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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

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Executive Summary

The social value of the pharmaceutical industry is apparent and profound. The industry provides us with myriad cost-effective treatments and cures that increase life expectancy and bring better lives. It is also a significant contributor to the strength of the United States economy. To offer such benefits, the pharmaceutical industry depends upon the opportunities that currently exist to obtain, exercise and protect intellectual property rights. The existence of these opportunities is a fundamental prerequisite to the investment necessary to support the innovation upon which the industry relies. This innovation leads both to new treatments and cures and to the creation of a market in which branded and generic producers alike can participate and compete.

The current legal environment, shaped substantially by Congress through the patent system and through the Hatch-Waxman Act of 1984, provides an appropriate set of incentives for innovation by research-based companies and for market entry by generic manufacturers. In response to these incentives, research-based and generic pharmaceutical companies have made good faith efforts both to exercise and protect the legal rights the Act grants to them and to comply with the legal requirements it imposes upon them. These good faith efforts must be allowed to proceed without undue and needlessly chilling antitrust scrutiny. Although antitrust, among other, measures have a role to play to discourage and penalize abuses, antitrust scrutiny must be applied judiciously to evaluate extreme circumstances, not to second guess good faith actors and actions. Pervasive, routine application of intensive scrutiny will undermine the certainty of the legitimate intellectual property rights upon which the industry relies.

As discussed in **Part I** of this paper, the private sector research performed by research-based pharmaceutical companies is essential to the innovation that has supported the health care revolution that has taken place in America. These research-based companies collectively are the single largest source of pharmaceutical R&D funding in the world. As a result, the American pharmaceutical industry now leads the world in pharmaceutical innovation.

New drug development is a lengthy process, and total drug development time has grown significantly. Average total drug development time has increased from approximately 8 years as of 1960, to over 14 years in the 1980s and 1990s. New drug development is also very risky. Most drugs do not survive the rigorous development process – only 20 in 5,000 compounds that are screened enter preclinical testing, and only 1 drug in 5 that reaches human clinical trials is approved by the FDA as being both safe and effective. Further, for those drugs that do reach human clinical trials, more and far larger trials are now typically performed. Accordingly, the average cost to develop a new drug has been estimated to now be approximately $800 million.

At the same time, average returns from marketing a new drug have dropped by approximately 12% since 1984. Despite popular misconceptions about the invariable profitability of pharmaceutical companies, most marketed pioneer drugs fail to cover their research and development costs. In contrast, the costs to develop generic drugs are, in both

relative and absolute terms, extremely low, allowing generics to enter the market at dramatically reduced prices, as they have done at increasingly high rates. In 1984, generics accounted for 19% of the prescription drug market; by 2000, generics accounted for 47% of that market.

These market dynamics clearly indicate the importance of maintaining strong intellectual property protection to the functioning of a vital, innovative pharmaceutical industry. The strength of intellectual property rights protection, in fact, profoundly impacts investment in the industry. Enormous investments are needed to encourage further pharmaceutical innovations, investments as large or larger than those that have supported the extraordinary progress from which individual patients, the public health, and society as a whole now benefit.

Similarly, existing incentives for investment are also essential to promote competition, both among research-based companies and between research-based and generic companies. Investment supports the constant efforts of research-based companies to develop innovative products to compete with the products of other research-based companies in a given therapeutic class. Investment also promotes competition between research-based companies and generic companies. Generic companies are in the business of copying products developed by research-based companies. To the extent investment does not occur to fund the development of new innovations, research-based companies and generics alike will have fewer new products to offer, and less competition will occur.

As explained in **Part II** of this paper, rigorous adherence to the procedures established by Congress in the Hatch-Waxman Act protects intellectual property rights for pioneer drug products and facilitates market entry for generic products. The Hatch-Waxman Act represents a legislative contract with the pharmaceutical industry that provides incentives for developing new drugs and promotes generic competition. It enables generic companies to bring products to market immediately upon expiration of any patents that may claim the product. At the same time, it establishes a set of procedures to promote resolution of patent infringement claims prior to market entry of potentially infringing products, which serves to protect innovators from unrecoverable losses, generic companies from overwhelming liability, and consumers, patients and their physicians from unnecessary confusion and complications.

The Hatch-Waxman procedures provide for applicants and potential applicants to learn in a timely way whether the product they wish to market is claimed by an existing patent. Similarly, the procedures provide innovators an opportunity both to learn in a timely manner that a potentially infringing product has been proposed for marketing and to defend their patent rights before such market entry occurs. These procedures set in place by Congress have greatly promoted both innovation and competition. Good faith efforts to fulfill the statutory obligations and protect the statutorily recognized rights established by Congress should not expose either research-based pharmaceutical manufacturers or generic manufacturers to antitrust claims.

As **Part III** of the paper explains, robust patent rights are needed for sequential as well as initial product development, to promote innovation and related competition. Sequential product innovation is an important feature of the innovative process for the pharmaceutical industry, expanding the variety of therapeutic choices available for consumers and their doctors to consider.

At the same time, the development of "patent thickets" is not a major factor for therapeutic products in the pharmaceutical industry. Patents in the pharmaceutical industry give exclusive rights only to a particular drug product or chemical compound, a specific molecule, or particular methods to use such a product, compound or molecule. However, sequential innovation leads to product improvements that enhance treatments and cures and spur competition in the pharmaceutical industry. Effective patent protection is an essential precondition for this innovation.

The ability to rely upon the full range of patent protections currently available is critical to achieving the benefits of sequential innovation. Collectively, available forms of patent coverage can provide a sufficient degree of intellectual property protection to warrant investment in new indications for existing products and for new dosage forms.

In **Part IV**, we discuss how innovation and competition in the pharmaceutical industry also require the ability to make economically efficient decisions regarding intellectual property transactions and disputes, whether with regard to licensing or pursuit of infringement claims.

The rights to license and to refuse to license are inherently interrelated and must both be fully protected to enable an innovator to realize the economic benefit of its intellectual property right. Good faith efforts to make economically sound decisions regarding the use of internally developed innovations should be shielded from antitrust liability.

Similarly, the right to defend patents through litigation is essential to the strength of intellectual property in the pharmaceutical industry. The right to settle such disputes, in part or in whole, is a critical aspect of this right to litigate. The ability to settle provides the innovator and the generic alike greater flexibility to resolve disputes efficiently. Settlement can reduce litigation costs and use of judicial resources, and promote competition by providing a means for potentially infringing products to reach the market earlier than they might otherwise. Good faith efforts to resolve patent disputes should be shielded from antitrust liability. Unless the underlying patent infringement claim is objectively baseless, or the settlement is outside the scope of possible litigation outcomes, antitrust liability should not apply.

The current system of patent rights and Hatch-Waxman procedures strikes a sound balance, providing predictability and protecting against abuses. As **Part V** of the paper details, should abuses arise, ample remedies exist, including under antitrust law. Bad faith and fraud, whether before the Patent and Trademark Office, the Food and Drug Administration or the courts, can be prevented and remedied without novel applications of antitrust law, or pervasive, intensive scrutiny of good faith actors and actions.

The Federal Trade Commission has an important and challenging role to play. It has a duty to protect against anticompetitive activity, and its performance of this duty serves to promote fair dealing within the pharmaceutical industry. At the same time, the Commission must take care not to undermine the balance of rights and obligations that currently exists. This balance allows for the exercise and enforcement of strong intellectual property rights. It should be maintained, to continue to foster the innovation and competition that enable the pharmaceutical industry to develop and provide the treatments and cures that so miraculously protect and enhance our lives.

Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights

> ***The impressive improvements in the health of Americans over the past several decades have not occurred in a vacuum, but arose because of work--much of it collaborative--by government, private and charitable organizations in support of basic research, clinical testing, and product development. The health care system of the future will need to preserve and encourage this product development, through direct support for research with potentially broad applications, and through the protection of patent rights, to help turn promising new research into treatments approved for clinical use.***
> Economic Report of the President, George W. Bush, February 5, 2002, at 184.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. Having invested over $30 billion in 2001 alone in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures. PhRMA presents this paper to demonstrate: the importance of intellectual property to the pharmaceutical industry, biomedical innovation, and the public health; the critical protections for competition and intellectual property rights that are carefully woven into in the Hatch-Waxman Act; the compatibility of competition and intellectual property rights; and the critical role that intellectual property management plays in the innovation cycle.

Introduction

Patents and other forms of intellectual property protect the promise of pharmaceutical innovation for the benefit of consumers and the public health. For the public to benefit from the promise of innovation, the pharmaceutical industry must have incentives to make investments in basic research, incentives to develop and refine final, marketable drug products, and the ability to secure financial resources in the future to continue to invest in such innovation and development. Strong and predictable intellectual property rights not only encourage further pharmaceutical innovation but promote competition. Factors that add uncertainty to intellectual property rights can only deter competition among innovators and diminish the pipeline of future medicines that is the sole source of products for the generics industry.

Strong and predictable intellectual property rights serve several important roles in the cycle of innovation for the pharmaceutical industry. ***First***, intellectual property rights protect early stage innovation, essential to the development of new treatments and cures. The ability to obtain intellectual property protection for basic research encourages research-based companies to make the necessary fundamental investments to support such development. ***Second***, intellectual property rights enable the development of final, marketable drug products and make further, related innovation possible. Intellectual property protection of a marketable drug product encourages not only development of that product but further development of that innovation and related innovations to develop and improve therapies and cures. ***Third***, protection of intellectual property in marketed products gives their manufacturers the opportunity to benefit financially from the potential commercial advantage created by the innovation. This provides the necessary incentive to promote further investment to support the research, development and refinement needed for future treatments and cures. ***Finally***, by promoting the innovation needed for the pharmaceutical industry to provide cures and treatments, intellectual property protection plays an integral role in the creation of a pharmaceutical market in which generic companies can compete with basic research companies following the expiration of intellectual property rights.

The interplay of intellectual property rights with the other factors that determine commercial success, creates the vigorously competitive markets for innovation within and between therapeutic categories of pharmaceutical products. Intellectual property protections do not create monopoly rights in treating particular diseases. As in all industries, intellectual property rights permit the owner only to exclude others from benefiting from the invention. In the pharmaceutical industry, intellectual property rights – at most – provide the innovator with a time-limited, exclusive right to market a particular medicine once it has been approved by FDA. The commercial success of the invention will depend upon many factors, including: the clinical benefits of the innovation; the price of the developed product; the availability of substitutes in the market; and the price of competing products from other manufacturers to treat the same disease.

The cycle of investment and innovation in the pharmaceutical industry requires strong and certain intellectual property rights to protect the innovation itself and to foster the circumstances that make innovation possible. To make the benefits of pharmaceutical innovation available to the public, the research-based industry must be able to continue to:

(a) Obtain and enforce the full range of intellectual property protection available under U.S. laws;

(b) Vigorously enforce and fully comply with Hatch-Waxman Act procedures that were designed to protect the intellectual property rights of pioneer manufacturers while permitting robust competition from generic producers; and

(c) Engage in economically efficient intellectual property transactions and dispute settlement.

The uncertainties associated with the development of pharmaceuticals are many and substantial. Maximizing the certainty that a research-based manufacturer can obtain, enforce, defend, and make full, legitimate use of intellectual property rights is essential to maintaining the cycle of innovation for the benefit of the public health. In the absence of strong intellectual property rights at each stage of the innovation cycle, the promise of pharmaceutical innovation could be lost.

PhRMA presents this paper to emphasize that strong and predictable intellectual property rights are essential for delivering on the promise of innovation.

I. Realizing the Promise of Pharmaceutical Innovation Requires Maintenance of Strong and Predictable Intellectual Property Rights.

A health care revolution is taking place in America. People are living longer and better lives largely as a result of increases in both the quality and availability of health care. At the heart of this revolution is the American pharmaceutical industry, working hard to create new and better medicines through its research and development efforts.

The American pharmaceutical industry now leads the world in pharmaceutical innovation. During the 1990s, the United States surpassed Europe as the leading site for pharmaceutical research and development ("R&D"). This increased investment in R&D in the United States is reflected in the fact that 8 of the top 10 worldwide prescription drugs by sale originated in the U.S., compared to 2 in Europe.[1] Of 55 breakthrough medicines expected to enter the market in 2002, 34 originated in the U.S., compared to 14 in Europe.[2] More than ever, there is a global reliance on the U.S. pharmaceutical industry to deliver life saving drugs.

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[1] European Federation of Pharmaceutical Industries and Associations, *2000/2001 The Year in Review*, EFPIA, at 17 (October 2001).

[2] *Id*.

Innovative prescription drugs not only alleviate immediate pain and suffering, but allow individuals to live longer and more productive lives. The use of these new medicines is also having a positive economic impact by curbing overall health-care costs through reduced use of other more expensive forms of treatment, such as hospitalization and surgery, and by increasing worker productivity.[3] In turn the pharmaceutical industry relies on strong intellectual property protection to enable it to make substantial investments in R&D that brings these new life saving drugs to consumers.

A. The Social Value of Pharmaceuticals.

The U.S. pharmaceutical industry continues to lead the world in pharmaceutical innovation and makes a significant contribution to the country's economy.[4] It is a substantial contributor to the $1.3 trillion health-care sector, which, overall, accounts for about 13% of the nation's economic output, is expected to reach 16% of output by 2010, and could exceed 20% by 2040.[5]

Over the past 100 years, pharmaceutical research has helped transform health care, contributing substantially to an increase of nearly thirty years in life expectancy (from 47 years in 1900 to 76.5 years today).[6] The death rate from disease has fallen by a third from 1.2 in 1,000 in 1920 to 0.8 in 1,000 in 1993, even as people live longer (sometimes succumbing to disease in later life, having benefited from control or elimination of diseases that previously struck earlier in life).[7]

Pharmaceuticals have also brought better lives, conquering infection, making mental illness highly treatable, enhancing independence in old-age, and making impressive inroads against cancer, heart disease, stroke and many other diseases. Pioneer pharmaceutical companies

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[3] For instance, a new breast cancer drug costing only $1,050 a year can reduce the incidence of breast cancer in high risk women, whereas the average cost of surgery or other invasive treatments is nearly $14,000 a year. *See* Morton Kondracke, *Investing Billions in Health Research Can Save Trillions*, Roll Call, May 25, 2000.

[4] Innovator pharmaceutical companies create new jobs and foster economic growth. Moreover, recent data show that the median level of the charitable contributions of six large pharmaceutical companies was 2.2 percent of consolidated pretax income, compared to a median level of 0.8 percent for all companies. PhRMA, Pharmaceutical Industry Profile 2002, at 6, *available at* www.phrma.com (PhRMA, 2002 Industry Profile).

[5] David Leonhart, *Health Care as Main Engine: Is That So Bad?*, N.Y. Times, November 11, 2001.

[6] PhRMA, Pharmaceutical Industry Profile 2001, at 4, *available at* www.phrma.org (PhRMA, 2001 Industry Profile).

[7] Boston Consulting Group, The Contribution of Pharmaceutical Companies: What's at Stake for America, at 3 (September 1993) (What's at Stake for America).

continue to play a critical role in addressing old and new challenges, including AIDS and Alzheimer's disease.[8]

Not only are pharmaceuticals worth the cost, they are also cost-effective, adding little to the cost of health care and replacing less effective, more expensive treatments. Over nearly thirty years, total GDP spent on drugs rose little from only 0.84% in 1965 to 0.86% in 1992.[9] As stated in the President's 2002 Economic Report, there is "a growing body of evidence that, for a wide range of diseases, the additional money spent on treatment is more than offset by savings in direct and indirect costs of the illnesses themselves. Indirect costs include lost productivity and, especially, poor health, which people are clearly willing to pay to avoid. Stated differently, because the quality-adjusted cost of treating many diseases has fallen, health care has become more productive over time, even as absolute costs are rising with greater use of more intensive treatments."[10]

B. Importance of Private Sector Research & Development.

The research-based pharmaceutical sector in the United States is the single largest global player in the research and development of new drugs, both in terms of new drugs brought to market, and R&D expenditures. Although the federal government through the National Institutes of Health ("NIH") and other federal agencies, universities, private foundations and charities fund drug research, particularly basic research, pioneer drug companies are responsible for the majority of all R&D related to new drugs. In fact, the research-based pharmaceutical industry in the United States is responsible for the discovery and development of over 90 percent of new drugs worldwide.[11]

PhRMA companies spent an estimated 17.7 percent of domestic sales on R&D in 2001. They devote the highest percentage of sales to R&D of any major U.S. industry.[12] The pharmaceutical industry is more research intensive than the electronics, communications and

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[8] *See* PhRMA, 2002 Industry Profile at 2, 3 (2002).

[9] What's at Stake for America, at 46.

[10] Economic Report of the President, George W. Bush, February 5, 2002, at 182. For example, "Even though annual expenditure on cholesterol-lowering drugs is well into the billions of dollars, they have been proved to be highly cost effective for many patients and have contributed to the improved life expectancy and better functioning of Americans today." *Id.* at 180. Similarly, "…even though the new treatments developed to prevent AIDS complications are quite costly and have many side effects, these survival improvements suggest they are well worth the cost." *Id.*

[11] A 1993 study published in the *Journal of Clinical Pharmacology* found that between 1981 and 1990, the research-based pharmaceutical industry was the source for 181 of the 196 new drugs approved by the Food and Drug Administration (FDA) (92.4 percent), academia was the source of 7 of the drugs (3.6 percent), and the government was the source of 2 of the drugs (1 percent). *See* Kaitin, et al, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. Clin. Pharmacol. 412-14 (1993).

[12] PhRMA, 2002 Industry Profile, at 12.

aerospace industries.[13] The typical PhRMA company spends more on research each year than such companies as Microsoft, Boeing, and IBM, as evidenced by a comparison of average research outlays reported publicly by PhRMA member companies and by Microsoft, Boeing, and IBM as stated in their annual reports.[14] National Science Foundation studies have shown that while the pharmaceutical industry recorded only 2.5 percent of the domestic sales of companies that conducted R&D in 1998, it accounted for 8.7 percent of all company-funded R&D, 18.7 percent of all company-funded basic research, and 4.8 percent of all research scientists and engineers.[15]

The research-based pharmaceutical industry continues to outspend the NIH on biomedical research and development.[16] In fact, PhRMA member companies spend more on pharmaceutical R&D than the NIH spends on all forms of research combined. In 2001, the research-based pharmaceutical industry invested $30.3 billion in drug R&D, a 16.6% increase over 2000.[17] In comparison, the total NIH budget, including its basic research costs, is about $20.3 billion.[18]

At these levels of investment, the U.S. pharmaceutical industry spends more on research than NIH or the international pharmaceutical industry.[19] In a report issued to Congress in July 2001, NIH confirmed that the industry pays for most of the research for the most widely relied upon prescription drugs. The report found that only 4 of 47 drugs with U.S. sales of $500 million a year had been developed, even in part, with technologies created with NIH funding.[20]

As NIH notes, "new chemical entities that lead to therapeutic products are hard to discover . . . ."[21] This assertion by NIH is backed by factual evidence of the efforts of research-

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[13] *Id.* (citing PricewaterhouseCoopers, *The Critical Roles of R&D in the Development of New Drugs*, Washington, DC (2001)).

[14] *Id.* (citing to Boeing, Microsoft, and IBM Annual Reports for 2002, *available at* (www.boeing.com/companyoffices/financial/finreports/ annual/01annualreport (Financials: Consolidated Statements of Operations) (Boeing); www.microsoft.com/msft/ar.htm# (Financials: Item 8) (Microsoft); www.ibm.com/annualreport/2001/financial_reports_fr_ncf_notes_p.html (IBM)).

[15] *See id* at 12-13.

[16] *Id.* at 14.

[17] *Id*. at 75 (citing PhRMA Annual Membership Survey, 2002).

[18] National Institutes of Health, *History of Congressional Appropriations 1992-2001*, Office of Budget (2001), *available at* http://www.nih.gov.

[19] PhRMA, 2002 Industry Profile, at 12.

[20] National Institute of Health, *A Plan to Ensure Taxpayers Interests are Protected*, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayer's Interests are Protected (July 2001), *available at* http://www.nih.gov/news/070101wyden.htm.

[21] *Id.*

based pharmaceutical companies. For each drug approved by FDA, a company typically screens between 5,000 and 10,000 compounds. [22]

From 1998-2000, research-based pharmaceutical companies allocated an average of 79.7% of their R&D expenditures to the research and evaluation of new drug products.[23] The remaining 20.3% is devoted to research into significant improvements and/or modifications to existing products.[24] Such significant adjustments can include enhanced efficacy, improved dosage and delivery forms and patient-tailored therapies. The clinical value of research into improvements and incremental innovations is high and should not be undermined. (See **Part III**.)

C. Strong Intellectual Property Protection is Essential to a Vital Innovative Pharmaceutical Industry.

The discovery and development of new medicines is an expensive and time-consuming process. As with most inventors, particularly those who cannot rely on trade secret protections, pharmaceutical companies rely on patent protection to provide an opportunity to recover their R&D investments. Because of the extraordinary costs and risks of drug development, and the relative ease and extremely low absolute and relative costs of generic copies, strong intellectual property protection is *the* key to a viable, innovative pharmaceutical industry. Without these protections innovation would stop and with it all meaningful competition for new cures.

The U.S. pharmaceutical industry leads the world in pharmaceutical research and development. However, the costs of developing a new drug are large and increasing. In fact, new drug development costs have skyrocketed. The Tufts Center announced on November 30, 2001, that the average cost to develop a new prescription drug is $802 million (in 2000 dollars),[25] a figure that includes costs of R&D failures and opportunity costs. Similarly, Boston Consulting Group modeling has found the average costs per drug to be approximately $818 million.

As of 1993, the Office of Technology Assessment estimated that the fully capitalized cost of developing a new pharmaceutical was $359 million in pretax 1990 dollars for drugs that first entered human testing in the period 1970-1982.[26] In 1996, because of the increasing complexity

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[22] *Id.*

[23] PhRMA, 2002 Industry Profile, table 4, at 78.

[24] *Id.*

[25] Press Release, Tufts University, Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million (Nov. 30, 2001), *available at* http://www.tufts.edu/med/csdd ; Backrounder, Tufts Center for the Study of Drug Development, A Methodology for Counting Costs for Pharmaceutical R & D (Nov. 30, 2001), *available at* http://www.tufts.edu/med/csdd

[26] Congress of the United States, Office of Technology Assessment, OTA-H-552, Pharmaceutical R&D, Costs, Risks and Rewards 67 (February 1993).

and cost of research, new drug development was estimated to cost on average somewhere in the vicinity of $500-600 million.[27]

As these average cost estimates evidence, new drug development is a lengthy process, and total drug development time has grown significantly. Average total drug development time has gone from 8.1 years as of 1960, to 11.6 years in the 1970s, to 14.2 years in the 1980s and 1990s. *See* Figure 1: Total Drug Development Time from Synthesis to Approval. Since 1980, the average number of clinical trials conducted prior to filing a new drug application (NDA) has more than doubled, and the number of patients in clinical trials has tripled.[28]

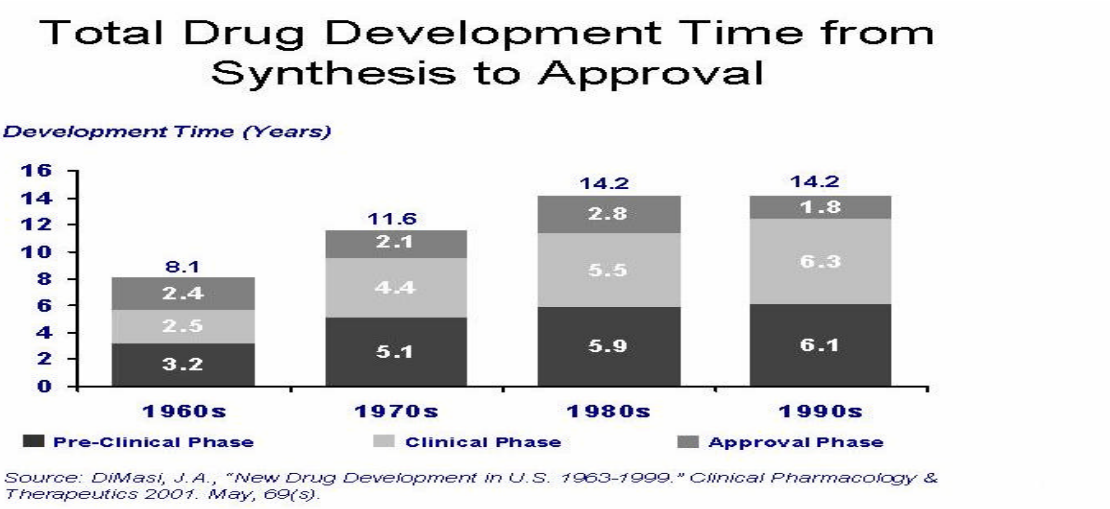

Figure 1

New drug development is also very risky. For every one drug that reaches market: (i) approximately 5,000-10,000 compounds are tested in pre-clinical trials; (ii) approximately 250 drugs are tested in pre-clinical animal trials; and (iii) approximately 5 are tested in full-scale, human clinical trials.[29] Companies generally allocate 30.6 percent of R&D expenditures to preclinical functions, and 25.6 percent of R&D costs to clinical trials (Phase I, II and III).[30] In addition, 8.8 percent of R&D costs are directed to Phase IV clinical trials, which occur after product approval by FDA.[31] *See* Figure 2 Compound Success Rates by Stages.

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[27] Boston Consulting Group, *Sustaining Innovation in U.S. Pharmaceuticals, Intellectual Property Protection and the Role of Patents* 13 (January 1996).

[28] PhRMA, 2001 Industry Profile, at VI; *see also id.* Figs. 3-3, 3-4 at 26, 27.

[29] PhRMA, 2002 Industry Profile, at 19, 20.

[30] *See id.* at table 5, at 79.

[31] *Id.*

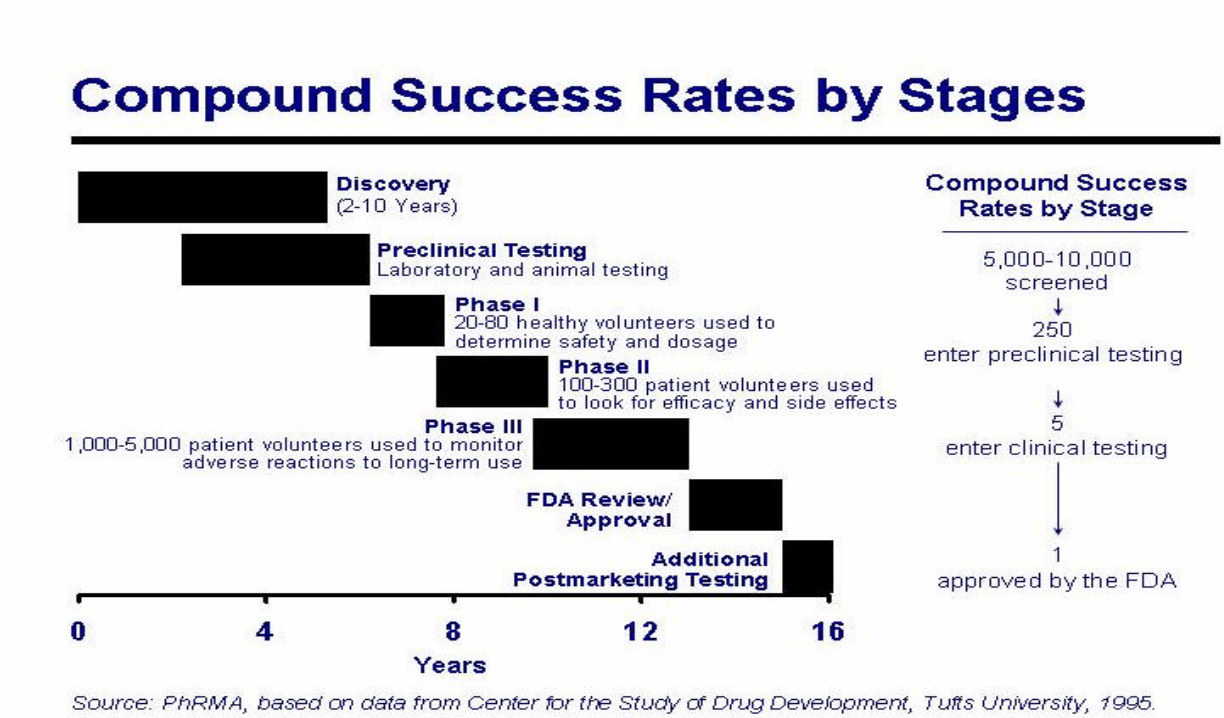

Figure 2

At the same time, average returns from marketing a new drug have dropped. A 1998 Congressional Budget Office report estimated that, for a variety of reasons, average returns to a pioneer from marketing a new drug had declined by approximately 12% since 1984.[32] Further, most marketed drugs are not profitable; "blockbusters" support most R&D.

According to a 1994 study of drugs introduced between 1980 and 1984, for every ten drugs that came to market, only three covered the average development costs.[33] The same study showed that the top 20% of products with the highest revenues generated 70% of the returns for the period 1980-1984.[34] Increasing development time and costs, and decreasing average returns suggest that even fewer new drugs now cover their development costs than did in 1980 to 1984.

Despite the great need for strong intellectual property protection, pioneer drug companies realize far less actual patent life than innovators in other industries. This is because of the lengthy drug development and approval process. On average, the effective patent life for drugs introduced from 1984-1995 that received patent term restoration, including such restoration, was

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[32] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* http://www.cbo.gov (CBO 1998).

[33] *See* Grabowski & Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. of Health Econ. 383 (1994).

[34] *Id.*

only about 11 years.[35] Any action that further impairs patent protection for innovative pharmaceutical products could substantially reduce the number of new products that come to market.

D. The Strength of Intellectual Property Rights Protection Impacts Investment Decisions.

Direct investors demand a potential return on their investment commensurate with the high costs and risks of drug development. Accordingly, the pharmaceutical industry relies, in particular, upon patents to provide the opportunity to realize such commensurate returns.

The importance of intellectual property to investment decisions is borne out by comparisons of countries with and without strong intellectual property protection for pharmaceutical innovation. Pharmaceutical industry research in the United States, which accounts for nine out of ten prescription medicines on the market, would not be economically feasible without strong intellectual property protection.[36] In Mexico, R&D tripled after adoption of full intellectual property ("IP") protection in 1991.[37] Other countries that experienced R&D growth corresponding to strengthened IP are South Korea, Japan, and Italy.[38] Italy has experienced a four-fold increase in R&D investment since instituting strong IP protection in 1978.[39] Canada established a compulsory licensing system in 1969, weakened that system in 1987 and abandoned it in 1993. R&D expenditures by companies in Canada rose to $900 million in 1999 from $166 million in 1988.[40] In contrast, India, which stopped providing full patent protection in 1970, conducts only 0.001% of worldwide R&D.[41]

Trading activity in secondary markets also has reflected the importance of patent protection to investors. For example, an announcement in March 2000 by the Clinton administration urging the free availability of raw data on the human genome resulted in a number of biotechnology companies losing a substantial percentage of their market capitalization. The chief concern of investors—who sold shares in record numbers until the President's remarks

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[35] *See* S. Shulman, J. DiMasi & K. Kaitin, *Patent Term Restoration; The Impact of the Hatch-Waxman Act on New Drugs and Biologics Approval 1984-1995*, 2 J. Biolaw and Bus. 63, 66 (1999) (The Impact of the Hatch-Waxman Act).

[36] PhRMA, 2001 Industry Profile, at 92.

[37] *Id*. at 99.

[38] *Id.*

[39] *Id.* at 105, (citing Farmindustria Indicatori Farmaceutici, 1994).

[40] Andrew Pollock, *Defensive Drug Industry; Fueling Clash over Patents*, N.Y. Times, April 20, 2001, at A.6.

[41] PhRMA, 2001 Industry Profile, at 100.

were clarified—was that biotechnology patent rights would be weakened or subject to uncertainty.[42]

Pharmaceutical industry investment is very high risk with very long-term payback. Essentially, investment in pharmaceutical development is much the same as venture capital investment, under which winners or "blockbusters" are responsible for the majority of all return on investment.[43] Even the largest pharmaceutical companies cannot diversify the underlying R&D-based investment risk. They must rely upon a handful of flagship products for the majority of their sales, and the commercial life of a drug (from market launch to patent expiration) was only 11-12 years in the mid-1990s,[44] compared to 18.5 years for non-pharmaceutical products.[45] Even major companies must, in fact, develop a block-buster every two to three years, or face massive financial contraction. The frequency of mergers of R&D companies is a direct consequence of this basic market dynamic. As market conditions have become increasingly competitive, this dynamic has become even more significant.[46]

E. Competition in the Pharmaceutical Industry Would be Impaired if Protection of Intellectual Property Rights Were Diminished or Made More Uncertain.

The commodity nature of the generic drug business does not and cannot sustain viable R&D programs that result in the discovery of new drugs. The availability of funds for R&D depends on the ability of companies to discover and then patent innovative products to bring to market.

Generic and pioneer manufactures alike rely upon this cycle of innovation as the source of products to provide to consumers. Allowing pioneers a sufficient opportunity to market their products without competition from generic versions of the same product is essential to the development of new products for the generic producers to copy and, therefore, to competition from generic manufacturers.

Studies have shown that pioneer drug products, or those products for which substantial research and development effort has been expended, are a major source of the profits that fund further innovative research.[47] However, the enormous cost of R&D associated with innovator

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[42] *See* CRS Report to Congress, A*n Examination of the Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies, at* 7-8 (2000) (CRS 2000).

[43] Henry Grabowski & John Vernon, The Distribution of Sales from Pharmaceutical Innovation 4-6 (1999); F. Scherer, *Pricing Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. Econ. Perspectives 97, 103-106 (1993) (Scherer).

[44] The Impact of the Hatch-Waxman Act, at 66.

[45] PhRMA, 2002 Industry Profile, Fig. 3-1, at 31.

[46] What's at Stake for America, at 96.

[47] James T. O'Reilly, *Knowledge is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. Cin. L. Rev. 1,3 (1985) (citing E. Kitch, *The Political Economy of Innovation in Drugs and*

drugs implies that for the innovator drug to be even potentially profitable, it must be free from unfair competition for a time sufficient for the innovator to have an opportunity to attempt to recover the R&D costs. If competitors enter the market even earlier than they do now, the drug product innovator will be less likely to recoup its research costs because the substantial drop in the retail price of the drug that occurs upon market entry by a generic version will also occur even earlier. In turn, the loss of return on investment will reduce incentives to further develop the specific drug or to invest in the development of future drugs.

Compared to innovators, generic pharmaceutical companies invest almost nothing in research and development and risk relatively little capital to gain FDA approval for marketing their products. A generic manufacturer can count on referencing the innovator's safety and efficacy data, and thus conducts only one or two bioequivalency studies before entering the market, at a small fraction of the R&D costs incurred by the pioneer drug companies. Further, a generic does not have to bear a significant market risk because the pioneer has already taken the risk to create a market for the drug product the generic has copied.

Because the costs to develop generic drugs are, in both relative and absolute terms, extremely low, generics can enter the market at dramatically reduced prices, as they have done at increasingly high rates. Statistical research shows that the first generic entrant will come in at a substantially reduced price from the pioneer, (excepting those who have 180-day relative exclusivity for challenging innovator patents), and subsequent generic entrants will lower the price even further.[48] Pioneers lose more than 40% of their market on average to generics after patent expiration.[49] Over the past decade, generics have more than doubled their share of the prescription market - from 19 percent at the end of 1984 to 47 percent in 2000.[50] Today, almost all innovator medicines face such competition.[51]

In short, unlike the pricing practices of the brand name manufacturer industry, the generic industry prices its products like any other commodity trying to optimize market share. The prices of generic drug products need not reflect any of the overhead costs and risks that are incurred during the long product and market development cycles of the pioneer drugs. As a result, upon entry of generic product, the market for the corresponding pioneer drug product is transformed entirely to that of a commodity -- completely unlike and incomparable to markets for innovative, proprietary products.

Climbing generic market share will become of concern for innovation and competition if it is occasioned not by the timely expiration of patent rights, but rather by the erosion or

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Drug Regulation Reform, The International Supply of Medicines: Implications for U.S. Regulatory Reform 71 (R. Helms ed. 1980)).

[48] CBO 1998, at chp. 3.

[49] *Id*. at 28-29.

[50] PhRMA, 2002 Industry Profile, Fig. 3-3, at 33.

[51] *Id*. at 33.

extinguishment of such rights. For current patent protections are essential to the innovation from which new drugs come and upon which both pioneer and generic manufacturers depend.

II. Intellectual Property Rights are Protected by Rigorous Adherence to the Procedures in the Hatch-Waxman Act.

Critical protections for intellectual property rights in the pharmaceutical industry are provided in the Hatch-Waxman Act. The Act incorporates mechanisms for meaningful protection of patents and other intellectual property rights. These protections are required to compensate for other changes the Act made to intellectual property rights to allow generic manufacturers both to rely upon safety and efficacy data developed and submitted by the pioneer and to immediately market their generic products upon the expiration of the pioneer product patents. Accordingly, the scope of intellectual property rights for pharmaceutical innovations must be determined consistently with the intent of Congress as manifested in the Hatch-Waxman Act.

Congress deliberately developed this system for protecting the innovation upon which the pharmaceutical industry -- research-based and generic alike -- fundamentally relies. This legal regime fosters competition but also promotes innovation. Novel application of antitrust law as a "backstop" to second-guess good faith efforts to operate within this Congressionally mandated system is both unnecessary and unwise; unnecessary because the current system provides ample protection against abuse of intellectual property rights; unwise, because any such attempt would create uncertainty regarding the strength and value of intellectual property rights, which for the reasons discussed above, would seriously undermine pharmaceutical innovation.

A. The Hatch-Waxman Act Represents a Legislative Contract with the Pharmaceutical Industry that Provides Incentives for Developing New Drugs and Promotes Generic Competition.

The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") was designed both to promote innovation and to facilitate generic competition. The intent was to encourage the growth of the generic industry by simplifying the procedures for approving generic copies of drugs and, at the same time, to encourage innovation both by restoring some of the patent term lost during the drug development and approval process and by providing procedures to resolve patent disputes in a timely manner. [52] Congress intended that consumers would benefit from expanded access both to generic versions of drugs and to new generations of drugs discovered through innovative research. Seventeen years later, the generic drug industry now accounts for over 48% of the U.S. prescription drug market by volume. Similarly, research

[52] As explained by FTC Chairman Muris when he announced the antitrust/IP hearings, "[t]he Hatch-Waxman Act of 1984 reflected an attempt to balance the benefits of greater competition from generic drugs with the benefits of having sufficient intellectual property protection to preserve the incentives to make the large, up-front, and risky expenditures necessary to develop new drugs successfully." FTC Chairman Timothy J. Muris, Remarks before ABA Antitrust Section Fall Forum, *Competition and Intellectual Property Policy: The Way Ahead*, Washington, DC, (November 15, 2001), *available at* http://www.ftc.gov/speeches/muris/intellectual.htm.

pharmaceutical companies have increased annual research and development spending to over $30 billion. The Hatch-Waxman Act has clearly been a success in attaining its dual goals.

1. The Pre-Hatch-Waxman System.

Prior to 1962, drugs were approved for safety only. The Pure Foods and Drugs Act of 1906, the predecessor to the modern food and drug statute, did not include any pre-market approval requirements for drugs. The Federal Food, Drug, and Cosmetic Act of 1938 provided a mechanism for FDA to prevent the marketing of a drug based on safety concerns; however, the 1938 statute did not consider efficacy. The addition of efficacy as a consideration and establishing both safety and efficacy as pre-market approval requirements did not occur until 1962.[53]

The 1962 amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") resulted in stricter FDA controls and lengthy approval times. This demanding pre-market approval process increased costs for developing innovative products and decreased the effective window of patent protection in which an innovator could expect to be free from competition from products subject to their patents. More patent time now had to be expended obtaining marketing approval.

These effects produced a rapid decline in the average number of pioneer drugs introduced to the market. For example, prior to the requirements for pre-market demonstration of efficacy, approximately 50 new pharmaceuticals were introduced on average from 1955-1961. After the 1962 amendments, the average number of products introduced to the market fell to an average of about 16 per year between 1963 and 1972.[54] By 1983, a broad bipartisan recognition existed that the patent life of drugs was being seriously eroded by increasing delays in the pre-market approval process due to dramatic increases in regulatory requirements and oversight.[55]

The 1962 amendments also affected generic manufacturers because they, too, were required to demonstrate safety and efficacy for their products. Although FDA permitted certain drugs to demonstrate safety and effectiveness based on published reports of data, this "paper NDA" approach was available only for some post-1962 drugs.[56] Generic companies did not

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[53] Interestingly, the 1962 amendments were the result of revelations about the birth defects associated with the rise of Thalidomide, a safety (rather than efficacy) issue. Gerald Mossinghoff, *Overview of The Hatch-Waxman Act and Its Impact on The Drug Development Process*, 54 Food & Drug L.J. 187 (1999) (Overview of the Hatch-Waxman Act).

[54] Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It A Healthy Long-Term Solution?* 21 Rutgers L.J. 147, n. 39 (1989).

[55] Ralph A. Lewis, Comment, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. Contemp. Health L. & Pol'y 361 (1992).

[56] *See* Draft Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System, 64 Fed. Reg. 7897, 7898 (Feb. 17, 1999).

want to spend the time and money to get off-patent drugs to market given the prospect of multiple generic entrants and a reduced market share and price structure.[57] Accordingly, by 1980, there were 150 drugs off-patent for which there were no generic competitors.[58]

At the same time, the patent code protected the intellectual property rights of all inventors by defining the manufacture, use or sale of a patented invention during the term of the patent as an act of infringement.[59] Although judicial interpretation of the patent code in cases such as *Northhill Co*. v. *Danforth*, 51 F. Supp. 928, 929 (N.D. Cal. 1942) held that use of a patented invention for experimental purposes did not constitute infringement, this exception only applied if the experimentation was not conducted for commercial purposes.

In 1983, Bolar Pharmaceutical Co., a generic manufacturer, tested the boundaries of what might constitute infringement by manufacturing for testing a generic version of Dalmane, a patented prescription sleeping pill manufactured by Roche Products Inc. On appeal, the newly created Court of Appeals for the Federal Circuit held that Bolar had not limited its acts to "scientific inquiry," but rather its "intended 'experimental' use was solely for business reasons" and, accordingly, was an act of infringement.[60]

As a result of these various regulatory and market dynamics, both pioneer and generic manufacturers appealed to Congress for legislative changes. Pioneer manufacturers wanted additional patent life to make up for the patent term lost during safety and efficacy testing to obtain regulatory approval for innovative drug products. Generic manufacturers wanted an abbreviated method to get generic drugs on the market following the resolution of any patent issues. Moreover, Congress wanted to address consumer groups concerns about the accelerating health care costs of the 1970s and early 1980s and the large number of off-patent drugs for which there were no generic versions.[61]

2. The Hatch-Waxman Act Compromise.

The legislative response was the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The final statute was contractual in nature. The Act grants generic manufacturers the ability to support their abbreviated new drug applications ("ANDAs") by relying on proprietary clinical data and test results obtained at great expense by pioneer companies, thereby reversing decades of regulatory practice recognizing an

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[57] Overview of the Hatch-Waxman Act, at 187.

[58] *Id*.

[59] 35 U.S.C. 271(a).

[60] *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

[61] *See* Alan R. Bennett & Allan M. Fox, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984*, Food & Drug Law. Inst., Inc., at 97 (1987), *quoting* House Report, Part 1, at 16-17.

innovator's sole proprietary right to its data.[62] The Act also allows generic manufacturers to infringe patents prior to expiration by granting them the right to make and test drugs, developed by pioneer companies, before the expiration of the patent term for the pioneer drug[63] – similarly reversing the important prohibition, discussed above, against such use of a patented invention. Further, the Act provides for generic applicants to obtain notice of patents potentially claiming their proposed products.

In exchange, Congress made three statutory promises to the research-based pharmaceutical industry. First, patent term restoration would make up for some of the period of government-imposed delay prior to FDA approval. Second, innovator companies would have a meaningful opportunity to defend their patent rights prior to FDA approval of potentially infringing generic products, through (a) prior notification of potential patent infringement, (b) the right to sue generic drug manufacturers for patent infringement prior to FDA approval of the generic's ANDA, and (c) an automatic stay of FDA approval of the ANDA of up to 30 months if the branded company asserts that right to sue in a timely fashion. Third, the circumstances in which generic companies could rely on innovator data would be somewhat limited.

These provisions reflected Congress's intent for the law to ensure that innovation would be sufficiently rewarded to justify the risks and the investment capital expended by the research-based companies. The research-based industry responded with "reasonable, investment backed" actions that increased domestic research and development spending as a percentage of sales from 14.6% in 1984 to 17.7% for 2001 (from approximately $3 billion in 1984 to nearly $24 billion in 2001 spent in the United States).[64] Meanwhile, as noted above, generic manufacturers' share of the drug market grew to 47% by 2000, more than double their share in 1984. If the statutory protections for the research-based industry are not respected and applied as Congress intended and provided in the Act, this carefully crafted compromise, which has so effectively achieved its goals, would be undermined.

3. Hatch-Waxman Litigation Procedures Protect Incentives to Innovate.

One of the fundamental principles of the Hatch-Waxman Act is that a generic drug should not be able to enter the market if it infringes a valid patent. Under U.S. law, patents are presumed to be valid,[65] and this presumption can be overcome only by clear and convincing

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[62] *See, e.g.*, 39 Fed. Reg. 44602, 44634 (Dec. 24, 1974).

[63] At least one court has further held that the Hatch-Waxman Act also protects generic manufacturers from copyright liability for drug product labeling and certain promotional materials. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc.*, 211 F.3d 21 (2d Cir. 2000) (holding that, under the Hatch-Waxman Act, copyright liability does not attach if generic sellers' use copyrighted labeling from pioneer drug products to label and prepare certain promotional materials for generic versions of the same drug, due to the Hatch-Waxman sameness standard for labeling).

[64] PhRMA, 2002 Industry Profile, table 2, at 76.

[65] 35 U.S.C. § 282.

evidence to the contrary.[66] Moreover, under the Hatch-Waxman Act, the generic applicant is proposing to market a drug that is the same as the pioneer's. Indeed, that "sameness" is the basis for the generic applicant to use the pioneer's data to demonstrate safety and effectiveness. Accordingly, in the event of a patent infringement dispute, ***we start with a circumstance where the generic manufacturer is making an identical copy of a drug that is covered by a presumptively valid patent***.

Failure to resolve patent issues prior to generic product approval presents problems for pioneer and generic manufacturers alike. The marketing of a product that is later determined to be infringing will severely and irreparably injure the pioneer's market at a magnitude that generally cannot be compensated by the infringing generic manufacturer. At the same time, the generic manufacturer is faced with the risk of having to pay crippling actual and enhanced damages for intentional infringement if it decides to market the approved product before the resolution of the patent infringement claim. In short, (in addition to being in the interest of physicians and patients who might otherwise have to address the difficulties associated with switching from the pioneer to the generic product and back again) it is in the interest of both the pioneer and the generic company to resolve all patent issues before the generic product goes to market.

Congress recognized that it would be preferable to resolve patent infringement disputes prior to FDA product approval. Accordingly, as noted above, the Act establishes patent litigation provisions to benefit both pioneer and generic manufacturers. These provisions provide for: (1) patent listing to notify generics of patents that may claim their proposed products; (2) patent certification to inform pioneers of proposed generic products that may infringe their patents; (3) up to a 30-month stay of product approval to allow for resolution of patent infringement claims; and (4) the grant of a 180-day period of market exclusivity to the first generic that successfully challenges a listed patent.

a. Patent Listing

An applicant who submits a New Drug Application ("NDA") under section 505(b) of the FDCA must submit information on each patent that "claims the drug or a method of using the drug . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale" of the drug.[67] According to FDA's regulations, patents that may be listed include drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process patents (i.e., patents that claim a process but not the product made by the process) are not covered by this section and information on process patents may not be submitted to FDA.

With respect to patents that claim a drug substance or a drug product, the applicant can submit information only on those patents that claim a drug product that is the subject of a pending or approved application or that claim a drug substance that is a component of such a

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[66] *See, e.g., Ethicon Inc. v. Quigg*, 849 F.2d 1422, 1427 (C.A. Fed. 1988).

[67] FDCA § 505(b)(1); 21 U.S.C. § 355(b)(1).

product. Similarly, with respect to patents that claim a method of use, the applicant can submit information only on those patents that claim indications or other conditions of use of a drug substance or drug product that is the subject of a pending or approved application.[68]

FDA publishes the submitted patent information in its official publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"). Upon approval of the application, FDA will publish in the Orange Book the patent number and expiration date of each patent that is submitted to FDA by an applicant.[69] For each use patent, FDA will also publish the approved indications covered by the patent.[70]

If any person disputes the accuracy or relevance of patent information submitted to the Agency and published by FDA in the Orange Book, that person must first notify the Agency in writing stating the grounds for disagreement. The Agency will request the NDA holder to confirm the correctness of the patent information or omission of patent information. Unless the NDA holder withdraws or amends its patent information in response to FDA's request, the Agency will not change the patent information in the Orange Book. An ANDA (or a 505(b)(2) application) submitted for a listed drug must – despite any disagreement as to the correctness of the patent information – contain an appropriate certification for each applicable listed patent, as discussed below.[71]

The purpose of the Orange Book listings is to provide clear notice to potential generic developers of the patents (other than process patents) that cover the product and may reasonably be asserted by the innovator against the generic drug manufacturer.[72] In doing so, it serves to protect the interests of both pioneer and generic manufacturers.

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[68] 21 C.F.R. § 314.53(b). An NDA applicant must submit the following information for each patent: (i) patent number and the date on which the patent will expire; (ii) type of patent, i.e., drug, drug product, or method of use; (iii) name of the patent owner; and (iv) the name of an agent (representative) of the patent owner or applicant (for foreign applicants). 21 C.F.R. §314.53(c).

[69] 21 C.F.R. § 314.53 (e).

[70] *Id.*

[71] 21 C.F.R. § 314.53(f).

[72] *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 934-35 (N.D. Ill. 1995) (purpose of Orange Book listing is notice to potential ANDA applicants of patents assertable against them, so as not to (in the FDA's words) "lead an applicant to submit an ANDA that it would have not submitted had the patent been listed" and "later subject the ANDA holder to an unnecessary patent suit"). The FDA also recognizes that Orange Book listings are for the benefit of potential generic competitors. In its commentary accompanying the issuance of the final listing regulation the agency stated: "The agency disagrees with the assertion that the NDA applicant would be the only party injured by the failure to list a patent…. Failure to list a patent may also result in injury to other applicants who devote resources towards submitting applications for duplicate products without realizing that those products may be covered by the patent." 59 Fed. Reg. 50,338, 50,344 (Oct. 4, 1994).

b. Patent Certification Requirements

The need for patent certifications arises from the legislative intent: (1) to permit the marketing of generic copies of pioneer products immediately upon the expiration of any relevant patents; (2) to encourage generic challenges of innovator patents; (3) to provide a timely, effective mechanism for patent holders to protect rights in patents alleged to be invalid or not infringed by the generic product; and (4) to prohibit FDA's approval of any abbreviated application whose marketing would infringe a valid patent covering the pioneer product, until the parties have had a meaningful opportunity to attempt to resolve the issue.

Accordingly, section 505(j)(2)(A)(vii) of the FDCA provides that an ANDA must include:

> a certification . . . with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . .
>
> I. that such patent information has not been filed,
> II. that such patent has expired,
> III. of the date on which such patent will expire, or
> IV. that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; . . . "[73]

The certification requirements determine the date on which approval of an ANDA can be made effective and, therefore, the date on which commercial marketing may begin. If the applicant makes either the first or second certification, approval can be made effective immediately. Under the third certification, approval of the application can be made effective on the date the patent expires. If, however, the applicant challenges the innovator's patent and makes the fourth certification (the "Paragraph IV" certification), the applicant is required to give notice to the holder of the patent alleged to be invalid or not infringed. As explained below, approval of an ANDA containing the fourth certification may become effective immediately only if the patent owner has not initiated a patent infringement suit within 45 days of receiving notice of the certification.[74] When a patent owner initiates such a patent infringement action, following

[73] 21 U.S.C. 355(j)(2)(A)(vii). Nearly identical certifications for "paper NDAs" can be found in section 505(b)(2)(A) of the FDCA. *See* FDCA § 505(b)(2)(A); 21 U.S.C. § 355(b)(2)(A). This provision is based on FDA's pre-Hatch-Waxman "paper NDA" policy, which applied to NDAs supported, in whole or in part, by published literature rather than by clinical trials cited or submitted by the applicant. As a general matter, the Hatch-Waxman litigation provisions apply equally to ANDAs and to applications filed under Section 505(b)(2) of the FDCA.

[74] FDCA §§ 505(j)(5)(B)(iii) and 505(c)(3)(C); 21 U.S.C. §§ 355(j)(5)(B)(iii) and 355(c)(3)(C).

the provocation of a Paragraph IV certification, FDA automatically stays approval of the ANDA.[75]

c. 30-Month Stay

For a patent holder to challenge the allegation in a Paragraph IV certification that the listed patent is invalid or not infringed, the patent holder must be able to bring a patent infringement action against the generic applicant. Without a provision expressly making it an act of infringement to file an ANDA containing a Paragraph IV certification, the patent infringement exemption provided by 35 U.S.C. § 271(e)(1) would likely prevent a finding of infringement with respect to such an ANDA filing.

To enable research-based companies to protect their intellectual property rights, Congress accordingly provided in 35 U.S.C. § 271(e)(2) that: "[i]t shall be an act of infringement to submit –(A) an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent, . . .if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." Through this provision, the Hatch-Waxman Act provides an exception to the exemption from patent infringement provided by 35 U.S.C. §271(e)(1).

The act of infringement occurs when the generic drug manufacturer submits an ANDA containing a Paragraph IV certification for a drug claimed in a listed patent, for manufacture, use or sale of the patented drug before the expiration of the patent.[76] For this act of infringement, a court may order that : (1) the approval date of the generic manufacturer's ANDA be no earlier than the expiration of the pioneer patent; (2) an injunction be granted against the infringer preventing the commercial manufacture, use, or sale of an approved drug; or (3) monetary relief be awarded against the generic drug manufacturer "only if there has been commercial manufacture, use or sale of an approved drug."[77] These are likely the only forms of relief available to the patent holder under Section 271(e), aside from the possibility of winning attorneys fees.[78] If the patent holder initiates a patent infringement action in response to a Paragraph IV Certification within 45 days of receiving notice of the certification, FDA cannot approve the ANDA for 30 months, unless either the action is resolved in favor of the generic applicant or the patent expires before that time.[79]

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[75] *Id.*

[76] 35 U.S.C. § 271(e)(2).

[77] 35 U.S.C. § 271(e)(4).

[78] 35 U.S.C. §§ 271(e)(4), and 35 U.S.C. § 285. *See also Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc*., 231 F.3d 1339, 1346-48 (Fed. Cir. 2000) (upholding awarding of attorneys' fees to plaintiffs for defendant's willful patent infringement in the filing of a Paragraph IV certification that was "without adequate foundation and speculative at best").

[79] *See* FDCA §§ 505(c)(3)(C) and (j)(5)(B)(iii), 21 U.S.C. § 355(c)(3)(C) and (j)(5)(B)(iii).

d. 180-Day ANDA Exclusivity

The first follow-on (generic) product approved through an ANDA containing a Paragraph IV Certification receives 180 days of market exclusivity during which no subsequent ANDA for the same product can be approved.[80] The purpose of the 180-Day ANDA exclusivity is to reward a generic drug manufacturer for the expense and effort involved in challenging a listed patent of the pioneer company. As a result of various lawsuits, however, the FDA has withdrawn its implementing regulations and the 180-Day ANDA exclusivity remains the subject of pending rulemaking.[81]

B. Orange Book Listing and Use of Proprietary Data: Preserving the Correlation Between Data Use and Patent Scope is Essential to Preserving the Legislative Contract of the Hatch-Waxman Act.

There is an important relationship between the statutorily mandated scope for Orange Book listings and the scope of use that generic companies may make of pioneer companies' proprietary data in seeking approval for their generic products. The fundamental premise of the abbreviated approval process is that the generic manufacturer makes the same (identical) drug as the pioneer. The identity between the products justifies the use of data collected on the pioneer's product to demonstrate safety and effectiveness for the generic copy. Just as the sameness of the products defines the boundaries within which the pioneer company's data can be used, it also defines the range of products that may be subject to any patents claiming the pioneer's product. Such an interpretation is consistent with the balance and compromise drawn by Congress in the Hatch-Waxman Act.

For example, FDA regulations provide that all patents covering the "drug substance" of a drug product (*i.e.*, an ingredient) must be listed. In the case of polymorphs and hydrates, FDA generally considers all variations to be the same, and the official names for the resulting drug products may not even identify the particular polymorph or hydrate involved.[82] A court has held that patents on all hydrates and polymorphs are listable, even though an approved product may use only one of the forms of the active ingredient.[83] The court's interpretation is fully consistent

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[80] *See* FDCA § 505(j)(5)(B)(iv), 21 U.S.C. § 355(j)(5)(B)(iv).

[81] The 180-day exclusivity provision does not apply to applications filed under Section 505(b)(2) of the FDCA. Section 505(b)(2) products are not the same as, and do not follow-on from, innovator products. As a result, there can be no subsequent generic copies, and no role for 180-day relative exclusivity.

[82] *See* FDA, *Preface to Twenty First Edition* of Approved Drug Products with Therapeutic Equivalence Evaluation, *available at* http://www.fda.gov/cder/orange/adp.htm "... polymorphs are considered pharmaceutical equivalents... where their equivalence is supported by appropriate bioavailability/bioequivalence studies."

[83] In response to a preliminary injunction motion, the court in *Zenith Laboratories, Inc. v. Abbott Laboratories*, found that the plaintiff was unlikely to succeed in showing that the defendant improperly listed a patent, since the patent was for a different polymorph of the active ingredient in the approved product. No. 96-1661, 1997 U.S. Dist. Lexis 23954, at * 13 n.4 (D.N.J. Oct. 2, 1997). *See also Ben Venue Laboratories v. Novartis Pharmaceutical Corp.*, 10 F. Supp. 2d 446, 456-58 (D.N.J. 1998).

with the purposes of the pre-approval litigation procedures. If an active ingredient occurs in a variety of crystalline forms, all of which are patented by the NDA holder and all of which are considered interchangeable by FDA, ***it would violate the statutory compromise of the Hatch-Waxman Act to allow a generic applicant using a different form of the approved active ingredient to assert simultaneously that its active ingredient is the "same" as the approved product for purposes of relying on the innovator's data but is different for purposes of denying the innovator the opportunity to defend its patent rights.***

The Bureau of Competition and Policy Planning Staff of the Federal Trade Commission ("FTC") has submitted a citizen petition to FDA, dated May 16, 2001, in which the FTC asks FDA to "clarify," on an expedited basis, the types of patents that can legally be listed in the Orange Book.[84] The petition seeks to have FDA state that a patent can be listed in the Orange Book only if the patent covers the approved product. The FTC is not asking FDA to confirm pre-existing interpretations. Instead, the petition asks FDA to arrive at new interpretations. For example, the petition asks FDA to state that, even though FDA considers various forms of an ingredient to be the same for approval purposes, the only patents that can be listed in the *Orange Book* are those covering the form in the approved product.[85]

The Orange Book process and the overall Hatch-Waxman litigation procedures are designed to notify the generic applicant about the patents that might be asserted against its product and to permit the resolution of patent issues before FDA approval of the generic products. Accordingly, these provisions that benefit both pioneer and generic manufacturer will be hindered – not helped – by further restrictions on Orange Book listings.

C. Pioneers Must be Able to List Later-Issued Patents to Protect Their Intellectual Property Rights.

A topic of recent misunderstanding, and some controversy, arises from so-called "late-listed" patents, a misnomer because the term inappropriately implies that the patent was not filed in a timely manner for Orange Book listing. A more appropriate term would be "later-issued" patents, to refer to those patents that claim the drug or method of using the drug, but are issued after the NDA is approved. The controversy concerns only a narrow subset of later-issued patents.

In limited circumstances, the United States Patent and Trademark Office ("PTO") may issue a patent that claims a drug or a method of using a drug that is the subject of an NDA after an ANDA for the same drug or use is filed. The patent owner is required to submit the patent information to FDA within 30 days of the issuance of the patent, for listing in the Orange

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[84] Citizen Petition, FTC submitted to FDA (May 16, 2001) (FTC Citizen Petition), *available at* http://www.fda.gov/ohrms/docket/daily/01/May01/052901/cpa.pdf.

[85] *Id.*

Book.[86] If the patent is listed within 30 days of the issuance of the patent, all pending and future ANDA applicants must provide an appropriate certification.[87]

If a generic company that has already filed a pending ANDA files a Paragraph IV certification to such a later-issued and later-listed patent, and the patent owner brings suit for patent infringement within 45 days of receipt of notice of the Paragraph IV certification, the stay of up to 30 months as to the new certification will begin to run upon the receipt of the notice provided as to this new, amended certification.[88] Thus, this new 30-month stay will begin to run after any original 30-month stay(s) has started and, therefore, will not run concurrently with the original 30-month stay(s) (though, depending upon the relative timing of the Paragraph IV certifications, the periods may overlap). However, the approval of the ANDA will be made effective only upon the expiration of this new stay of up to 30-months.

The risk of multiple stays is, nonetheless, largely illusory. In most circumstances, the stays for all listed patents will run concurrently. The likelihood that the pioneer could exploit the requirement for a new 30-month stay for a later listed patent is small for the following reasons: (1) the patent applicant has a limited ability to control patent prosecution developments; (2) the generic applicant will likely be aware of the non-listed patent because companies who patent generally do so globally and, accordingly, the patents will be published; (3) the PTO, not pioneer manufacturers, determines when a patent will issue; (4) unreasonable delay in patent prosecution could render a patent unenforceable on equitable grounds;[89] and (5) if the pioneer manufacturer fails to notify FDA within 30 days of the patents' issuance, then no Paragraph IV certification is required for an ANDA filed prior to the listing.[90] In addition, ample other remedies exist to address efforts to abuse the listing process. *See* Part V. Also, assertion of later-issued patents only impacts generic manufacturers who choose to use the new patented invention.

D. Good Faith Orange Book Listings Must be Protected.

Significant impacts upon innovation and competition could arise from uncertainty regarding the right of innovators to list in good faith any patent that an innovator could reasonably view as falling within the scope of the statutory and regulatory requirements for patent listing.

Patent owners are required to submit all patents that satisfy the statutory requirements of listing, as compelled by Congress, and the FDA must list them in the Orange Book. This listing

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[86] 21 CFR § 314.53(d).

[87] 21 C.F.R. § 314.94(a)(12)(vi).

[88] *See* Sections 505(c)(3)(C) and (j)(iv)(B)(3) of the FDCA, 21 U.S.C. §§ 355(c)(3)(C) and (j)(iv)(B)(3).

[89] *Symbol Technologies, Inc. v. Lemelson Med. Educ. & Research Found.*, 277 F.3d 1361 (Fed. Cir. 2002).

[90] *See* 21 C.F.R. § 314.94(a)(12)(vi).

process is a critical component of the statutory compromise established under the Hatch-Waxman Act. When the patent owner submits the information for listing, the patent owner is fulfilling a statutorily mandated requirement, triggering two obligations for the FDA. The FDA must list the patent to notify generic applicants. In addition, it must condition the formal acceptance of any ANDA pertaining to that drug upon the certification the ANDA applicant makes concerning the listed patent. If the applicant certifies under Paragraph IV that the proposed generic does not infringe the listed patent, the FDA must not issue final approval for the ANDA for up to 30 months if litigation is timely joined as a result of the patent listing and Paragraph IV certification. Without these protections triggered by Orange Book listing, generic companies would not have an important source of notice of patent rights that could delay market entry for their proposed products, and innovators would not have a viable and timely judicial remedy for infringement.

E. The "30-Month" Stay is a Key Feature of the Hatch-Waxman Legislative Contract.

The provision for up to a 30-month stay of FDA approval delays the market entry of a potentially infringing product. It is intended to allow the orderly and timely resolution of patent disputes before marketing of the generic product.

1. The 30-Month Stay Protects Both Pioneers and Generics from the Extraordinary Consequences of Patent Infringement.

This mechanism decreases the likelihood of the detrimental situation that would occur if a generic manufacturer were to market its version of a pioneer drug prior to resolution of the patent conflict and then subsequently lose the suit. Congress understood that such a situation would harm the public, destroy market share and pricing structure for the pioneer product, and expose the generic manufacturer to crippling damage claims.[91]

It is particularly significant that the 30-month stay enables patent owners to avoid having to seek preliminary injunctions, because they are especially difficult to obtain for pioneer manufacturers. Accordingly, a stay of generic product approval is critical in the specific context of pharmaceutical patents.

Congress' concern that preliminary injunctions could not be relied upon to provide adequate protection for the patent rights of pioneer companies was well-founded. In fact, over the past twenty years, federal courts, and the Federal Circuit in particular, have granted preliminary injunctive relief for patent infringement in fewer and fewer instances.[92] For a preliminary injunction to issue, the plaintiff must demonstrate: (1) a reasonable likelihood of success on the merits of the case; (2) that the plaintiff will be irreparably harmed if the injunction is not issued; (3) that the threatened harm to the plaintiff outweighs the harm the injunction may

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[91] Remarks of Rep. Waxman, House Floor Debate, Cong. Rec. of Sep. 6, 1984, at H9115.

[92] M.A Cunningham, *Preliminary Injunctive Relief in Patent Litigation*, 35 IDEA 213 (1995); Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

inflict on the defendant; and (4) that the injunction will serve the public interest.[93] Generally, courts will not find irreparable harm if the injury can be remedied with monetary damages.[94] Further, courts have tended to find irreparable harm in patent litigation only when the patent holder has been able to make a strong case for validity and infringement in its motion for preliminary injunction.[95] In the pharmaceutical context, however, application of this standard is unsound and would have substantial negative consequences.

Pharmaceutical patent infringement analysis is highly complex and technical, requiring both close evaluation of the scope of the claims of the patent that define the invention and an often challenging, fact-intensive determination of whether the defendant's product or method falls within this scope. It may be virtually impossible to demonstrate a likelihood of success on the merits without the benefit of evidence that would be gathered through lengthy discovery and that would, in some cases, be presented at trial. Further, in the pharmaceutical context, patent holders would have to develop the case for and obtain the preliminary injunction (and potentially defend the injunction on appeal), all before FDA approves the ANDA, which typically occurs within eighteen months.[96]

If, as their practice to date indicates, courts were to deny requests for preliminary injunction, their failure to grant such relief would not just harm the patent holders, but consumers. First, there is an important harm to the public if a generic product is allowed on the market before the patent claim is fully litigated and then is found to infringe, because this requires the generic to withdraw its product from the market, which could be disruptive to patients and doctors. Making changes to medication can be quite challenging, potentially requiring attempts to use various alternatives and reset dosage levels, as well as causing a significant degree of unnecessary distress to many patients.

In addition, because a generic product enters the market at a price well below that of the pioneer product, the very entry of the generic into the market, as acknowledged by Congress, irreparably changes future pricing in that market. Finally, in many cases, generic companies would not have the financial capacity to satisfy the damage awards that courts would appropriately impose. As a result, without the benefit of the 30-month stay, the pioneer would likely have no means to prevent or recoup its financial losses.

By eliminating the uncertainty of the preliminary injunction "roll of the dice," the 30-month stay provides greater certainty that a drug product covered by a presumably valid patent will not enter the market before the pioneer company has had an opportunity to assert its patent

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[93] Laurence H. Pretty, *Injunctions Against Patent Infringement*, 669 PLI/Pat 179, 183 (2001).

[94] *See, e.g.*, 13 James Wm. Moore, Moore's Federal Practice 3d § 65-21[2] (2001).

[95] 7 Donald S. Chisum, Chisum on Patents, § 20.04[1][e] (2002).

[96] *See* FDA, CDER Report to the Nation: 2000, *available at* http://www.fda.gov/cder/reports/RTN2000/RTN2000.HTM.

rights. This greater certainty is essential to encourage innovation and the development of new drug products.

2. The 30-Month Stay Can Only be Triggered by Generic Patent Challenges, and Does Not Extend Past the Patent Term.

It is important to understand that the 30-month stay is not automatic. The stay can only apply if a generic applicant provokes an innovator's defensive patent infringement lawsuit by challenging the applicability of a presumptively valid, listed patent. The stay is triggered only if the pioneer manufacturer makes a timely decision to sue the generic manufacturer for patent infringement – a decision that must be made in light of the civil and criminal remedies available (*see* Part V) including for frivolous suits and for fraud, for knowing assertion of an invalid patent.

As explained above, ANDA applicants may make "Paragraph III" or "Paragraph IV" certifications in their applications. When a Paragraph III certification is made, the ANDA cannot be approved until the patent expires but then is eligible for immediate approval. Under Paragraph IV, the ANDA approval date is subject to the 30-month stay if patent litigation is initiated within 45 days of receipt of notice of the certification.[97] The ANDA applicant may, however, change its certification from Paragraph IV to Paragraph III. If it does, then the 30-month stay does not apply and the application becomes eligible for approval immediately upon patent expiration.[98]

The 30-month stay does not extend the patent term. After patent expiration, the 30-month stay terminates, and the approval of an ANDA is no longer delayed by the stay. Moreover, a change from Paragraph IV to Paragraph II certification (that the patent has expired) is allowed if "the patent expires before the lawsuit is resolved."[99] In other words, a change from Paragraph IV to Paragraph II always is permitted if the patent expires while the lawsuit is pending. At that point, the 30-month stay also no longer applies.

3. Eliminating or Undermining the 30-Month Stay Would Upset the Legislative Contract of Hatch-Waxman.

As part of the Hatch-Waxman contract, generic manufacturers received unique privileges to infringe intellectual property rights in preparing ANDAs, and other advantages in speeding generic introduction. This bargain allows a generic drug to go on the market immediately once valid patents on the drug product expire. The 30-month stay provides a counterbalancing protection for innovator drug companies. The 30-month period was intended to reduce the

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[97] *See* 21 U.S.C. § 355(j)(5)(ii) and (iii); 21 C.F.R. § 314.107(b)(2) and (3).

[98] *See* 21 C.F.R. § 314.94(a)(12)(viii) (patent certification "may be amended at any time before the effective date of approval of the application").

[99] *Id.*

likelihood that a generic drug manufacturer would put its competing drugs on the market before resolution of the patent dispute.[100]

Limiting or reducing the scope of the 30-month stay would essentially gut the legislative contract of Hatch-Waxman. Generics would continue to enjoy the right to non-infringing manufacture and use of the pioneer drug for purposes of preparing an ANDA (as well as the right to rely on the pioneer's safety and efficacy data to support their applications), but pioneer companies would lose a critical protection they were given in exchange for the loss of these pre-Hatch-Waxman patent and proprietary data rights. This would seriously compromise the value and certainty of the patent rights that Congress sought to enhance to encourage innovation, the same patent rights that are so important to pharmaceutical innovation.

* * *

As the above discussion shows, the Hatch-Waxman Act is composed of many complex provisions that protect and enhance innovation and competition in the research-based pharmaceutical industry. The Act creates a system of rights and obligations, constructed in a finely balanced, even contractual manner, so that seemingly simple modifications to one of the provisions may upset the statutory arrangement in extraordinary and unintended ways that adversely affect the incentives for innovation and competition. Any such changes could stifle innovation and competition in the pharmaceutical industry.

III. Robust Patent Rights for Initial and Sequential Product Development are Needed to Promote Innovation and Related Competition.

The Federal Register notice of the hearings and the speech of Chairman Muris express interest in the relationship between sequential innovation and patent protection.[101] The FTC has also expressed interest in evaluating the merits of strengthening incentives and opportunities for follow-on innovators, as opposed to promoting sequential innovation of drug products by the research-based companies that developed them.[102] Sequential innovation is, however, an important source of product improvement, which in turn, is an important catalyst of competition in the pharmaceutical industry. Patent protection is an essential precondition for this innovation. Much of this sequential innovation is the result of internally generated research. The motivations behind this research are generally valid, and the results beneficial to consumers. Any effort to intrude the antitrust laws further into the research and patenting decisions of innovating firms, including with respect to sequential innovations, would be an unwise departure from current law and policy.

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[100] Remarks of Rep. Waxman, House Floor Debate, Cong. Rec. of Sep. 6, 1984, at H9115.

[101] *See* Timothy J. Muris, supra *Competition and Intellectual Property: The Way Ahead* (Nov. 15, 2001); FTC, Notice of Public Hearing and Opportunity for Comment (Nov. 15, 2001), *available at* http://www.ftc.gov/os/2001/11/ciphearingsfrn.htm. (FTC Hearing Notice).

[102] *See* John H. Barton, Statement before the FTC on *Patent Breadth and Antitrust: A Rethinking* (November 27, 1995), *available at* http://www.ftc.gov/opp/global/barton.htm (providing invited testimony on promoting follow-on innovation).

A. Sequential Innovation is Important to Product Development and to Competition in the Pharmaceutical Industry.

Over 20% of pharmaceutical annual R&D expenditures are devoted to improvements and/or modifications to existing products.[103] This sequential product innovation is spurred by and fosters competitive pressures. Moreover, sequential product innovation expands the variety of therapeutic choices available to consumers.

The pharmaceutical industry is characterized by significant first-mover advantages. At the same time, breakthrough drugs generally face competition within their initial patent life from other branded drugs of the same therapeutic class. *See* Figure 3: Shrinking Period of Market Exclusivity Between Introduction of Breakthrough Medicine and Competing Innovators.

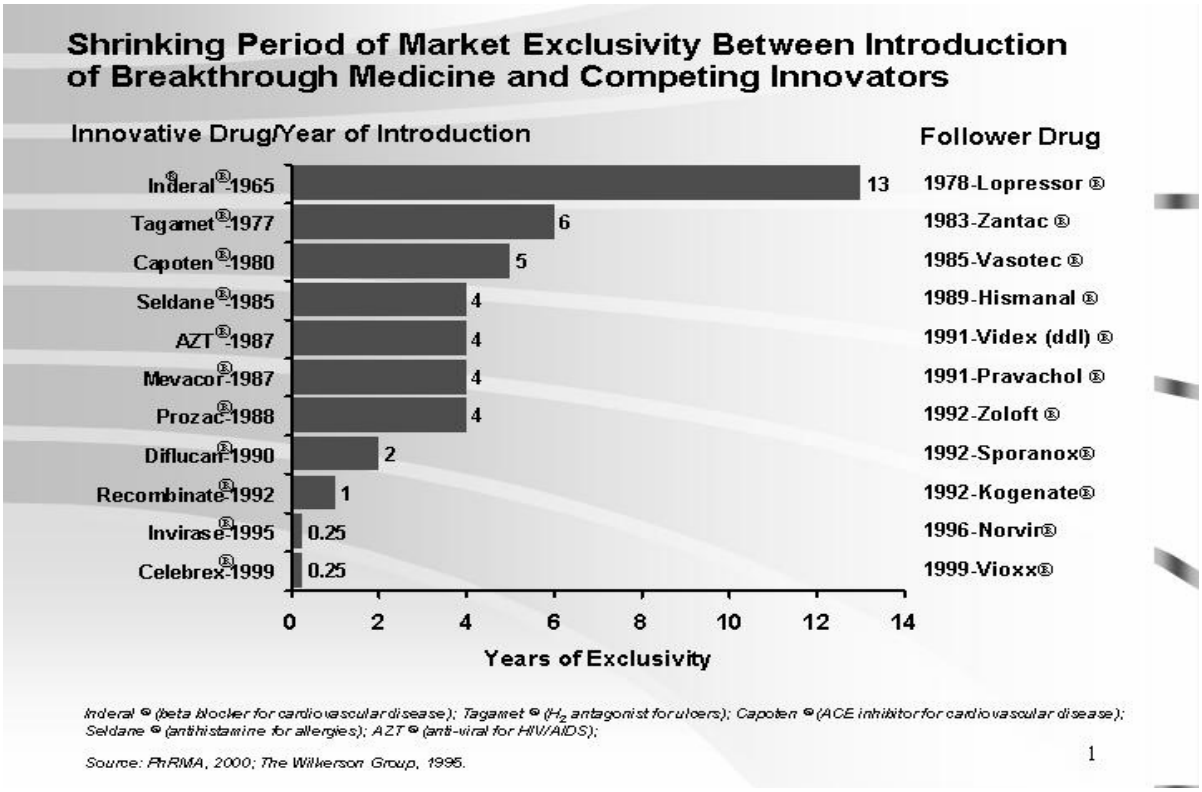

Figure 3

This market dynamic sets up a competitive environment in which branded rivals rely heavily on product differentiation to achieve competitive advantage over other branded rivals. Furthermore, the virtual certainty of eventual generic competition due to the Hatch-Waxman ANDA procedures enhances the existing incentives that generic competition creates for branded manufacturers to try to develop improved products to retain sales. In addition, by expanding the

[103] *See* PhRMA, 2001 Industry Profile, at 14.

range of available therapies, sequential innovation itself can promote competition, driving prices down.[104]

The process of repeated incremental improvement is an important mechanism of innovation and product development within most high-technology industries including the pharmaceutical industry. Over time a succession of small improvements can add up to a major advance in therapy. Further, the collective therapeutic advantage to a drug class, as a whole, may be of greater clinical significance than the original advantage to the pioneer compound. Many of the major classes of drugs – antihistamines, beta-blockers, calcium channel blockers – owe their overall effectiveness and clinical significance to important modifications in pioneer agents.[105]

Sequential product innovation also produces further substantial consumer benefits by generating a variety of different drugs within the same therapeutic class that have different clinical and side-effect profiles. This gives physicians more options to fit the drug to the needs of the individual patient. For example, differentiated competition within the selective serotonin reuptake inhibitor and serotonin/norepinephrine reuptake inhibitor ("SSRI/SNRI") category has produced a wide variety of new therapeutic indications for this class of drugs, including treatment of obsessive-compulsive disorder, panic disorder, social anxiety disorder, post-traumatic stress disorder, and premenstrual dysphoric disorder.[106]

Antitrust concern about "switching strategies," in which branded manufacturers attempt to introduce new patented versions of their products on the eve of generic competition, is misplaced. This concern implies a market failure that does not exist in today's pharmaceutical marketplace. If the product does not deliver a genuine improvement to patients, doctors simply will not prescribe it; managed care entities will not pay higher prices for it; and it will lose sales to generic competition. If the product does deliver such benefits, it will gain sales. In neither case should the antitrust laws attempt to override the decision of the marketplace. As Commissioner Anthony has stated:

> The [share-switching concern] is founded on the premise that [the new product] will … offer few new benefits - and that patients and their doctors will nevertheless be persuaded to use the new drug rather than using the presumably cheaper generic form….While

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[104] *See* Richard Levey, Thomas W. O'Connor, Albert Wertheimer, *Too Many Drugs? The Clinical and Economic Value of Incremental Innovation,* 14 Investing in Health: The Social and Economic Benefits of Health Care Innovation 77-118 (2001) (Too Many Drugs?).

[105] *See* Richard Levey, Thomas W. O'Connor, Albert Wertheimer, *Too Many Drugs?: Executive Summary* (2001).

[106] *See, e.g.*, FTC Commissioner Sheila F. Anthony, Remarks before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property*, (June 1, 2000), *available at* http://www.ftc.gov/speeches/anthony/sfip000601.htm ("[Drugs within SSRI class] have different clinical profiles in "terms of effectiveness for a given patient, side effects, etc.").

there may be circumstances where a scenario like this presents a real risk, as a general matter, I'm inclined to trust doctors and patients to determine the relative worth of a new product.[107]

B. The Full Range of Patent Protection is Critical to Achieving the Benefits of Sequential Innovation.

As a general rule, as discussed above, most innovation in the pharmaceutical industry would not occur without the expectation of patent protection. *See* **Part I**. The full range of patent protection measures are needed to justify investment in sequential innovation in particular.

Multiple patent protection measures for innovative formulations or methods of use may be needed to justify investment in further innovation. In the case of new indications, method-of-use patents can protect the use itself.[108] However, the potential for substantial "off-label" use can make this form of protection illusory.[109] With regard to innovations involving a new version of the compound or a new formulation, the new version can often be separately patented. However, competitors may acquire patents that block the use of the innovation. Innovators can attempt to obtain additional patents on related discoveries in the field, to strengthen their intellectual property rights and protect against such potential threats. Examples would include patenting different molecular structures that could appear in trace amounts in the marketed product or through *in vivo* conversion. Such patenting can protect against the risks of being either forced off the market or subjected to an extortionate royalty by a competitor who patents some aspect of the existing drug.

Collectively, this available patent coverage can provide a sufficient degree of protection to warrant investment in new indications for existing products and in new dosage forms. Such coverage can allow the pioneer innovator the freedom to develop new indications, new formulations and other modifications such as for lower-cost manufacturing processes.

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[107] Sheila F. Anthony, supra, *Riddles and Lessons from the Prescription Drug Wars* (June 1, 2000).

[108] 1 Chisum on Patents § 1.03(8)(c).

[109] Physicians can prescribe drugs for indications not listed on the product label. *See* FDA Drug Bulletin, April 1982 ("Once a product has been approved for marketing, a physician may prescribe it for use or in treatment regimens or in patient populations that are not included in approved labeling"). As a result, a generic version of a product, not supported for a particular indication, may, for example, be able to compete with the pioneer version that is labeled for such a use. The generic manufacturer would not be allowed to promote such an "off-label" use of its product (because the FDCA requires that drugs be tested and approved for their stated uses by the FDA prior to being placed on the market – s*ee* 21 U.S.C. §§ 301, et seq. (2001)), but could still benefit from claims made on behalf of the pioneer product.

C. Applying Antitrust Principles for the Purpose of Limiting the Patenting of Internal Innovations Will Stifle Competition and Hinder Product Improvement.

Although the acquisition of patents from others can, in certain circumstances, violate the Clayton or Sherman Act, such rules have never applied, and should not apply, to obtaining patents resulting from the innovator company's own funded research.

Courts have uniformly held that the accumulation of patents resulting from a company's own internal research does not violate the antitrust laws.[110] The courts' refusal to attach antitrust liability to mere accumulation of patents through internal research represents sound antitrust policy. Innovation is the kind of competitive activity that the antitrust laws were intended to promote. As the Supreme Court has opined with respect to antitrust rules applicable to predatory pricing, antitrust rules applicable to innovation should be narrowly circumscribed, otherwise they will "chill the very conduct which the antitrust laws are designed to protect."[111]

In the words of one noted antitrust treatise, "[w]e would never hold internal patent development to be a §2 exclusionary practice because we do not wish to discourage innovation…."[112] This is particularly true since the incumbent firm is often in the best position to innovate and should not be discouraged by antitrust rules from doing so. Incumbent firms often have access to the most knowledgeable scientists in the field and the best understanding of the needs of the customer base. They have accumulated experience about promising avenues to

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[110] *Automatic Radio Mtg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 834 (1950) *overruled in part on other grounds by Lear, Inc. v. Adkins*, 395 U.S. 653, 671 (1969) ("The mere accumulation of patents, no matter how many, is not in and of itself illegal."). *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2d Cir. 1979), *cert. denied*, 444 U.S. 1093 (1980) ("Because… a monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success that it may achieve through 'the process of invention and innovation' is clearly tolerated by the antitrust laws."); *Dollac Corp. v. Margon Corp.*, 164 F. Supp. 41, 62 (D.N.J. 1958), *aff'd*, 275 F.2d 202 (3d Cir. 1960) ("The mere accumulation of these patents by the defendant, no matter how many, may not be condemned as illegal under the antitrust laws in the absence of some evidence that they were misused to unlawfully extend the patent monopoly. . . . The principle is particularly applicable where, as here, most of the unexpired patents cover inventions conceived and developed by the employees of the defendant under an established research program.").

[111] *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). *See also In re IBM Peripheral EDP Devices Antitrust Litigation*, 481 F. Supp. 965, 1003 (N.D. Cal. 1979), *aff'd on other grounds*, 698 F.2d 1377, 1382 (9th Cir. 1983) (internal citations omitted) (proclaiming in the context of a dispute over computer hardware design that "Truly new and innovative products are to be encouraged, and are an important part of the competitive process").

[112] III Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 704c, at 162 (2d ed. 2002); *see also* W. Holmes, Intellectual Property and Antitrust § 11.01, at 11-2 (1999) ("The firm that successfully creates valuable intellectual property does not thereby ipso facto violate the antitrust laws, even if its success has adverse effects on its competitors.").

explore and dead-ends to avoid. Because they have more at stake, they may have a greater incentive to stay ahead of their competitors.[113]

As explained above, research and innovation in the pharmaceutical industry are pursued in the context of an elaborate framework of patent protections and procedures. To introduce further, novel antitrust limitations on the research process itself, with all of its uncertainty, unpredictability and fragility, would threaten major harm with very little prospect of corresponding benefit. There is simply no workable antitrust rule that could distinguish "good patenting" from "bad patenting." Whether based on intent, utilization, or timing, any such rule would unduly hinder innovation and competition.

1. Intent

Any rule predicated on intent would sweep far too broadly and chill beneficial innovation. As a general rule, "[i]ntent does not help to separate competition from attempted monopolization and …. complicates litigation."[114] Relying on exclusionary intent to separate good from bad patenting is especially inappropriate since "exclusion of competitors is the very essence of the right conferred by a patent."[115] In sum, imposing antitrust liability for obtaining patents based on evidence of an intent to use the patent to exclude competitors, when the right to exclude is the essence of the patent grant, would sweep up most patenting activities by firms with any significant market position, and chill a great deal of beneficial innovation in the process.[116]

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[113] *See* III Antitrust Law ¶ 704c, at 162.

[114] *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989), *cert. denied*, 494 U.S. 1019 (1990) (addressing a pricing dispute); *see also In re IBM Peripheral EDP Devices*, supra, at 1003 ("[U]sually [with innovation] many results are intended, and if only one, even the predominating, intent is illegal, and thus punished, legitimate incentives will be imperiled. Discerning corporate intent is seldom easy, and, in any event, the law against monopolization is much more concerned with the effect of conduct rather than with its purpose.").

[115] *United Shoe Machinery Corp. v. O'Donnell Rubber Products Co.*, 84 F.2d 383, 386 (6th Cir. 1936). As Areeda and Hovenkamp point out: "[N]o commercial firm invents except with the hope of prevailing over its rivals. And no one can apply for a patent without knowingly intending to acquire the legal power to exclude – that is the entire point of the patent grant." III Antitrust Law ¶ 704c, at 162.

[116] "[T]he inventor's intent rarely or never provides a guide to determining liability." III Antitrust Law ¶ 704c, at 162. "[I]t seems probable that nearly all commercial research rests on a mixture of motivations across the spectrum ranging from (1) a desire to block off alternative products and processes from competitors to (2) the study of alternatives in the hope of finding new and superior products and processes, and even (3) to the hope of finding the route to profound innovations. Because the examination of alternatives will often light the way to superior inventions, finding and patenting alternative equivalent inventions does not imply that the research was antisocially motivated. We see little prospect for illumination in the search for the monopolist's research motivations and would not therefore ground §2 liability on findings of fact about the motivations with which research or patenting was undertaken." *Id.*

2. Utilization

Similarly, any rule predicated on utilization would likewise deter much beneficial innovation. As discussed in **Part IV** below, the antitrust law today is clear that the owner of a patent "has no obligation either to use it or to grant its use to others."[117] Expanding the current scope of antitrust law to base liability, in whole or in part, on non-use of a patent would also represent an unsound antitrust policy.[118] In reality, the usefulness of a patent is seldom known at the time the patent is sought. To impose liability later if the patent turns out not to be useful would severely chill patenting activity and the innovation that relies on patent protection.[119]

3. Timing

Any rule predicated on the timing of research would likewise deter potentially valuable innovation. Whether additional related patents are obtained before or after a product is commercialized should have no bearing on the legality of the conduct. Antitrust law currently draws no such distinction based on the timing of internally generated patents. By contrast, when the issue is the lawfulness of acquiring patents from others, as opposed to internal research, the law does draw a distinction based on timing between acquisitions made before a market for the patented product exists and those made after such a market exists.[120]

As shown earlier, many pharmaceutical products during their life cycle undergo improvements and acquire expanded therapeutic profiles that benefit consumers. Any antitrust limitation on post-commercialization patenting would discourage this innovative activity. A rule discouraging post-commercialization activity would also create an incentive for firms to delay commercialization of new products until a broader patent estate could be built, depriving

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[117] *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945). *See also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 867 (1995). This principle was codified in the patent law in 1988, which now declares that a patent owner is not guilty of misuse or illegal extension of the patent right if it "refuses to license or use any rights to the patent." 35 U.S.C. § 271(d)(4).

[118] III Antitrust Law, supra, ¶ 708, at 214-18 (rejecting antitrust liability based on non-use of internally developed patents).

[119] An antitrust rule directed at patents that are not utilized could also lead to socially wasteful product proliferation by driving companies to commercialize products they would not otherwise bring to market, to avoid antitrust exposure. The resulting increased costs to commercialize and maintain that expanded product portfolio would ultimately be borne by consumers. Further, patents that are not used often serve a pro-competitive function. As described above in Part III.A, B, surrounding utilized patents with a "patent estate" of unused patents on alternatives is often a prerequisite to commercialization or to post-commercialization improvements. This is a common practice in many industries. To introduce antitrust restrictions into this practice would have serious negative ramifications for the way research is conducted throughout the economy.

[120] *See SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982).

consumers of the benefits of the new product in the interim. Such a rule also ignores the disclosure benefits of patenting.[121]

An incumbent firm's efforts to develop new product variations or to protect its products from imitation also provide a spur to innovation by competitors. Antitrust restrictions on an incumbent firm's innovation efforts would lessen this incentive for competitors to innovate as well.

D. Good Faith Efforts to Patent Innovations Should Be Protected from Antitrust Liability.

For all the reasons presented here, good faith efforts to protect innovation through patenting should be protected from antitrust liability under the *Noerr-Pennington* doctrine as petitioning activity. The prosecution of a patent application is classic petitioning activity. The applicant is petitioning the PTO for the issuance of a patent and the decision whether or not to issue the patent lies exclusively with the PTO. Consequently, if the existence of the patent itself causes any anti-competitive effect, that effect flows directly from government action, and should, therefore, be immune under *Noerr-Pennington*.[122]

Under the *Noerr-Pennington* doctrine, petitioning activity, including legislative, administrative and judicial petitioning activity is generally immune from antitrust liability. This immunity generally applies where alleged anti-competitive effect of challenged conduct flows from government action sought by the petitioner, as opposed to solely from the petitioner's own, private act.[123]

The underlying grounds for the doctrine follow from: the limited scope of the Sherman Act; the First Amendment right to petition; the potential to chill the flow of information to government decision-makers if parties may be subject to antitrust liability for expressing their views; and the risk that the antitrust laws could be used as a vehicle to second-guess government decisions.[124] Exceptions to this immunity for fraud and sham, among other remedies, protect against abuses. *See* Part V. The doctrine applies with equal force to the FTC Act as to the Sherman Act.[125]

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[121] *See* 3 Chisum on Patents § 7.01.

[122] *See Procter & Gamble Co. v. Paragon Trade Brands, Inc*., 61 F. Supp. 2d 102, 109-110 (D. Del. 1996).

[123] *See, e.g.*, I Antitrust Law ¶ 201.

[124] *Id.*

[125] *See FTC v. Super. Ct. Trial Lawyers Assoc.*, 493 U.S. 411, 424-25 (1990) (holding the rationale presented by the defense--regarding the justification for a lawyers boycott to obtain higher compensation--insufficient to support *Noerr-Pennington* immunity under Section 5 of the FTC Act); *Ticor Title Ins. v. FTC*, 922 F.2d 1122 (3d Cir. 1991) and 998 F.2d 1129, 1138 (3d Cir. 1993) (on remand from the Supreme Court) (agreeing with the FTC that the activity at issue, collective ratemaking, was of a commercial rather than political nature, in finding that *Noerr-Pennington* immunity from liability under

IV. Innovation and Competition in the Pharmaceutical Industry Require the Right to Make Economically Efficient Decisions Regarding Intellectual Property Transactions and Disputes.

The FTC's hearing announcement raises, as an issue for consideration, the antitrust significance of unilateral "refusal to deal" and competition issues arising from settlement of patent disputes.[126] Chairman Muris has stated that the FTC believes tensions can arise between antitrust and IP doctrines when a patent or copyright holder unilaterally refuses to license its intellectual property.[127]

With regard to settlement of patent infringement claims, the FTC has expressed concern on numerous occasions and investigated several settlements because it considered them inappropriately anticompetitive. For example, the FTC investigated an agreement between a pioneer company and a generic company in which the parties allegedly reached a settlement whereby the generic manufacturer would not enter the market with any generic version of the product until patent litigation concluded, and would not relinquish the 180-day period of exclusivity granted under the Hatch-Waxman Act.[128] The FTC believes that agreements of this type may unreasonably delay the initiation of generic drug competition.[129]

Innovators must have the ability to make economically efficient decisions regarding the utilization and protection of their intellectual property. Specifically, innovators must have the right to license or unilaterally to refuse to license this property and to litigate and settle infringement cases to protect it.

A. Licensing and Unilateral Refusal to License Intellectual Property.

Firms have a right to exercise freely their independent discretion to decide with whom to deal, so long as their purpose in doing so is to pursue a legitimate business goal and not to create

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Section 5 of the FTC Act did not apply to this activity); *Ehlinger & Assoc. v. La. Architects Assoc.*, 989 F. Supp. 775, 786 (E.D. La. 1998) (relying on the Supreme Court's implicit assumption in *Super. Trial Ct. Trial Assoc.* of the availability of *Noerr-Pennington* immunity to liability under Section 5 of the FTC Act, in holding that *Noerr-Pennington* immunity also applied to Louisiana state consumer protection law).

[126] *See* FTC Hearing Notice.

[127] Timothy J. Muris, supra, *Competition and Intellectual Property Policy: The Way Ahead* (Nov. 15, 2001).

[128] *See In re Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, Nos. C-3945 and C-3946 (March 16, 2000), *available at* http://www.ftc.gov/os/2000/03/index.htm#16.

[129] *See* Timothy J. Muris, supra, *Competition and Intellectual Property Policy: The Way Ahead* (Nov. 15, 2001).

or maintain a monopoly.[130] Some courts have also required firms to deal with third parties with respect to "essential facilities."[131]

Licensing of patent rights, however, raises special considerations, since patents are sought and granted with the intent to create exclusive rights. It has long been recognized that patent holders posses "the untrammeled right" to license, exclusively or otherwise, or refuse to license at all.[132] The rights to license and to refuse to license are inherently intertwined. A right to license would have no strength if the patent holder could not choose instead to refuse to license, and the right to refuse to license would be too imprecise a tool for protecting patent rights if the patent holder could not also choose to pursue its economic goals through licensing. In response to FTC queries and concerns, this discussion focuses on the right to refuse to license. However, it is important to bear in mind at the outset that the right to license and refuse to license are really two aspects of one right to protect and realize the benefits conferred by patents.

Although courts and Congress have differed as to whether and how antitrust principles should apply, in accordance with the explicit statutory right granted by Congress, the Federal Circuit and other courts have recognized that the refusal to license intellectual property cannot form the basis for an antitrust violation. This rule reflects due deference to Congressional intent and promotes both innovation and competition.

1. Refusal to License Should Not be an Antitrust Violation.

Some courts, such as the First Circuit in *Data General Corp. v. Grumman Sys. Support Corp.*,[133] and the Ninth Circuit in *Image Technical Services, Inc. v. Eastman Kodak Co.*,[134] ("Kodak"), have attempted to fit refusals to license intellectual property into general monopolization law by creating a presumption that an intent to protect intellectual property is a legitimate business justification. Under those cases, however, such a presumption is rebuttable.

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[130] *See United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919) (holding that in the absence of any purpose to create or maintain a monopoly, a private business has the right freely to exercise its own independent discretion as to the parties with whom it will deal); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602-605 (1985) (holding that Aspen Skiing Co. had violated Section 2 of the Sherman Act, having failed to present any evidence of valid business reasons motivating the refusal to deal).

[131] The Seventh Circuit has identified four elements necessary to prove liability under the doctrine of essential facilities: "(1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility." *MCI Communications Corp. v. American Tel. & Tel. Co.*, 708 F.2d 1081, 1132-33 (7th Cir), *cert. denied*, 464 U.S. 891 (1983).

[132] *See E. Bemont and Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 88-89 (1902); *United States v. Westinghouse Electric*, 648 F. 2d 642, 647 (9th Cir. 1981).

[133] 36 F.3d 1147, 1187-89 (1st Cir. 1994).

[134] 125 F.3d 1995, 1218-20 (9th Cir. 1997).

Under the Ninth Circuit's ruling in *Kodak*, specifically, the presumption can be rebutted by evidence that the intellectual property rationale was pre-textual.

By far the larger number of courts, however, including the Federal Circuit in *In re Independent Service Organizations Antitrust Litigation*, have held that a refusal to

license intellectual property cannot form the basis for an antitrust violation, except in very narrowly defined circumstances (such as a tying arrangement or enforcement of a patent procured by fraud).[135]

Further, in 35 U.S.C. § 271(d)(4), Congress provided that "No patent owner otherwise entitled to relief for infringement or contributory infringement shall be denied relief or deemed guilty of misuse *or illegal extension of the patent right* by reason of his having … refused to license or use any rights to the patent" (emphasis added). At least one court, the Ninth Circuit, has argued that Section 271(d)(4) only applies in the context of a patent misuse defense and does not bar antitrust claims based on a refusal to license.[136] Such a narrow interpretation of §271(d)(4), however, is inconsistent with the language of the statute, which plainly prohibits not only the assertion of a misuse defense but any finding, based solely on a refusal to license, that the patent owner has illegally extended its patent right.[137] The rule established by the Federal Circuit, and other courts that have applied the same approach, reflects appropriate deference to Congress' action and intent.

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[135] 203 F.3d 1322, 1327-28 (Fed. Cir. 2000). In this case, Xerox unilaterally decided to stop supplying patented replacement parts and diagnostic software to a group of independent service organizations ("ISOs"). The ISOs challenged this conduct as an antitrust violation, alleging that Xerox's purpose was to undermine the ISOs' capacity to compete effectively in the service aftermarket. On appeal, the Federal Circuit upheld the district court's grant of summary judgment for Xerox, observing that in the absence of any indication of illegal tying, fraud on the PTO, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention, free from liability under the antitrust laws. *See also Cygnus Therapeutic System v. Alza Corp.*, 92 F.3d 1153, 1160 (Fed. Cir. 1996) (patentee "under no obligation to license"; affirming dismissal of antitrust claim); *Miller Insituform v. Insituform of North America*, 830 F.2d 606, 609 (6th Cir. 1987), *cert. denied*, 484 U.S. 1064 (1988) (mere refusal to license not a §2 violation); *W. L. Gore & Assocs. v. Carlisle Corp*., 529 F.2d 614, 623 (3d Cir. 1976) ("right to refuse to license is the essence of the patent holder's right…").

[136] *See* Kodak, 125 F.3d at 1214 n. 7.

[137] *In re Independent Services Organizations Antitrust Litigation*, 989 F. Supp. 1131, 1135 (D. Kan. 1997), *aff'd* 203 F.3d 1322 (Fed. Cir. 2000) (holding that the Ninth Circuit's limited interpretation of 271(d)(4) "is contrary to the statutory language and legislative history of the amendment"); *see also* III Antitrust Law ¶ 709b, at 220 ("To interpret the highly general and older language of the Sherman or Clayton Acts inconsistently with the highly specific and newer language of the Patent Act would frustrate Congress's intentions to protect the refusal to license.").

2. The Right to Exclude is Inherent to Patent Protection.

The right to exclude is an explicit statutory right given to the owner of intellectual property by Congress. There is simply no basis for conditioning the exercise of that right on a subjective inquiry into the patent holder's motivation for refusing to license. Moreover, an inquiry into whether a refusal to license was motivated by exclusionary intent makes no sense as the ability to exclude is precisely what intellectual property rights are intended to confer. In fact, the value of intellectual property derives solely from the rights to prevent copying or infringing. When these rights are lost, the value of the intellectual property itself is severely impaired if not fully lost.

In addition, imposing a duty to license could diminish alternatives available to consumers by reducing the incentives for rival firms to develop their own alternative products that can be commercialized without having to rely upon the availability of a license to use another party's existing intellectual property.[138] Further, imposing a duty to license requires an undesirable regulatory remedy. To remedy the violation, a court would have to establish and monitor the royalty and other terms of the license -- a task to which courts are ill-suited.[139]

B. Pursuit and Settlement of Intellectual Property Litigation.

The right to protect patent rights through litigation of infringement claims is clear, and good faith settlement of such claims must remain available as an efficient means to resolve disputes in whole or in part as expeditiously as possible. Unless the underlying infringement claim is objectively baseless or the settlement would produce a result outside the spectrum of possible litigation outcomes, settlements should not be subject to antitrust liability. Settlements promote both innovation and competition goals by providing certainty to the parties and minimizing risks and costs. These efficiency benefits have been acknowledged in federal antitrust guidelines, with respect to cross-licensing arrangements.[140] In addition, settlement serves the important public policy goal of reducing the use of limited judicial resources.

1. Promotion of Innovation and Competition by Reducing Uncertainty.

Litigation of patent disputes is costly and unpredictable. Even the most meritorious cases can fail at the hands of judges and juries. The large number of patent cases in which district court decisions on validity, unenforceability and infringement have been overturned by courts of appeals (over 50 during the period from 1997 through April, 2000[141]) attests to the fallibility of courts in this complex, technical area. By reducing the risk and cost of determining patent rights,

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[138] *See* III Antitrust Law ¶ 709b, at 220.

[139] *See Id.*

[140] *See* DOJ/FTC, Federal Antitrust Guidelines for the Licensing of Intellectual Property § 5.5 (1995).

[141] Stephen A. Stack, Jr., Comment on Proposed Consent Order, Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395 (April 17, 2000).

settlements increase the value of those rights in the hands of patent holders, enhancing the incentive to engage in research and development.

Settlements can also promote competition by generic drug companies. This effect can be two-fold. Without the ability to settle patent litigation, many generic companies would likely be unwilling to risk proposing to market a potentially infringing product because it could trigger patent litigation that would be a "duel to the death." The ability to settle cases eliminates this disincentive to challenge pioneer patents. Additionally, settlements will often provide the generic competitor with a license that will allow for competition within the patent term that would not occur if the generic competitor lost the infringement case.

Settlements promote other public policy goals as well by conserving judicial resources -- a goal that is well recognized in the law, especially in the case of patent litigation: "[T]he general policy of the law is to encourage settlements rather than litigation, as all the cases since *Standard Oil* have observed, and also the government's 1995 Guidelines."[142] "Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute."[143]

2. Good Faith Efforts to Settle Infringement Claims Should Be Protected from Antitrust Liability.

For all the reasons presented here, good faith efforts to settle patent infringement claims should be protected from antitrust liability. Settlement should not be subject to *per se* analysis. Rather, the current application of *Noerr-Pennington* immunity (under the Rule of Reason) to litigation and acts incidental to litigation is appropriate and should be maintained.

Applying *per se* horizontal agreement analysis to settlements of *bona fide* patent disputes is manifestly improper. Patent rights necessarily change the paradigm because one party presumptively has the lawful right to exclude the other from competition. In such a situation, the

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[142] XII Herbert Hovenkamp, Antitrust Law ¶ 2046 (1999).

[143] *ARO Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976). "Settlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements. When such cross-licensing involves horizontal competitors, however, the Agencies will consider whether the effect of the settlement is to diminish competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the cross-license. In the absence of offsetting efficiencies, such settlements may be challenged as unlawful restraints of trade." DOJ/FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 5.5 (1995). As discussed in Part IV.B.2 infra, a settlement between a patent owner and a challenger should generally be analyzed as a settlement between vertical entities, however, rather than between horizontal competitors.

excluded party may not be a true "potential competitor." The existence of the patent rights may, instead, create a vertical relationship.[144]

Courts and commentators agree: "Having found a bona fide dispute and what appeared to be a reasonable attempt to settle it, [the court in *Clorox*] applied the rule of reason and dismissed the complaint for lack of any showing of harm to competition. When analyzing a settlement the courts generally follow this approach."[145] "[T]he issues raised by pharmaceutical patent settlements are complex, fact intensive and not susceptible to hard-and-fast rules, at least at this stage."[146] Further, under such rule of reason analysis, settlements of *bona fide* litigation that fall within the scope of possible litigation outcomes should be subject to *Noerr-Pennington* immunity. If the litigation is objectively baseless or the settlement falls outside the scope of possible litigation outcomes, various remedies including antitrust remedies, would be available. *See* Part V.

3. The Application of the *Noerr-Pennington* Doctrine to Patent Infringement Settlements as Incident to Patent Litigation.

Antitrust doctrine has long recognized that *Noerr-Pennington* immunity protects not only acts of petitioning (and the results achieved from them), but also those activities and effects that are incidental or attendant to the petitioning process.[147] When the petitioning takes the form of litigation, activities such as transmitting a demand letter or threatening suit, activities that do not themselves involve any direct judicial participation, consistently have been deemed protected by *Noerr-Pennington* because they are incidental to the exercise of judicial petitioning.[148] Accordingly, the "decision to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."[149]

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[144] *See* DOJ/FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 3.3, at Ex. 5 (". . .FarmCo is not a likely potential competitor of AgCo in the relevant market because, even if FarmCo could develop an improved emission control technology, it is likely that it would infringe AgCo's patent. This means that the relationship between AgCo and FarmCo with regard to the supply and use of emissions control technology is vertical.").

[145] XII Hovenkamp, Antitrust Law ¶ 2046.

[146] FTC Commission Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes*, (Nov. 3, 2000) *available at* www.ftc.gov/speeches/leary/learypharma.htm.

[147] *See Allied Tube & Conduit Corp. v. Indian Head, Inc*., 486 U.S. 492, 499-500 (1988).

[148] *See, e.g., McGuire Oil Co. v. Mapco, Inc*., 958 F.2d 1552, 1560 (11th Cir. 1992); *Coastal States Marketing, Inc. v. Hunt*, 694 F.2d 1358, 1367 (5th Cir. 1983).

[149] *Columbia Pictures Indus., Inc. v. Professional Real Estate Investors, Inc*., 944 F.2d 1525, 1528 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993); *see also A.D. Bedell Wholesale Co., Inc. v. Philip Morris Inc.*, 263 F3d. 239, 253 (3d. Cir. 2001).

With respect to claims arising from activities incidental to protected petitioning, like settlements of litigation, it is necessary for the plaintiff to allege and prove fraud or "sham" for *Noerr-Pennington* immunity not to apply. The lawsuit underlying the settlement can be a sham only if it is a case in which no reasonable litigant realistically could expect success on the merits.[150] Likewise, a settlement (of non-sham litigation) itself could be a sham only if it does not reflect a genuine effort on the part of the parties to settle the underlying dispute or that portion which is immediately in dispute.[151]

4. Settlements Within the Spectrum of Possible Outcomes of *Bona Fide* Litigation Should be Immune from Antitrust Sanctions.

Competition authorities should not look beyond whether the dispute was *bona fide* to attempt to determine probabilities of litigation outcomes. Attempting to assign probabilities to litigation outcomes in order to measure whether the settlement is anticompetitive would unjustifiably deprive the courts and the parties of the certainty of settlements. It would also be inconsistent with the Supreme Court's ruling in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus. Inc.*,[152] which protects the right of parties to litigate suits that are not "objectively baseless."

Parties in an adversarial litigation position are best equipped to assess the merits of their litigation and to determine what they believe are acceptable and unacceptable risks and settlement outcomes. Post-hoc efforts by courts and enforcement agencies are not more likely to "get it right" than the parties themselves. Competition authorities have no special competence to determine probabilities with respect to patent-infringement litigation.[153] Indeed, no one can do this with any certainty, which is why parties settle.

If the dispute is *bona fide*, a settlement which provides for a result that is within the range of potential litigation outcomes should be presumptively lawful. "[S]ome settlement agreements . . . would be illegal per se if created in the absence of a genuine intellectual property dispute[,] . . . assuming a genuine dispute, the outcome of even a settlement agreement producing a per se antitrust violation might be no more anticompetitive than the outcome of litigation. . . . As a result, some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide dispute. In this category are agreements

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150 *See Professional Real Estate Investors v. Columbia Pictures*, 508 U.S. 49, 60 (1993).

151 *See generally City of Columbia v. Omni Outdoor Advertising, Inc*., 499 U.S. 365, 380-82 (1991) (discussing non-genuine petitioning).

152 *Professional Real Estate Investors*, 508 U.S. at 61.

153 *See* FTC Commissioner Thomas B. Leary, *Antitrust Issues in The Settlement of Pharmaceutical Patent Disputes, Part II* (May 2001) ("The FTC does not claim to have any particular expertise in the resolution of patent disputes….") *available at* www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm.

whose outcomes are no more anticompetitive than a likely outcome of intellectual property litigation permitted to run its course."[154]

A settlement within the range of possible outcomes can be substantially more pro-competitive than a fully litigated judgment.[155] As stated earlier, settlements may, and often do, permit generic entry (without the risks of infringement) earlier than if the litigated result favored the patent-holder.

Settlements between pioneer drug companies and generic ANDA filers that merely give the generic a license for delayed entry any time prior to the expiration of the patent, should be presumptively lawful.[156] Delayed entry is feasible and permits competition prior to patent expiration. It is, therefore, pro-competitive viewed against the possibility that the generic infringer might lose the case and be off the market until the patent expires.

As a practical matter, a delayed license is usually the only basis on which infringement suits against generics can be settled to allow generic entry before the patent expires. Immediate entry with a royalty is not feasible. Because of the high costs of pioneer drug development compared to the low cost of generic copying, the fair royalty value of a pioneer's patents is much higher than a generic is likely to be willing or able to pay. Since time of entry is, as a result, the only feasible focus for compromise, antitrust rules that challenge the delayed-entry feature of settlements could discourage such pioneer/generic settlements to the point of making them impossible.

A license that provided for delayed entry would be lawful under current judicial precedent. A license that allows the licensee to practice the patented art at a later date within the patent term is simply a license of less than all of the patent owner's rights. As such, it operates entirely within the scope of the patent and cannot constitute patent misuse or an antitrust violation.[157]

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[154] XII Hovenkamp, Antitrust Law ¶ 2046.

[155] The anti-competitive concerns raised by the 180-day exclusivity provisions of the Hatch-Waxman Act are not problems that should dictate intensive scrutiny of patent litigation settlements generally. These are problems that should cause, if anything, a rethinking of the 180-day exclusivity period and its triggers.

[156] *See* FTC Commissioner Thomas B. Leary, supra, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001) (Settlement agreement that provides that "the generic manufacturer will get a royalty-free license that permits entry at some future date before the expiration of the patent….without more, should be presumptively regarded as benign.").

Closer scrutiny could be appropriate for settlement arrangements that appear to fall outside the scope of possible litigation outcomes. For example, if the settlement provides for compensation to the generic in excess of the economic benefit it could reasonably have been expected to realize through marketing of the generic product at issue.

[157] *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction be found to be reasonably within the patent grant, i.e., that it relates to subject matter within the

V. It is Both Unnecessary and Unwise to Use Antitrust Law to Alter Either Patent Rights or the Intellectual Property Protections Embodied in the Hatch-Waxman Act.

In several policy statements, speeches, and amicus briefs, the FTC has suggested the need for – or argued for – changes in the intellectual property protections for pharmaceutical products.[158] These position statements have raised concerns with the quality and scope of patents issued by the PTO.[159] Similarly these positions have challenged implementation and reliance upon the provisions of the Hatch-Waxman Act that protect patents and other forms of intellectual property.[160] The current application of the Act has successfully achieved Congress' dual goals, however, of promoting both innovation and competition in the pharmaceutical industry. It is both unnecessary and unwise to use antitrust laws in novel ways to attempt to alter this existing approach.

Case-by-case enforcement cannot take into consideration all of the significant policy issues and evidence that must be considered when contemplating changing the balance between generic competition and incentives to innovate. Congress -- not the FTC or DOJ -- is best equipped to consider the impact that potential changes in legislation, policy, and/or enforcement may have on the costs of existing drugs and incentives to develop new drugs. As Congress did when it passed Hatch-Waxman, it can carefully study these issues and propose changes if necessary.[161]

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scope of the patent claims, that ends the [misuse] inquiry"); *see also B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419, 1426 (Fed. Cir. 1997).

[158] *See* Timothy J. Muris, supra, *Competition and Intellectual Property Policy: The Way Ahead* (Nov. 15, 2001); FTC Chairman Robert Pitofsky, Speech at the Antitrust, Technology and Intellectual Property Conference, *Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy* (March 2, 2001), *available at* www.ftc.gov/speeches/pitofsky/ipf301.htm; Timothy B. Leary, Speech at the ABA Section on Antitrust Law Program: Intellectual Property and Antitrust: Navigating the Minefield, Phila., PA, *The Patent-Antitrust Interface* (May 3, 2001), *available at* http://www.ftc.gov/speeches/leary/ipspeech.htm; FTC Citizen Petition; Brief of Amicus Curaie Federal Trade Commission, *In re Buspirone*, MDL No. 1410 (S.D.N.Y. Jan. 1, 2002) (*In re Buspirone* Amicus Brief).

[159] Robert Pitofsky, supra, *Antitrust and Intellectual Property* (March 2, 2001) (". . . it may be that the 'system' drives companies to seek, and the government to grant, more flimsy IP than is justified."); *see also* Timothy J. Muris, supra, *Competition and Intellectual Property Policy* (Nov. 15, 2001).

[160] FTC Citizen Petition (calling for the FDA to narrow the scope of patents listed in the Orange Book); *In re Buspirone* Amicus Brief, at 2, 13-20 (characterizing Orange Book listings as "remote and distinct" from patent infringement litigation, rather than incidental to it).

[161] Although not a focus of this paper, it bears noting that generic pharmaceutical companies have been the subject of enforcement actions for anticompetitive practices. For example, the FTC brought a monopolization case against Mylan Laboratories, which concluded with "a record $100 million settlement - almost full recovery of the alleged $120 million in ill-gotten gains. Mylan, the nation's

A. The Current System Strikes a Sound Balance, Providing Predictability and Protecting Against Abuse.

The current system functions well. It promotes innovation, while providing sufficient means to remedy abuse. Interference with this system is not needed and deprives pharmaceutical companies of the certainty and predictability they need to support R&D expenditures, which, as explained in **Part I**, now average in excess of $800 million per new drug. These costs cannot be incurred without sufficiently robust and predictable intellectual property protection. *Ad hoc* changes in the law prompted by enforcement actions substantially undermine this necessary certainty and predictability.

Statistical evidence shows that the current regulatory system is robust and fair. From 1984 through January 2001, 8,259 generic applications were filed with FDA.[162] Of these applications, 7,781 – 94 percent – raised no patent issues.[163] Only 478 generic applications – 5.8 percent – asserted a patent issue, either challenging a patent's validity or claiming non-infringement of a patent.[164] Further research shows that only 58 court decisions involving just 47 patents have been rendered resolving generic challenges to innovator patents – a tiny fraction of the number of generic applications.[165] We are aware of only 3 cases in which the FTC has challenged settlements of patent disputes between innovator and generic companies.[166]

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second-largest generic drug manufacturer, and others were charged with monopolization, attempted monopolization and conspiracy to eliminate much of Mylan's competition for generic versions of two drugs used by millions of patients to treat anxiety, lorazepam and clorazepate. . . . The conduct led to sudden and huge price increases of up to three thousand percent. The case was settled before trial with Mylan agreeing to disgorge $100 million into a fund to compensate injured consumers and state agencies. The $100 million judgment was the largest to date for the Commission in a Section13(b) antitrust action." Molly S. Boast, Report from the Bureau of Competition (March 29, 2001) (prepared remarks presented at the American Bar Association Antitrust Section Spring Meeting 2001, Washington, D.C.), *available at* http://www.ftc.gov/speeches/other/boastmollys.htm

[162] Cecelia M. Parise, R.Ph., Presentation to the National Ass'n of Pharmaceutical Manufacturers, Update: 180-Day Generic Drug Exclusivity for ANDAs and Patent Listing (March 20, 2001), *available at* http://www.fda.gov/cder/ogd/Exclusivity/.

[163] *Id.*

[164] *Id.*

[165] Based on a review of published cases conducted on June 5, 2001 by Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

[166] The Prepared Statement of the Federal Trade Commission "*Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*," before the Committee on the Judiciary, United States Senate, Washington, D.C. (May 24, 2001), *available at* http://www.ftc.gov/os/2001/05/pharmtstmy.htm.

B. Remedies for Abuses.

The generic industry asserts that the prospect of receiving the initial 30-month stay, combined with FDA's current policy permitting successive 30-month stays for challenges to additional, applicable patents, provides brand-name companies with an enormous incentive to: (1) apply for frivolous patents; (2) submit patents for listing in the Orange Book even if the patents do not satisfy the listing criteria contained in the Hatch-Waxman Act; and (3) bring baseless patent infringement suits. Generic manufacturers make these assertions with no acknowledgment of the many measures in place to protect against illegitimate patent prosecution, false Orange Book listings, and frivolous litigation, including antitrust remedies for fraud or "sham" in all of these contexts. Moreover, no pattern of abuse has been shown to exist. We are, in fact, aware of only a handful of instances in which the FTC has investigated such activities for antitrust violations.[167]

There are robust measures under antitrust law, patent law and other federal law to address abuses of the system. These remedies are workable and sufficient. They provide ample protection against abuses while minimizing uncertainty for pioneer and generic companies alike who attempt in good faith to comply with the obligations of the Hatch-Waxman Act and to exercise and protect their rights as Congress intended.

1. Remedies for Abusive Patent Prosecution.

To obtain a patent an applicant must satisfy the numerous requirements designed to grant patent protection only to that which is useful and innovative. Should an applicant attempt to mislead the PTO, severe penalties can be imposed.

a. Non-Patentability

For an invention to be patentable, it must be of patentable subject matter;[168] useful;[169] new;[170] and non-obvious.[171] In addition, before an inventor can obtain a patent for a patentable invention, he or she must be an original inventor;[172] avoid statutory time bars;[173] adequately

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[167] We understand that the FTC is currently conducting a study of Orange Book listings to determine if there is a pattern of abusive practice, but has not yet reported any results.

[168] 35 U.S.C. § 101.

[169] *Id.*

[170] *Id.* §§ 101, 102 (a), (e) and (g).

[171] 35 U.S.C. § 103.

[172] 35 U.S.C. § 102(f).

[173] 35 U.S.C. §§ 102 (b), (c) and (d).

disclose the invention;[174] and distinctly claim it.[175] Failure to satisfy any of these requirements may be asserted as a rebuttal to the presumed validity of the patent.

b. Inequitable Conduct

Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith and honesty.[176] This duty extends both to the applicant and its representatives.[177] Affirmative representation or failure to disclose material information to the PTO during the prosecution of the patent with intent to deceive the PTO constitutes inequitable conduct,[178] and renders the patent unenforceable by any party.[179] A breach of the duty of candor early in the prosecution may render unenforceable all claims that eventually issue from the same or a related application.[180] Similarly, unreasonable delay in the prosecution of a patent may render the patent unenforceable.[181] The PTO may bring a disciplinary action against patent agents who engage in misconduct.[182] Since only registered patent agents may prosecute patents,[183] this enforcement tool can provide an additional, significant disincentive for inequitable conduct.

c. Fraud

Among the statutes that provide for criminal prosecution of individuals or corporations who submit fraudulent filings or make misrepresentations to a government agency is 18 U.S.C. § 1001, which provides that anyone who knowingly and willfully "makes any materially false, fictitious, or fraudulent statement or representation" to a government agency can be subject to

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[174] 35 U.S.C. § 112, Para 1.

[175] 35 U.S.C. § 112, Para 2.

[176] *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co*., 324 U.S. 806, 818 (1945); *Molins PLC v. Textron, Inc*., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

[177] *Molins*, 48 F.3d at 1778; *see also FMC Corp. v. Manitowoc Co*., 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987).

[178] *Fox Indus., Inc. v. Structural Preservation Sys., Inc.,* 922 F.2d 801, 803 (Fed. Cir. 1990); *FMC*, 835 F.2d at 1415; *Molins*, 48 F.3d at 1178.

[179] *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001).

[180] *See Fox*, 922 F.2d, at 803-04; *see Baxter Int'l, Inc. v. McGaw, Inc.,* 149 F.3d 1321, 1331 (Fed. Cir. 1998).

[181] *See Symbol Technologies, Inc. v. Lamelson Med., Educ. & Research Found., Ltd.*, 277 F.3d 1361 (Fed. Cir. 2002) (holding that the equitable doctrine of laches could be applied to bar enforcement of a patent issued after unreasonable delay).

[182] 37 C.F.R. §§ 10.130 et seq.

[183] 37 C.F.R. § 10.10.

criminal fines and imprisonment of up to five years. In addition, 18 U.S.C. § 1505, which provides for criminal fines and imprisonment for obstruction of agency proceedings, may also apply as a remedy for fraud or misrepresentation in the patent prosecution process. Mail and wire fraud statutes could apply as well, to false filings transmitted by mail or fax and can result in criminal fines and imprisonment.[184] If any of these statutes is violated, the wrong-doer(s) may also face additional charges under 18 U.S.C. § 37 (conspiracy) and 18 U.S.C. § 2 (anyone who "aids, abets, counsels, commands, induces or procures … commission [of an offense against the United States] is punishable as a principal").

d. Antitrust Violations

Efforts to mislead the PTO, fraudulently obtain a patent and, thereby, illegitimately achieve anti-competitive benefits would also expose the applicant to antitrust enforcement. *Noerr-Pennington* immunity granted to protect good faith petitioning of a government agency, such as the PTO, would not apply.[185] In addition, as discussed more fully below, liability may apply under Section 2 of the Sherman Act both for enforcement of a patent procured by inequitable conduct in extreme cases (courts have typically required a showing of fraud[186])[187] and for infringement actions initiated and conducted in bad faith.[188]

2. Remedies for False Orange Book Filings and Misuse of Orange Book Listings.

Severe penalties can also apply for abuse of the Orange Book listing process, including under general federal law, the FDCA, and federal antitrust law.

a. Fraud

Applicants and registrants may only submit patents that meet the statutory requirements for Orange Book listing. If the patent-holder attempts to mislead the FDA, all of the criminal sanctions discussed above, which apply generally to false filings and misrepresentations to the government could apply. Further, as the Supreme Court recently made clear, there are a variety of other statutory provisions available "aimed at detecting, deterring, and punishing false statements" made to the FDA.[189]

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[184] *See* 18 U.S.C. § 1341 et seq.

[185] *See Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*., 382 U.S. 172, 174 (1965).

[186] *See* 6 Chisum on Patents § 19.03(6).

[187] *See Walker Process*, 382 U.S. at 174.

[188] *Handguards, Inc. v. Ethicon, Inc*., 601 F.2d 986, 996 (9th Cir. 1979).

[189] Specifically, the FDA has various authorities under the FDCA, including to investigate suspected fraud (*see* 21 U. S. C. § 372; 21 C.F.R. § 5.35), seek injunctive relief to remedy the fraud (*see* 21 U.S.C. § 332), and pursue criminal prosecution for such acts (*see* 21 U.S.C. § 333(a)). Further,

b. Antitrust Violations

Just as in the case of patent prosecution, efforts to mislead the FDA, fraudulently obtain an Orange Book listing and, thereby, illegitimately achieve anti-competitive benefits would also expose the applicant to antitrust enforcement. Immunity that would be available either for actions taken in good faith to comply with a government mandate or for good faith action incidental to litigation under *Noerr-Pennington*, would not apply.

Good faith Orange Book listing should be immune from antitrust liability as action taken to comply with a federal scheme established under the Hatch-Waxman Act. Where the obligation to submit listing information is clear or is judicially confirmed in an action challenging that submission, antitrust exemption has applied to good faith actions expressly commanded by statute or an agency of the federal government.[190] As Professors Areeda and Hovenkamp explain: "If a valid statute compels a certain kind of conduct, that conduct enjoys an 'express' statutory antitrust immunity, notwithstanding that the statute at issue says nothing about the antitrust laws."[191] The authors point out, for example:

> [I]f a federal statute should order firms in an industry to publish and make publicly available detailed information about costs, sales, output and so on, mere compliance with the statute cannot be treated as an unlawful exchange of price information ordinarily addressable under § 1 of the Sherman Act. Or if a federal statute requires all cars sold in the United States to be equipped with air bags or equivalent passive restraints, an auto maker's refusal to sell a car without such a restraint system could not be challenged as an unlawful tying arrangement under the antitrust laws."[192]

As a general matter, where a comprehensive regulatory scheme exists, a regulatory body is in place to implement the scheme, and Congress has empowered the regulatory body to authorize or

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citizens may report this or any other wrongdoing and petition the Agency to take action. *See* 21 C.F.R. § 10.30. In short, "The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency." *See Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001).

[190] *See Name.Space, Inc. v. Network Solutions, Inc.*, 202 F.3d 573, 583 (2d Cir. 2000) ('"Congress could not have intended to require [a private entity] to [act] subject to [federal governmental] directives and, at the same time, have intended that [it] proceed at its own antitrust peril in carrying out that official role…."' *quoting Alpha Lyracom Space Communications, Inc. v. Communications Satellite Corp.*, 946 F.2d 168, 174 (2d Cir. 1991)); *Williams v. Honeywell*, 772 F. Supp. 1224, 1231 (N.D. Fla. 1991) ("When a federal agency or official is authorized by law to, and does, direct or require a non-government party's anticompetitive conduct, the non-government party acting pursuant to that direction or requirement is immune from federal antitrust liability"); *Alabama Power Co. v. Alabama Electric Cooperative, Inc.*, 394 F.2d 672, 676-77 (5th Cir. 1968) (electric cooperative's compliance with loan requirements compelled by Rural Electricification Administration immune from antitrust attack).

[191] IA Antitrust Law ¶ 243b2, at 38.

[192] *Id.* at 39.

require the challenged conduct, the Supreme Court has granted antitrust immunity to both the government regulatory body, and the private parties acting under it.[193]

Similarly, because Orange Book listings are not merely incidental to, but essential for, timely and effective litigation of patent infringement claims, as discussed in **Part II.D** above, the *Noerr-Pennington* doctrine should be expected to provide a substantial measure of protection from antitrust liability. ***See* also IV.B.3.**

3. Remedies for Frivolous or Abusive Litigation and Sham Settlement.

In addition to the remedies discussed above to address directly abuse of patent prosecution and Orange Book listing, there are several mechanisms in place for addressing frivolous and/or abusive litigation and sham settlement. Viable remedies are available, for example, under patent law and the federal rules of civil procedure, as well as antitrust law.

a. Inequitable Conduct and Patent Misuse

As explained above, inequitable conduct renders a patent unenforceable, and it can be asserted as a defense to patent infringement. In addition, defendants in a patent infringement suit also have recourse to a patent misuse defense.

Broadly defined, misuse is any act by which the patentee "has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect."[194] Bad faith patent litigation has been identified by the courts as a category of behavior that constitutes patent misuse.[195] In cases where an accused infringer establishes patent misuse, courts will not enforce the patent and will not grant the patentee any remedy for infringement until the misuse is purged.

Although some courts have held otherwise, patent misuse has generally been easier to prove than an antitrust violation.[196] For example, proof of market power, a key element of an

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[193] *See e.g., Gordon v. New York Stock Exchange*, 422 U.S. 659, 95 S.Ct. 2598, 2612 (1975); *United States v. NASD, Inc.*, 422 U.S. 694, 95 S.Ct. 2427, 2450 (1975) (both cases finding implied antitrust immunity, where antitrust laws conflict with the operation of the Securities Exchange Act (*Gordon*) and Section 22(f) of the Investment Company Act (*NASD, Inc.*), respectively).

[194] See *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986), *cert. denied*, 477 U.S. 905 (1986).

[195] *See, e.g., Glaverbel Societe Anonyme v. Northlake Mktg & Supply, Inc.* 45 F.3d 1550, 1558-59 (Fed. Cir. 1995). Additional categories of behavior that have been identified by the courts as patent misuse include: tying of unpatented items to the purchase of patented products (where the patent-holder has market power); requiring licensees to covenant not to produce or sell competing goods; requiring licensees to acquire a package of licenses; requiring royalties based on total sales rather than on actual use of the patented product or process; price fixing; and discriminatory royalties. *See* 6 Chisum on Patents § 19.04[3].

[196] *See Transparent-Wrap Mach. Corp.* v. *Stokes & Smith Co.*, 329 U.S. 637, 645 (1947) (misuse may be made out even though challenged practice does not actually violate antitrust laws); *see also Zenith Radio* v. *Hazeltine Research*, 395 U.S. 100, 140-141, *on remand*, 418 F.2d 21 (7th Cir. 1969),

antitrust case, has not been necessary to prove patent misuse.[197] Moreover, any defendant can prove that it was actually affected by the misuse. In contrast, a party asserting an antitrust violation under section 4 of the Clayton Act, must prove that it has suffered antitrust injury even if there has been a *per se* antitrust violation.[198]

b. Sanctions against Parties and Their Attorneys for Frivolous Suits

Under Rule 11 of the Federal Rules of Civil Procedure, attorneys, law firms and parties who file lawsuits for "any improper purpose," including harassment or to cause unnecessary delay through litigation, are subject to a range of sanctions, including monetary sanctions. Further, a defendant may be able to recoup costs and attorneys' fees from a plaintiff (or attorneys) who are responsible for filing frivolous or abusive lawsuits.[199]

c. Antitrust Violations

As noted above, if a patentee asserts a patent that it is aware was acquired by fraud, that conduct can expose a patentee to liability under the antitrust laws.[200] The immunity afforded to a litigant under the *Noerr-Pennington* doctrine is lost in this situation. It is also lost if the litigation is a mere sham, i.e., objectively baseless and subjectively motivated by a desire to harm a rival through the use of the litigation process, as opposed to a legitimate effort to obtain judicial relief.[201] Similarly, reliance upon a sham infringement claim as a pretext to enter into an anti-

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cert. granted, 397 U.S. 979 (1970), *rev'd*, 401 U.S. 321 (1971), *reh'g. denied*, 401 U.S. 1015 (1971) (maintaining distinction between patent misuse and antitrust laws); *Va. Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 873 (Fed. Cir. 1998) (noting that "violation of the antitrust laws… requires more exacting proof than suffices to demonstrate patent misuse").

[197] *See Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 670 (Fed. Cir. 1986).

[198] *Compare with Atlantic Richfield Co. v. USA Petroleum Co.*, 110 S. Ct. 1884, 1893-95 (1990) (holding that even where there has been a *per se* violation of antitrust law, a party bringing suit under § 4 of the Clayton Act must show that it has suffered antitrust injury).

[199] *See* 28 U.S.C. § 1927 (allowing costs and attorneys fees from counsel); 35 U.S.C. § 285 (allowing attorneys' fees).

[200] *Walker Process*, 382 U.S. at 177.

[201] *Professional Real Estate Investors,* 508 U.S. 49.

competitive arrangement also would be susceptible to antitrust sanctions. While a settlement would ordinarily enjoy immunity as an action incidental to litigation,[202] such a sham-based agreement would not.

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Collectively, these available remedies should be more than sufficient to satisfy any concerns of the FTC. The Commission need not, and should not, apply novel antitrust theories to patent protections for pharmaceutical products, the complex intellectual property rights embodied in the Hatch-Waxman Act, or the defense, enforcement and full utilization of those rights. The uncertainty created by such an enforcement approach would harm the very innovation that spurs pharmaceutical industry competition to the benefit of consumers.

Conclusion

The current system of intellectual property protections has permitted research-based pharmaceutical companies to develop extraordinary innovations on the basis of enormous investments. These investments are possible only due to strong and certain intellectual property rights. Meanwhile, under this system, the proportion of generic products on the market has grown dramatically, and brand-to-brand competition is fierce. All this has enured to the great, cost-effective benefit of consumers, patients, and society as a whole.

For all the reasons discussed above, it is essential to maintain the current scope of rights for good faith patent prosecution, patent listing in the Orange Book, infringement litigation settlement, and licensing (or refusal to license) patent rights. The current application of patent law and the Hatch-Waxman Act is functioning efficiently and effectively, as intended by Congress, enabling competition while reducing confusion and promoting certainty regarding patent rights.

Antitrust measures should remain an extraordinary remedy available to redress bad faith, fraud and sham, not a general qualification of the legitimate rights granted under patent law and the Hatch-Waxman Act. Such novel and unnecessary application of antitrust liability could serve only to undermine a system that is functioning well. The current system provides the level of certainty regarding patent rights and the ability to exercise and protect them that is necessary to innovation. This innovation is the engine that drives the industry, making both better drugs and greater competition possible.

We urge the FTC to act with care, to avoid undermining this complex and carefully balanced system. Antitrust protections have an important role to play. The scope of this role must be carefully defined, to reduce the likelihood of abuses while promoting productive, legitimate rights and activities. A safe harbor for good faith efforts to exercise and protect patent rights is essential to promote efficiency and certainty, and to deliver on the promise of pharmaceutical innovation.

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[202] *See Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492 *(1988); Columbia Pictures Indus., Inc. v. Professional Real Estate Investors, Inc.*, 944 F.2d 1525, 1528 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993).