunction is critical to its ability to appropriate the invention's value, and thus will likely weigh in favor of finding for the plaintiff on most, if not all, of the four equitable factors.

In some limited circumstances, however, the grant of an injunction, or even the threat of an automatic injunction, may allow the patent owner to appropriate more than the full value of its invention. For example, conduct referred to as "hold-up" can lead to overcompensation of patent owners, to the detriment of competition and innovation. This problem typically arises when a patentee that sells no products and licenses non-exclusively asserts its patent after the accused infringer has sunk substantial costs into design, development, and commercialization of the accused product. In such circumstances, the threat of an automatic, permanent injunction following patent litigation may expand a patentee's leverage in the licensing negotiations beyond the value of its inventive contribution. The government's brief in this case suggested that, in a hold-up scenario, a district court might properly conclude that injunctive relief is inappropriate. 15

Patents have proliferated in some industries, due in part to the nature of the technology at issue. The technology developed in the semiconductor, computer hardware, and software

¹⁴IP Report Ch. 2 at 29-31; Ch. 3 at 37-40, 52-53.

¹⁵Brief for the United States as *Amicus Curiae* Supporting Respondent, eBay Inc. v. MercExchange, L.L.C., Civ. No. 05-130 2006 WL 622120, at *21 (Mar. 10, 2006).

industries can contain a large number of incremental innovations.¹⁶ For example, a single semiconductor product can be covered by hundreds, or even thousands, of patents.¹⁷ The overlapping patent rights covering complex products create a "patent thicket."

With so many patents at issue, infringing another firm's patent can be inevitable. Yet there is often no economically feasible way, prior to making sunk investments, to identify and obtain rights to all the relevant patented technologies. If a manufacturer learns that it has infringed a patent only after it has committed substantial sunk costs to its innovation and production – and, to avoid the patent, the manufacturer would incur substantial switching costs, which effectively lock the manufacturer into the effort – the patent owner may be in a position to demand supra-competitive royalty rates that over-compensate it for the value of its invention. If, before lock-in, the manufacturer had known about the patent and could have designed its product around it, then the firm might have used that alternative as leverage for seeking a competitive royalty rate. But after lock-in, redesigning the product may not be economically feasible, and the cost of being enjoined may be unacceptably high where, for example, it means shutting down a high-volume manufacturing facility. In that hold-up situation, the manufacturer may have no viable option but to accede to the patent owner's demands, either by settling the litigation or taking a license at a price that is greatly enhanced by an injunction or the threat of an injunction.

¹⁶*IP Report*, Ch. 2 at 25-26, 27; Ch. 3 at 34-35, 52.

¹⁷*Id*. Ch. 2 at 28; Ch. 3 at 34-35.

¹⁸*Id*. Ch. 3 at 37, 39-40.

¹⁹*Id*. Ch. 2 at 29; Ch. 3 at 38, 40.

To avoid such circumstances, firms in industries with patent thickets typically have accumulated large patent portfolios; if a rival producer attempts a hold-up, they draw on their patent portfolio to assert counterclaims against the rival. Because each firm needs access to the other's patents, this scenario usually results in cross-licensing. This strategy is not effective, however, where the patent owner is a non-practicing entity (NPE). An NPE is a firm that owns relevant patents but does not produce an associated product.²⁰ An NPE is therefore invulnerable to a countersuit for patent infringement and uninterested in a cross-licensing offer. An NPE may be a non-practicing design firm, or a patent assertion company that buys patents from other companies, particularly those that are bankrupt, and then asserts them against practicing entities. Patent litigation brought by NPEs has increased since the 1990s.²¹

From a competition perspective, one important question in evaluating the first two equitable factors – irreparable harm and adequacy of damages – may be whether the patentee uses its patent exclusively or non-exclusively. For instance, when a patent owner uses its invention in its own products, or intentionally keeps it from the market to avoid competition with its products, denial of an injunction may cause irreparable harm by creating competition with the exclusive use that the patentee has decided to pursue. Similarly, when a patent owner exclusively licenses its invention for development by others, denial of an injunction may irreparably harm its ability to use exclusive licensing to earn profits.

On the other hand, in a hold-up scenario, when the patentee's goal is to license its patent

²⁰*Id.* Ch. 2 at 30-31: Ch. 3 at 38-39, 52-53.

²¹*Id.* Ch. 3 at 39.

non-exclusively, the threat of injunction can serve as a strategic means to extract a higher licensing fee that overcompensates the patent owner compared to the value of its invention before the infringer became locked in due to substantial switching costs. Further, in evaluating the balance of the hardships, courts may wish to consider the effect of an injunction on the infringer's business in the hold-up scenario, where infringement is inevitable, and practically unknowable in advance.

B. Independent Ink

In *Independent Ink*, the Supreme Court again rejected a bright-line rule in favor of an approach that considers the economic status of patents and their impact on competition. The facts of the case are similar to those of other tying arrangements that the Court has confronted in the past. The petitioner, Illinois Tool Works, owned a firm that manufactured a patented ink jet printhead, a patented ink container fitted to the printhead, and specially designed, but unpatented, ink. The firm sold these printing systems to original equipment manufacturers (OEMs), which incorporated them into printers that are used to print bar codes on product cartons. The OEMs agreed to purchase their ink exclusively from the petitioner and agreed that neither they nor their customers would refill the patented containers with ink of any kind.

Independent Ink, a competing supplier of printer ink, challenged the arrangement between Illinois Tool Works and the OEMs as illegal tying under Section 1 of the Sherman Act, contending that it was *per se* illegal because it leveraged the patentee's market power in the tying market – patented ink jet printing systems – to that of the tied market, ink jet ink. Relying

²² 126 S. Ct. 1281 (2006).

on a series of older Supreme Court tying cases,²³ Independent Ink argued that the patentee presumptively had market power in the market for the tying product by virtue of its patent.

The district court granted summary judgment in favor of Illinois Tool Works, rejecting the presumption of market power and finding that Independent Ink had otherwise presented no evidence on market power or even market definition.²⁴ On appeal, the Federal Circuit reversed. The Federal Circuit held that despite a general consensus that the presumption that a patent produces market power did not comport with economic reality, it was bound by the Supreme Court's earlier holdings to presume that a patent conveys market power in an antitrust tying arrangement.²⁵

From an economic perspective, the presumption that patents convey market power had been undermined long before the Supreme Court agreed to review *Independent Ink*. Numerous legal and economic scholars, judges, and practitioners had criticized the economic viability of the presumption. In 1995, the FTC and the Department of Justice's Antitrust Division explicitly rejected the presumption that patents – or any other form of intellectual property – convey market power, because there often are sufficient actual or potential substitutes for a patented item to prevent the exercise of market power.²⁶ Congress implicitly reached a similar

²³ E.g., United States v. Loew's, Inc., 371 U.S. 38 (1962); International Salt Co. v. United States, 332 U.S. 392 (1947).

²⁴Independent Inc., Inc. v. Trident, Inc., 210 F. Supp. 2d 1155 (C.D. Cal. 2002).

²⁵Independent Inc., Inc. v. Illinois Tool Works, Inc., 396 F.3d 1342 (2005).

 $^{^{26}}$ Antitrust Guidelines for the Licensing of Intellectual Property, 4 Trade Reg. Rep. (CCH) \P 13,132, §§ 2.2, 5.3 (1995).

conclusion in the related doctrine of patent misuse when, in 1988, it amended the Patent Code to eliminate the presumption of market power for patented goods in patent misuse cases.²⁷

Competition does not benefit from reliance on a presumption of market power, and applying the presumption might well encourage meritless claims. By shifting to the defendants the burden of disproving market power, the presumption increases the costs of defending meritless suits, and may, therefore, lead defendants to settle these suits. In addition, unwarranted reliance on a market power presumption may have a negative impact on efficiency and innovation incentives. The presumption would likely cause some IP owners that do not possess market power to avoid tying practices, even in cases where the conduct may be efficient. Reducing a patentee's options for efficient exploitation of its patents may, in turn, adversely impact the incentives to innovate.

In light of these competition concerns, the United States in an *amicus* brief stated that a "presumption that a patent holder possesses market power sufficient to impair competition in the tied product market is unsound because it blurs the distinction between the legal right, based in intellectual property law, to exclude a copyist's infringing product – and the economic concept of market power."²⁸ The patent right cannot give the holder market power if, as is usually the case, there are alternatives to the patented product that qualify as reasonable economic substitutes.²⁹ The government explained that many patented goods are not commercially viable

²⁷ 102 Stat. 4674, 35 U.S.C. § 271(d)(5).

²⁸ Brief of the United States as *Amicus Curiae* Supporting Petitioners, Illinois Tool Works Inc. v. Independent Ink, Inc., No. 04-1329, 2005 WL 1864093, at *11 (Aug. 4, 2005).

²⁹ The concept of examining economic alternatives to patented technology is a familiar one within patent law. To determine whether a patentee is entitled to damages for infringement under the "lost profits" analysis, the courts have long considered whether non-infringing

at all "'because the product has little use or because the patentee's product differs too little from [more preferred] rival versions."³⁰ Even if a patented product is commercially viable, it is still often subject to competition from non-infringing substitutes.

The Supreme Court relied on the United States analysis in rejecting its prior holding, stating: "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not confer market power upon the patentee. Today, we reach the same conclusion "31 The Court recognized not only the economic status and actual role of patents in markets, but also the reality that ties by patent holders may yield efficiencies that benefit consumers.

C. MedImmune

The Supreme Court currently is considering another patent case with implications for competition. In February, the Supreme Court granted *certiorari* in *Medlmmune*, *Inc. v*. *Genentech*.³² The case presents the question of whether a patent licensee in good standing has standing to challenge the validity and scope of the licensed patent. The rule currently used by the lower courts effectively precludes these suits. The government filed an *amicus* brief in support of petitioners, and the case will be heard in the fall.

substitutes exist, and whether the infringer's sales were drawn from non-infringing substitutes as opposed to the patented product. *See*, *e.g.*, Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978). Absent this consideration, the patented technology would be overvalued.

³⁰Brief of the United States as *Amicus Curiae* Supporting Petitioners, Illinois Tool Works Inc. v. Independent Ink, Inc., 2005 WL 1864093, at *12 (citing 10 *Antitrust Law* ¶ 1733b, at 14).

³¹ 126 S. Ct. at 1293.

³²Medlmmune, Inc. v. Genentech, Inc., No. 05-608 (S. Ct.).

The petitioner, MedImmune, had entered into an agreement under which it licensed a group of patents and patent applications from Genentech. Several years later, Genentech obtained an additional patent from one of the applications covered by the license. After the patent issued, Genentech informed MedImmune that, because its most profitable product would infringe the claims of the newly-issued patent, MedImmune must pay royalties under the license. MedImmune denied that the new patent covered its product, but ultimately agreed to pay royalties.

Shortly thereafter, MedImmune filed a federal action seeking a declaration that the patent was invalid, unenforceable, and not infringed, and that MedImmune had no royalty obligation under the license agreement. The district court dismissed MedImmune's declaratory judgment action for lack of subject matter jurisdiction,³³ holding that it was bound by the Federal Circuit's rule that, by eliminating any controversy between the parties, a licensee's continued payment of royalties precludes jurisdiction. The Federal Circuit affirmed, applying its test that requires a declaratory judgment plaintiff to have a reasonable apprehension of suit in order to establish a justiciable controversy. The court reasoned that, without breaching the license, MedImmune could have no apprehension of suit.³⁴

The Supreme Court will consider what is the proper test for determining when a patent

³³ MedImmune, Inc. v. Genentech, Inc., Case No. CV 03-2567 MRP (C.D. Cal. Apr. 26, 2004) (Amended Memorandum of Decision and Order Re: Motion to Dismiss for Lack of Subject Matter Jurisdiction).

³⁴ MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958 (Fed. Cir. 2005). Following a recent series of its own decisions, the court held that determinative factor was its application of the first portion of the two-part test it uses to evaluate standing in declaratory judgment cases: whether there is a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit.

licensee has standing to bring a declaratory judgment action challenging a patent. As it had in *eBay*, the FTC staff participated in the formulation of the position expressed in the government's *amicus* brief.³⁵ In its brief, the United States argues that the court of appeals' rule that requires a reasonable apprehension of suit is an overly rigid interpretation of the Constitutional requirements. Instead, the government urged the Court to apply the traditional flexible fact-based approach of whether an "actual controversy" exists: that is, whether there is a substantial controversy, between parties with adverse interests, that is, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Applying this test, the brief argues that a licensee need not breach the agreement to present a justiciable controversy concerning a patent's validity and scope. The parties contest validity and infringement, and the licensee is harmed when it pays royalties unnecessarily.

As the government's brief explains, given the harm that invalid patents can inflict on competition and consumers, there is a strong public interest in ensuring challenges to invalid patents, to the extent Constitutionally-permissible. Licensees typically are the only entities with enough knowledge and economic incentive to challenge invalid patents, but they may be unwilling to risk breaching the license for fear of an injunction and charges of treble damages. A rule that always denies licensees standing to challenge patents, absent breach, encourages continued royalty payments for patents that otherwise might be held invalid, to the potential detriment of competition. Thus, the *MedImmune* case presents another opportunity to promote a legal analysis that recognizes the economic realities of patent-based relationships, rather than a formalistic rule.

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³⁵Brief of the United States as *Amicus Curiae* Supporting Petitioner, MedImmune, Inc. v. Genentech, Inc., No. 05-608, 2006 WL 1327303 (May 15, 2006).

D. KSR

We are awaiting the Supreme Court's decision, expected next week, on whether it will grant certiorari in *KSR v. Teleflex*, ³⁶ another patent case with strong competition implications. *KSR* deals with the important and recurring question of when a patent should be denied on the grounds that the invention described in the patent application is "obvious." The Patent Act requires that a patent not be granted where the invention was "obvious at the time the invention was made to a person having ordinary skill in the art" of the subject matter of the invention.³⁷ The application of this provision turns on whether such a person would, in light of the level of knowledge and inventive skill attributed to him or her, find the purported invention "obvious."

The question before the Court is whether the Federal Circuit has incorrectly narrowed this statutory analysis by imposing a "suggestion" test, which arguably places undue emphasis on finding explicit statements that provide a suggestion to combine existing elements into the claimed invention. The Court invited the government's view on whether to take the case, and the government filed a brief in May urging review.³⁸ FTC staff again assisted in developing the government's position.

The patent at issue in *KSR* covered an adjustable pedal apparatus that combined two "off the rack" features commonly seen in automobile pedal systems.³⁹ In litigation over infringement

³⁶ KSR International Co. v. Teleflex, Inc. & Technology Holding Co., No 04-1350.

³⁷ 35 U.S.C. § 103.

³⁸Brief for the United States as *Amicus Curiae*, KSR International Co. v. Teleflex, Inc. & Technology Holding Co., No 04-1350, 2006 WL 1455388 (May 25, 2006).

³⁹Before the 1970's, gas pedals in automobiles were typically bolted in a fixed location in the footwell of the car. The pedal would act as a lever, and pull a cable or mechanical linkage to actuate the engine throttle. Since the 1970's, automobile manufacturers have offered adjustable

and validity of the patent, the accused infringer – KSR – argued that the patent was invalid as obvious. The district court agreed, finding on cross motions for summary judgment that a person of ordinary skill in the art would have been motivated to combine the two pre-existing components to avoid known problems with other adjustable pedal assemblies. The Federal Circuit reversed, holding that the district court failed to make specific findings as to a suggestion or motivation to combine the two components, and vacated and remanded the case.

Citing the FTC's IP Report, the government brief reiterates that the Federal Circuit's obviousness test has important consequences for the economy, because allowing these obvious patents can negatively impact competition and innovation. As the brief points out, the present test unduly grants patent applicants rewards for disclosing non-innovative subject matter, while foreclosing competitors from freely using technology that should be in the public domain.

Obvious patents deter innovation if they lead the patentee's competitors to forgo research and development. Expensive and time-consuming litigation to challenge a patent on an obvious technology wastes resources. And, if obvious patents are granted, consumers may be required to pay a premium where no real innovation was made.

brake pedal assemblies, designed to accommodate drivers of different heights, that allow drives to adjust the position of the brake pedal forwards and backwards within the automobile's footwell. Since the 1990's, automobile manufacturers also have increasingly made automobiles with computer-controlled engines and electronic throttle controls. The manufacturers of gas pedal assemblies adapted their non-adjustable brake assemblies by attaching an electronic sensor to the pedal, in place of the mechanical linkage, to determine the pedal position and transmit a corresponding electronic signal to the throttle. The patent at issue in *KSR* combines an adjustable gas pedal assembly with an electronic pedal position sensor. The patent explains that the pedal assembly "can be any of various adjustable pedal assemblies" and that the electronic pedal position sensor can be any such sensor "known in the art." U.S. Patent No. 6,237,565, Col. 2, Il. 54-65; Col. 3, Il. 22-24.

⁴⁰Brief for the United States as *Amicus Curiae*, KSR International Co. v. Teleflex, Inc. & Technology Holding Co., 2006 WL 1455388, at 19.

In line with these interests, the government's brief argues that the "suggestion" test is too narrow. The test leaves no room for the possibility that "persons of ordinary skill in the art" could combine elements to solve a problem on their own initiative, without a specific written suggestion. The brief argues that the test ignores other possible reasons for obviousness – such as the possibility that the solution to the problem may have been too obvious to bother to write it down. 42

E. Schering

Finally, it is legal analysis that reflects economic realities that we seek in the *Schering* matter.⁴³ The Hatch-Waxman legislation altered the competitive landscape in a manner that has a significant impact on antitrust analysis. By increasing the potential economic value of generic entry, the statute also increased the incentive for brand and generic manufacturers to conspire to share rather than compete for the expected profits generated by sales of both brand and generic drugs. For example, a brand manufacturer and generic pharmaceutical company now have an incentive to divide up the profits from the Hatch-Waxman 180-day generic exclusivity period -- a period that did not exist prior to the passage of the Act. In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-drug company would make from the same sales. Consequently, it will often be more

⁴¹*Id.* at *9-10;

⁴²*Id.* at *14.

⁴³Federal Trade Commission, Petition for a Writ of *Certiorari*, 2005 WL 2105243 (Aug. 29, 2005); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005); Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp., (Consent Order as to American Home Products) (Apr. 2, 2002).

profitable for the branded manufacturer to buy off generics. Indeed, Congress expressly recognized the risk that the Act might promote such market allocation agreements, and implicitly directed the enforcement agencies to prosecute such agreements by amending the Hatch-Waxman Act in 2003 to require brand pharmaceutical companies and generic applicants to file patent settlement agreements with the FTC and the Antitrust Division.

The *Schering* matter has been hotly debated. Some who disagree with the Commission's position argue that we must presume the validity of the patent and its exclusionary power for the full term unless patent litigation proves otherwise, and that we must permit parties to settle patent litigation, which they may choose to do regardless of their positions on the merits, according to their own risk calculus at the time. This argument, however, ignores both the law and the facts. There is no question that the result of patent litigation, and therefore the timing of generic entry, is uncertain. But the antitrust laws prohibit the paying of a potential competitor, as well as an existing competitor, to stay out of the market, even if the entry is uncertain. And, again, given the high rate of generic success in patent litigation strongly suggests that it is tough come up with a compelling argument for the position that generic entry before the end of a patent term is too uncertain or unlikely to be of competitive concern under the antitrust laws.