Testimony of

The Hon. Billy Tauzin

CEO
PhRMA
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Testimony of Mr. Billy Tauzin before the Senate Committee on the Judiciary
"Paying Off Generics to Prevent Competition with Brand Name Drugs"
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Chairman Leahy, Ranking Member Specter, and Members of the Committee:

Thank you for the invitation to participate in today's hearing on pharmaceutical companies' settlements of patent disputes. My name is Billy Tauzin and I am the President and Chief Executive Officer of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to developing medicines that allow patients to lead longer, healthier, and more productive lives. Our member companies invested more than $39 billion in 2005 discovering and developing new medicines. PhRMA companies are leading the way in the search for new and better treatments for patients.

As most of you know, I have a very personal reason to be deeply grateful to the thousands of men and women who work every day to bring these new medicines to patients. Because I too have been a patient. Just about three years ago, I was diagnosed with cancer, and I left Congress to battle that disease. Today, with support from family and friends and the help of some amazing doctors and nurses, I am now a cancer survivor. I also know that I would not be here now without the help of the innovative medicines made by America's research-based biopharmaceutical companies. Because of those medicines, I am cancer free and living a healthy, full life.

Ten years ago - even five years ago - that might not have been true. Some of the medicines that helped save my life would still have been in the development process then. It took the efforts of innovative pharmaceutical companies willing to risk money, time, resources and manpower to get these medicines all the way through the regulatory approval process and into the hands of physicians and patients. And because of these efforts, patients like me everywhere are better off.

In order to foster these much-needed medical breakthroughs, we must continue to pursue public policies that provide for strong patents - patents that allow pharmaceutical companies and their investors an opportunity to recoup and secure the benefits of their significant investments. This testimony will address the importance of patents to pharmaceutical innovation and the importance of preserving options to reach pro-consumer settlements of expensive and time consuming patent litigation among brand and generic pharmaceutical companies.

Courts and experts have stated unequivocally that settlement of litigation should be encouraged and that settlement of patent litigation can benefit consumers. Blanket prohibitions on certain types of settlements could force both sides to spend valuable resources litigating their patent dispute to judgment. Statistics show that innovators will win a significant number of those cases, and a win by the patent holder means the generic likely would not be able to enter the market before the patent expires. In addition, both innovators and generics would have to absorb - or pass on to consumers - the costs of increased litigation. In the face of these alternatives, it is better for companies, the courts and consumers if the parties are permitted to negotiate settlements that could bring the generic product to consumers before the patent expires and save considerable litigation costs.

A total ban on settlements in which the brand company gives something of value to the generic could stop pro-consumer settlements, reduce the value of patents, and reduce incentives for innovation. The sweeping prohibition could also have the unintended consequence of reducing generic companies' incentives to challenge patents in the first place, as they will have to consider that their options of settling patent litigation will be dramatically reduced.

Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis, looking at all relevant facts including the scope of the patent. In the Medicare Modernization Act, Congress gave the FTC and the Department of Justice the authority and ability to evaluate patent settlement agreements between brand and generic companies before the generic is due to come on the market. This approach will give the agencies and courts the chance to consider all the relevant facts and circumstances and address settlements that would harm consumers without eliminating those that will promote competition.

I. Patents Are Essential To Pharmaceutical Innovation

Intellectual property protection has deep roots in the United States, all the way back to the protection authorized by Article I of the U.S. Constitution. Patents are crucial because they make it possible for society to realize or secure the benefits of genius, creativity and effort. Since our patent system was created in 1790, it has been key to critical advances in science and technology - think of life without the plow, the steam engine, the jet engine, the laptop computer, the wireless phone or fiber optic cable, to name a few. Of all of the advances in the last century, from aviation to the Internet, few have been as important and valuable to the preservation and enhancement of life as pharmaceutical innovations. According to University of Chicago economists, "Over the last half century, improvements in health have been as valuable as all other sources of economic growth combined."1

Patents are given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.2 In the antitrust context, courts have held that the antitrust laws should be interpreted not to supplant the patent right.3 Indeed, courts recognize that antitrust and intellectual property are "two bodies of law [that] are actually complementary, as both are aimed at encouraging innovation, industry, and competition."ll Consistent Withthe antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited Iicenses.5 Generally, only when a restriction on use goes "outside the scope of the patent granf' are the antitrust laws implicated.6

Innovators across industries rely on patents to ensure that their inventions are protected and that they will be given an opportunity to recover their research investments. Strong intellectual property protection is essential for the preservation and growth of the research-based pharmaceutical industry. It takes on average 10-15 years and more than $800 million, according to the Tufts Center for the Study of Drug Development, to bring a new medicine to consumers.7 Let's take Gleevec?, for example, the breakthrough treatment for chronic myeloid leukemia that won PhRMA's Discover's Award in 2004: researchers spent two years isolating the molecule that would become Gleevec and devoted another eight years to safety testing and development before they were ready to try the drug in patients. Early clinical trials showed great promise; the innovator moved quickly to expand clinical trials to include more patients; and the drug was granted "fast-track" designation to receive accelerated FDA review. And even with all this promise and focus, Gleevec still took more than 11 years to get from the laboratory through FDA approval.

And of course, there are no guarantees. While investors may love the success stories like Gleevec, it is clear that market success for a particular medicine depends on many factors beyond the manufacturer's and investors' control, including for example, demand for a particular drug therapy and competition from other brand drugs. Consider these odds:

? Only one in 5,000 to 10,000 compounds eventually reach patients.
? Only two out of every ten compounds that enter clinical testing reach the market
? Only three out of every ten drugs that reach the market ever earn back enough money to match or exceed the average R&D cost of getting them to the marketplace.

Given these odds, it's easy to see why patents are a crucial factor in innovation. Patents provide the minimum degree of assurance for investors to risk the capital necessary to fund the pharmaceutical discovery process despite the uncertain chances of producing a commercially viable product. Simply put, scientific advances made in recent years would have been impossible without a system of intellectual property laws to provide the structure, stability and opportunity for recouping investment.

II. Congress Has Attempted To Strike a Balance Between Policies That Foster Innovation and Those That Promote the Availability of Generic Pharmaceuticals

Even as we discuss the critical role of patents in pharmaceutical innovation, it is important to recognize that pharmaceutical products effectively receive a shorter period of useful patent life than other types of products. To better understand this, first consider the basics about patents in other industries. The basic patent term in the U.S. is 20 years from the date the patent application is filed. Innovators in other industries -- who don't have to wait for regulatory approval before going to market -- can benefit from the patent as soon as it is granted. Recent statistics from the Patent and Trademark Office demonstrate that it takes about two and a half years, on average, from the date a patent application is filed until a patent is issued.8 Thus, patent holders that do not have to obtain FDA approval of their products may receive about 17.5 years of effective patent life, or time on the market before the patent expires.9

By comparison, pharmaceutical companies are required to obtain FDA approval before they can market their products. Let's say that it takes, as one peer reviewed study indicates, 14.2 years to

proceed through the phases of drug development from early discovery, to pre-clinical work, to clinical trials, to FDA review, and finally, to FDA approvar.10 Even if we assume that a pharmaceutical company is in a position to file for a patent within the first few years of that process and that a patent issues about two and half years later, the additional time consumed by the FDA approval process means that the time the medicine is actually on the market before the patent expires will be less than the effective patent life of other products.

Congress has taken some steps to address this dilemma. The Drug Price Competition and Patent Term Restoration Act of 1984 (better known as "the Hatch-Waxman Acf) 11 strove to balance the interests of innovative and generic companies and granted innovators products marketing exclusivity for limited periods and restored some of their effective patent time lost during the clinical research and FDA regulatory review of the product. Still, research demonstrates that the average period of effective life for new medicines, even with patent term restoration granted under the HatchNWaxmanAct, is between 11 and 12 years.12 And there are examples where the time of useful patent life is even less - for instance, Orudis?, a medicine used to treat pain, fever and inflammation, was approved by FDA with only 5 years remaining before its patent was set to expire. In short, pharmaceutical companies typically have less time than innovators in other industries under their patents to recoup their investments.

It is important to remember that, while a patentee holds an exclusive right to manufacture, distribute and sell the patented invention for a period of time, patents do not provide immunity from competition. Pharmaceutical manufacturers always are free to - and often do - research and bring to market different innovative medicines to treat the same disease, and increasingly, there is strong competition between different patented products within the same therapeutic class. A recent study by the Tufts Center for the Study of Drug Development showed that the amount of time between the entry of the first and second drug in a class has fallen by about 78 percent since 1970.13 In fact, the average length of time before a first-in-class drug got its first direct competitor dropped from 8.2 years in the 1970s to 1.8 years in 1995.14

And of course, there is increasing and earlier competition among brand companies and generic companies as well. The same Hatch-Waxman Act that restores some of the patent life for innovative medicines also provides mechanisms to speed the development and approval of generic copies of those medicines. The law created the Abbreviated New Drug Application (ANDA), under which a generic product needs only to be shown to be "bioequivalent" to an innovator drug and can be approved without any additional research once the innovator's patent and exclusivity periods have expired.15 In addition, the Hatch-Waxman Act created a unique exception to patent law by allowing generic manufacturers to use innovator medicines still under patent to obtain bioequivalency data for their FDA applications (a use that otherwise was considered patent infringement).16 This allows the generic company to forego the burden and expense of performing its own studies on safety or efficacy and puts it in a position to be ready to market its copies as soon as the innovator patents expire. The generic company may even seek approval for a generic version of a drug prior to the expiration date of the innovators' patents, provided it certifies that the patents are invalid or will not be infringed by the manufacture, use, or sale of the generic drug.17 This certification, known as a Paragraph IV certification, may be filed as early as four years after FDA approval of the brand product.

The Hatch-Waxman Act stimulated the development of a robust generic pharmaceutical industry in the U.S. Since the law's passage, the generic industry share of the prescription drug market has jumped from less than 20 percent to almost 60 percent today.18 Before the 1984 law, it took three to five years for a generic copy to enter the market after the expiration of an innovator's patent. Today, generic copies often come to market almost as soon as the patent on the innovator product expires.19 Prior to Hatch-Waxman, only 35 percent of top-selling innovator medicines had generic competition after their patents expired.20 Today, many more innovator medicines face such competition.21 In addition, there are increasing examples of generic competition before patent expiration. And in most cases, sales of innovator medicines drop by as much as 90 percent or more within weeks after a generic copy enters the market.22

III. Public Policy Favors Settlements of Expensive, Burdensome Patent Infringement Litigation

In this climate of growing brand-to-brand and generic-to-brand competition, research-based pharmaceutical companies obviously have strong incentives to defend their patents against potential infringers. Generic companies also have strong incentives to challenge the innovators' patents, particularly because the Hatch-Waxman statutory scheme permits them to mount such challenges without first bringing their product to market. Therefore, it should come as no surprise to the Committee that patent litigation among brand and generic pharmaceutical companies is both common and costly.23

Numerous courts have recognized that "public policy wisely encourages settlements.',24 Courts and experts likewise have stated unequivocally that settlement of patent litigation can benefit consumers. As the Eleventh Circuit has stated there is "no question that settlements provide a number of private and social benefits" when compared to the costs of Iitigation.25 The Sixth Circuit has said "[t]he importance of encouraging settlement of patent-infringement litigation ... cannot be overstated...26 And leading antitrust expert Herbert Hovenkamp explains that the general principle encouraging settlements is so strong that some agreements that would be unlawful outside of the litigation context may be lawful when used to settle a bona fide patent dispute.27

It is basically a truism that patent litigation is complex, lengthy and extremely expensive for all concerned. U.S. patent litigation overall has been estimated to cost about $1 billion annually.28 Another study found that the median expense for patent litigation with more than $25 million dollars at risk is $4.5 million.29 The costs of patent litigation in the pharmaceutical industry likewise are significant. In fact, at the administrative hearing in the Schering-Plough - FTC case, one expert witness estimated that for every dollar spent on pharmaceutical research and development, about 27 cents is spent on patent Iitigation.3O And it is not uncommon for a patent dispute to last several years.31 As these figures illustrate, settlements allow both litigants and the court system to conserve resources that can then be put to more efficient use.

Aside from these direct costs of patent litigation, the uncertainty surrounding an ongoing patent dispute can stall a company's business activities indefinitely. Particularly at early stages of a case, litigants face uncertainty over how the case will be resolved, because that resolution is dependent on a myriad of unknown factors, including a judge's interpretation of difficult legal questions, heretofore unknown facts uncovered during discovery, unpredictable juries, and even lawyer competence. This uncertainty can chill productive activities that are affected by a case even if

they are not directly implicated by it. For example, a pharmaceutical company with even a strong patent nevertheless might face an uncertain judgment in a case brought by a generic challenger, and therefore may delay or forego innovative activity because of the prospect of an adverse judgment affecting its bottom line.

Settlements create an environment of certainty, which allows parties to make business planning decisions with more efficiency and flexibility than can be achieved in the midst of an all-or-nothing legal dispute that may take years to resolve. It is therefore important that PhRMA members continue to have options to enter into procompetitive settlements, which allow them to get on with the business of developing new medicines for patients.

IV. A Rule That Bans The Transfer Of Anything of Value From a Brand to A Generic in Connection with Patent Settlements Would Make Settlements Less Likely and Less Efficient and Would Threaten Both Innovation and Generic Drug Development

A law that would ban patent settlements just because the brand company transfers something of value to the generic (as proposed in legislation introduced in the 109th Congress, S. 3582) would chill all patent settlements. In fact, as Judge Richard Posner has pointed out, this broad description could almost cover any settlement agreement because a generic challenger logically would only settle in exchange for something of value. And a law restricting parties' ability to settle their patent dispute would have significant adverse consequences for brand and generic companies and ultimately for patients. Fewer options for settlement would raise the cost of patent enforcement (and patent challenges) by forcing both sides to incur additional litigation costs. It could also reduce generic manufacturers' incentives to challenge patents in the first place by reducing their options in litigation against patent holders.

Settlements are not easily crafted or achieved. Often - as in the context of patent infringement litigation involving pharmaceuticals - the parties have a different risk-reward calculus, a different appetite for risk, and different litigation costs. Consider the incentives of the parties in a patent dispute within the Hatch-Waxman framework. The innovator and generic are likely to face significantly different risks and rewards from patent litigation. For example, the innovator stands to lose the market exclusivity through which it recoups the hundreds of millions of dollars invested in making new products available to patients. On the other hand, the generic may risk losing comparatively little. The generic's development costs are just a fraction of the innovator's costs because the generic takes advantage of much of the innovator's development efforts. Moreover, the generic is not exposed to any infringement damages as a result of the Hatch-Waxman statutory scheme.32

The innovator and generic can also face lopsided benefits from winning. If the innovator wins, it merely maintains the status quo. If the generic wins, however, it is rewarded by profits from the sale of a new product. The parties' differing risk exposure, however, should not suggest that the innovator always has more at stake, or that the innovator is always more willing to settle. For example, the innovator may be less willing to settle precisely because of the value of the marketing exclusivity conferred by its patent. The innovator may be willing to take the risk of losing in return for a chance of a court judgment securing its entitlement to market exclusivity for the full life of its patent. On the other hand, the generic may have significant incentives to settle because it may not be able to afford the staggering costs of patent infringement litigation.

The parties' risk exposure and perceptions affect their willingness to settle as well as the settlement terms each party is willing to accept. When the parties' risk exposure and perceptions differ, as they are likely to in the context of brand-generic litigation under the Hatch-Waxman framework, settlement may be very difficult to achieve.33

Patent litigation - and settlement of patent cases - also cannot be viewed in a vacuum. Companies generally, and drug companies involved in patent litigation specifically, are often interacting on multiple levels, involving separate deals and perhaps disputes. Many times, they also have assets that are not involved in the suit that are more valued by the other party. For example, one of the parties may possess technology that can be more effectively marketed by the other party. The ability to license this technology, and offer that as part of a settlement, can facilitate the parties' efforts to reach and structure a mutually acceptable - and procompetitive - settlement. This has in fact been demonstrated in the very cases that have come before the courts.34

The parties to a patent dispute are, in short, often repeat players that have interactions or potential interactions on a number of different levels. Foreclosing the ability of innovators and generics to exchange assets that mayor may not be involved in the litigation, as would be the case if there was a blanket prohibition on the exchange of anything of value, would put a straight jacket on the settlement negotiations. Not only would it make settlements less likely, but it also would make them less efficient. It would also harm consumers, since "Hatch-Waxman settlements ... which result in the patentee's purchase of a license for some of the alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production and encouraging further innovation."35

Finally, a broad ban on payments of anything of value would open any transaction between the innovator and generic up to scrutiny. It is not hard to imagine an argument that a wholly separate license deal or other business transaction was in fact part of a patent settlement and therefore should be deemed illegal. Opening up this pandora's box of litigation would be expensive and wasteful.

For these reasons and others, courts and competition experts have expressed significant concerns about a rule that broadly condemns all settlements where the innovator transfers something of value to the generic. As the Eleventh Circuit stated in the Schering-Plough case;

Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law.

The Eleventh Circuits concern that a ban on all payments from an innovator to a generic will have negative effects on settlements was echoed by the United States in its amicus curiae brief on the FTC's petition for certiorari in the Schering case. In its amicus brief, the United States stressed that lithe public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic

invalidation."3? It further recognized that the Hatch-Waxman Act creates a unique litigation dynamic that makes some settlements reasonable.

Given the importance of settlement and the obstacles to reaching settlement, any limit on the ability of parties to achieve settlement must be approached with great caution. Any limit on settlement options increases the risk that the parties may not be able to reach settlement or that the settlement will be less efficient - and ultimately worse for consumers - than prohibited alternatives.

Limits on the ability to settle brand-generic lawsuits also increase the uncertainty over the scope and duration of patent protection. Faced with this increased uncertainty, innovator pharmaceutical companies likely will be less willing to make the astronomical investments necessary for developing and testing novel pharmaceuticals. Innovators can only afford to make these investments because they have the opportunity to recoup them through market exclusivity guaranteed by patent protection. Innovators can therefore be expected to develop fewer new products under a regime that constrains settlement options.

This effect on innovators has been recognized by the courts and has been one of the key drivers in their refusal to accept a rule that would effectively prohibit all reverse payments. As one court put it, "the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product."38

The consequences of reduced innovation likely would in turn be felt throughout the health care system. Medicines represent just 10.5 cents of each dollar that is spent on healthcare, and only seven cents of that is attributable to brand name medicines.39 Yet evidence shows that new medicines reduce the cost of healthcare. One study found that for every dollar spent on newer medicines in place of older medicines, total healthcare spending is reduced by $6.17.40 Another found that every additional dollar spent on healthcare in the U.S. over the past 20 years has produced health gains worth $2.40 to $3.00.41

Overly broad limits on the ability to settle patent litigation may also have detrimental effects on generics. As Judge Posner recognized, limits on settlement structure, like a rule prohibiting reverse payments, "would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive...42 Moreover, limits on settlement will limit a generic's ability to gain access to technology or other assets in the pioneer's possession that may improve the generic's ability to bring to market other substitutes for brand-name products.

Similarly, sweeping limits on settlements will increase the possibility of a court ruling of infringement. An infringement ruling prevents a generic from making any sales to recoup its investment in developing its product. Generic manufacturers may, therefore, develop fewer generic drugs and may take longer to bring those drugs to market under a legislative regime which constrains settlement options.

Finally, fewer settlements mean that litigants will spend more time and money litigating. By spending more time and money on litigation, the litigants will have to make corresponding cuts in their other expenditures, including expenditures invested in new drug development.

V. A Case-By-Case Approach By Courts And Enforcement Agencies Will Allow Procompetitive Patent Settlements to Proceed and Still Deter Settlements That Harm Consumers On Balance

The question then is what is the best way forward in addressing the competitive nature of brand-generic settlements in patent litigation. PhRMA respectfully submits that a legislative solution may not be necessary, and, more importantly, a broad per se ban on all settlements involving payments by the innovator to the generic is not in the best interests of patients or competition. The antitrust agencies and courts are in the best position to evaluate the facts of particular cases and determine whether particular settlements are truly anticompetitive.

Questions relating to the antitrust validity of settlements that include payments from innovator to generic are currently working their way through the courts. The United States filed a brief before the Supreme Court in Schering-Plough expressing the correct view that this issue is important and there is room for debate, but that consideration by the Supreme Court was premature.43 As the brief explained, the courts' views on this issue are still emerging. As more cases work their way through the courts, a more defined body of antitrust law will emerge addressing this question and perhaps solving the debate. At the least, these opinions will further enhance understanding of this complex subject.

We urge the Committee and other policymakers to continue to make policy choices that will balance patent and antitrust considerations and provide for both innovation and a strong generic industry. While the role of generics is important to our health care system, the existence of generics is dependent upon innovative pharmaceuticals being developed. Policies that incentivize research and development and allow innovator companies time to recoup their significant investment, while encouraging generic entry at the appropriate time, are essential to the lifeblood of both industries.

Fundamentally, a policy that would provide for a per se ban on all settlements that contain some payment from a brand manufacturer to a generic company would put additional stress on the drug development system. It would decrease the value of patent protection generally and decrease incentives for taking the risks necessary to develop new products. One court noted, "a rule prohibiting settlements of Hatch-Waxman litigation can have grave consequences for R&D and, in turn, severe consequences for consumers ... .'144

Instead of a blanket rule banning certain types of patent settlements, enforcement agencies and courts should continue to evaluate these patent settlements on a case-by-case basis. Courts are in the best position to balance the deeply-instilled policy of settlements against a claim that a patent settlement unreasonably restrains trade and therefore harms consumers. Whether a particular patent settlement is appropriate turns on whether the settlement excludes competition beyond the scope of the patents protection. As Hewitt Pate, the former head of the Department of Justice's Antitrust Division, has recognized, "[if] a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder."45 This kind of analysis can only be done on a case-by-case basis.

And, of course, the enforcement agencies already have the authority and ability under current law to review and evaluate individual patent settlements. Under the Medicare Modernization Act, brand and generic companies settling patent litigation arising out of the generic company's Paragraph IV certification must file a copy of their settlement agreement or a written description of it with FTC and with the DOJ's Antitrust Division before the date when the generic product may enter the market. Thus, Congress has already given enforcement authorities the ability to review and evaluate patent settlement agreements between a brand and generic company on a case-by-case basis. Reports in the press and the FTC's own public reports indicate that the FTC maintains its interest in monitoring these agreements, and it retains the power to challenge any agreement that it deems anticompetitive. A total ban on an entire category of settlements is unnecessary - that kind of blanket rule is overbroad and would chill all settlements I even those that allow generic entry before patent expiration or contain other provisions that facilitate the availability of products to help patients live longer, healthier lives.

Thank you again for the chance to speak with you today. PhRMA and its member companies believe it is crucial for this Committee and other policymakers to find public policy solutions that will strike a balance between patent and antitrust considerations and will foster innovation while still allowing for a strong generic industry. We welcome your interest in this issue, and look forward to working with members of the Committee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.

1. Kenin Murphy. Ph.D., and Robert Topel, Ph.D., Measuring the Gains from Medical Research: An Economic Approach (Chicago: The University of Chicago Press, 2003).

2. 35 U.S.C. ? 282.

3. See Simpson v. Union Oil Co., 377 U.S. 13, 24 (1964) ("[T]he patent laws ?.. are in pari materia
with the antitrust laws and modify them pro tanto.'1.

4. Atari Games Corp. v. Nintendo, Inc., 897 F.2d 1572, 1576 {Fed. Cir. 1990}.

5. See, e.g., Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940).

6. Monsanto v. McFarland, 302 F.3d 1291, 1298 (Fed. Cir. 2002).

7. See, e.g., JA DiMasi, "New Drug Development in the United States from 1963 to 1999", Clinical Pharmacology & Therapeutics, 69 (2001): 5, 286-96.

8. See The United States Patent and Trademark Office, "Frequently Asked Questions About Patents," (accessed January 15, 2007) htlp://WWW.uspto.gov/web/offices/pac/doc/generallfaq.htm

9. See U.S. Patent And Trademark Office, Performance and AccountabilitY Report Fiscal Year 2006 - Management's Discussion and Analysis, http://www.uspto.gov/web/offices/com/annuaI120Q6I3020100patentpertrm.html

10. J.A. DiMasi, "New Drug Development in the United States from 1963 to 1999," Clinical Pharmaaology & Th9rapeutics, 69 (2001): 5,286-296.

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- The Waxman-Hatch Acts After One Decade," Pharmacoeconom;cs 10, suppl. 2 (1996): 110-123.

13. DiMasi JA, Paquette C. The Economics of Follow-On Drug Research and Development: Trends in Entry Rates and the Timing of Development, Pharamacoeconom;cs 2004, 22, suppl. 2, 1-13.

14. Op. Cit.

15. 21 U.S.C.3550).

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17. 21 U.S.C. ? 3550){2){A}(vii}(IV).

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19. Congressional Budget Office. How Increased Competition frOm Generic Drugs Has Affect9d Prices and Returns in the Pharmaceuticallndustry (Washington, D.C., July 1988) {"1998 CBO Report'1

20. 1998 cbo Report (citing Henry Grabowski and John Vernon, Longer Patents for Lower Imitation Barriers: The 1984 Drug Act, American Economic Review, vol. 76, no. 2 (May 1986), 195-198).

21. 1998 cbo Report.

22. Javed Sayed, "Indian firms' U.S. generic market scope looks bleak," The Economic Times: November 15, 2005.

23. The Paragraph Four Report, Frequently Asked Questions, accessed on January 15, 2007
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24. McDermott, Inc. v. AmClyde, 511 U.S. 202, 215 (1994).

25. Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056,1072 (11th Cir. 2005).

26. Schlegal Mfg. Co. v. V.S.M. Corp.? 525 F.2d 775, 783 (6th Cir. 1975)

27. Settlements Resolving Intellectual Property Disputes, 12 Herbert Hovenkamp, Antitrust Law ~
2046, at 265-66 (1999).

28. Steven C. Carlson, Patent Pools and the Antitrust Dilemma, 16 Yale J. Reg. 359. 380 (1999).

29. Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 2005, at 22 (2005).

30. Opening Brief of Schering-Plough Corp., 2004 WL 3557974, at 48 (11th Cir. June 1, 2004).

31. Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002, at Hi ('On average, the time between the filing of a patent infringement lawsuit and a court of appeals decision in the case was 37 months and 20 days.").

32. Schering-Pfough, 402 F.3d at 1074 (explaining that "the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or
risking enormous damages flowing from any possible infringement.. ..Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude").

33. Schering-Plough, 402 F.3d at 1073 C'Schering presented experts Who testified to the litigation
truism that settlements are not always possible. Indeed, Scharing's experts agreed that ancillary agreements may be the only avenue to setUement.").

34. See, e.g., Schering-Plough, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).

35. Schering-Plough, 402 F.3d at 1075.

36. Schering-Plough, 402 F.3d at 1076.

37. Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp.? No. 05~273 (filed
May 17, 2006).

38. Schering-Plough, 402 F.3d at 1075.

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43. Brief for the United States as Amicus Curiae, FTC v. Schering~Plough Corp., No. 05-273 (filed
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44. In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F. SUppa 2d at 256.

45. R. Hewitt Pate, Assistant Attorney General, Antitrust Division, Address to the American Intellectual Property Law Association, January 24.2003.