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Congressional Testimony: Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition

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Hearing on Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition

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* The title and affiliation are for identification purposes. The views expressed here are my own, and do not reflect the views of Boston College or any other organization.

Introduction

Patent law exists to solve market failure by incentivizing the invention and distribution of products and processes that could be copied by competitors at costs lower than that for the initial inventor. Patent law provides incentive and solves the market failure by giving exclusive rights in their inventions to inventors for limited times—currently twenty years from the date of a patent filing. There is debate among scholars as to whether patent law provides more benefit than harm. Some studies of the patent system purport to show that patents do not increase invention that much and therefore the monopoly effects of patents cause more harm than the benefit from the additional invention that patents incentivize. But even studies casting doubt on patent law's efficacy generally tend to find that in the area of pharmaceuticals,[1] patent law has a large, positive effect on social welfare by providing incentive for significant levels of drug development that otherwise simply would not occur. Patents are particularly useful for promoting a beneficial level of invention in pharmaceuticals not only because the cost of research and development is high, but also because complying with FDA requirements to get a new drug approval (NDA) is expensive and time consuming. If competitors could free ride not only on the R&D of the inventing firm, but also on the FDA approval for a new drug, they could bring drugs to market at much cheaper cost than that incurred by the original inventor. Thus, without some sort of exclusive rights, drug development would be severely deficient. Accordingly, there is strong, widespread agreement that patent law is beneficial to promoting drug development.

[1] In this written submission, I use the term "pharmaceutical" as shorthand for both traditional pharmaceuticals and biologics.

While some patent protection is beneficial, too much protection can be socially harmful. The optimal level of patent protection is enough protection to incentivize a substantially beneficial level of new drug development, but not so much as to allow monopoly pricing of new drugs once the initial investment (including adequate returns to investors for the risks and costs incurred) has been adequately recouped. Every year of patent protection beyond what is necessary to adequately incentivize drug production results in higher prices to insurers, employers, patients, and hospitals. The deadweight loss to society from monopoly prices on drugs beyond the time needed for adequate incentive is not only costly, but it means some patients simply will not have access to certain drugs, and will suffer the adverse health consequences that could have been treated. It is thus critically important to find the right amount of patent protection (in terms of breadth and duration) that encourages adequate drug development but does not provide inefficiently long monopolies.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.[2] Among other provisions, the Act provided term extension for drug patents in an attempt to restore some of the patent term that is lost in FDA approval processes. Hatch-Waxman patent term extension provisions provide a maximum extension of 5 years, and does not allow an extension to increase the patent term past 14 years of market exclusivity.[3] In addition to patent protection, U.S. law provides other exclusive rights to encourage drug companies to invest in beneficial activity, including new chemical exclusivity (5 years),

[2] Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§68b-68c, 70b; 21 U.S.C. §§301 note, 355, 360cc; 28 U.S.C. §2201; 35 U.S.C. §§156, 271, 282).
[3] 35 U.S.C. §156.

orphan drug exclusivity (7 years), new clinical investigation exclusivity (3 years), pediatric studies exclusivity (six months), and certain new antibiotics (5 years).[4]

Given the importance of market exclusivity to drug companies, it is rational for drug companies to take advantage of all patent and exclusivity protections available that may protect or increase their revenue. It is therefore very important to strike the right balance between market exclusivity protections for drug companies and competition.

I. CREATES ACT

One important way to provide competition is to ensure that generic drug companies have access to samples of the drugs for which they seek abbreviated new drug approvals (ANDAs). If name brand drug companies are able to prevent generic drug makers from getting samples of the drugs that generics need to prove bioequivalence or biosimilarity, then brand name drug makers can prevent generic drugs from coming to market.[5] The pending CREATES Act is an excellent way to cure refusals to share samples and to share REMS drug distribution systems, as I testified in 2017.[6] In addition to supporting the CREATES Act, my further investigation of this area leads me to the conclusion REMS programs should not be patentable subject matter. Simply put, REMS programs are relatively cheap to create, and are done as part of FDA compliance to market drugs that have certain risks. The need to comply with an FDA directive is enough incentive to come up with and

[4] 21 U.S.C. §355.

[5] In this statement, I use "generic" as shorthand for both small-molecule generic drugs and biologic biosimilars, except where otherwise noted.

[6] Written Submission of Professor David S. Olson, House Committee on the Judiciary Subcommittee on Regulatory Reform, Commercial, and Antitrust Law, Hearing on Antitrust Abuses and the FDA Approval Process, July 27, 2017, available at: https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-OlsonD-20170727.pdf

put in place REMS systems to market dangerous drugs. No further incentive is needed by patent law. Moreover, examples exist of drug companies using REMS and REMS with ETASU to prevent generic competitors from marketing their drugs.[7] Congress could amend the patent statute to exclude REMS from patentability. Alternatively, Congress could require that drug companies agree to license any REMS they invent via fair, reasonable, and nondiscriminatory (FRAND) licenses. This would not hinder innovation, and would help prevent abusive refusals to share REMS systems.

II. Pay for Delay Reform

Another possible avenue for reform is to the practice known as "pay for delay." The Hatch-Waxman Act sets up a process by which generic drug makers can seek approval of generic versions of drugs before the patents for the original drugs expire. Before the patent expires, an applicant can file an ANDA with a Paragraph IV certification with the FDA indicating that the applicant believes that the patent on the drug is not infringed or invalid. The patent holder may then bring a civil lawsuit of infringement against the generic company, to which the applicant can counterclaim that the patent is invalid. The Act encourages generics to secure ANDAs ahead of time so that they can be ready to enter the market as soon as drug patents expire. The Act also encourages generics to file Paragraph IV certifications challenging the validity of drug patents with the goal of bringing generics to market sooner if the patent on a drug is invalid. The Act provides incentive to be the first to challenge the validity of a drug patent by providing 180-day exclusivity to the first generic that successfully challenges a patent's validity.

[7] *See id*. at 12

"Pay for delay" occurs when a pharmaceutical patent owner enters a settlement agreement to pay a generic drug company money or other things of value in exchange for the generic drug company dropping its invalidity contentions and agreeing to delay entering the market. In *FTC v. Activis, Inc.*,[8] the Federal Trade Commission contended that agreements by which brand name drug companies paid generics to stay off the market were presumptively illegal. The Supreme Court disagreed, instead holding that the FTC may bring suit under the rule of reason. Under this rule, the government must prove, by a preponderance of the evidence, that the agreement is anticompetitive. The Supreme Court stated that large payments made to a generic to stay out of the market are good evidence of anticompetitive effects. In the six years since *Activis*, the lower courts have wrestled with when non-cash settlements may be anticompetitive.[9]

Reverse payments to keep generic competitors off the market are anticompetitive and thus are antitrust violations, as the Supreme Court held in *Activis*. While the FTC wanted a presumption that such payments are anticompetitive, the Supreme Court instead followed its standard approach to antitrust law, and applied the rule of reason. In antitrust law, the Supreme Court has held that per se and quick look approaches to antitrust law should only be applied in areas with which the Court has substantial experience and has found that the behavior at issue is almost always, or at least generally, anticompetitive. The Court was thus following its general approach to antitrust law when it applied the rule or reason to reverse payment cases.

[8] 133 S. Ct. 2223 (2013).

[9] *See, e.g., King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015); In Re: Loestrin Antitrust Litigation, 814 F.3d 538 (1st Cir. 2016).

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The Supreme Court, with substantial assistance from lower courts and the FTC and DOJ, generally does a good job of eventually getting to the right answer when it comes to determining whether certain behavior is anticompetitive. When the Court sees from experience that a certain type of behavior is almost always anticompetitive—for instance, exchanging detailed pricing information between competitors—the Court may then announce that it is subject to per se analysis, or at least "quick look" rule of reason. Per se illegal actions are held to be anticompetitive as soon as they are identified. Quick look analysis applies to behavior that is likely anticompetitive, but deserves a quick look.

It is possible that, in time, the Supreme Court will determine that pay for delay reverse payments are generally anticompetitive and therefore should be subject to a presumption of illegality, as the FTC wanted. In general, it is best to let the courts operate to evolve antitrust law efficiently. And, indeed, the circuit and district courts that have had to apply *Activis* over the last six years have been doing a fairly good job of determining anticompetitive conduct. Thus, I would generally caution against changing antitrust law by an act of legislation, given that if the legislation is overly broad or narrow, it may be harder to correct than a court decision that the Supreme Court can revise over time. In the case of pay for delay in pharmaceuticals, however, I think a case may be made that a presumption of anti-competitiveness is appropriate in the case of pay for delay. The last dozen years has allowed the courts to rule on a number of types of reverse payments, and there have not been greatly compelling, procompetitive reason to allow such payments, while the anticompetitive effects have generally been plain. Accordingly, in the case of reverse payments, I think that it is reasonable to pass legislation that presumes anticompetitive behavior whenever there is a reverse offer of something of value other than a date of generic entry to the market and

reasonable attorneys' fees. This may indeed deter some settlements, but the purpose of the Hatch-Waxman Act is to encourage generic drug makers to challenge and invalidate bad patents, not to threaten drug companies only until such time that the generic company gets a share of the monopoly profits. If, however, I am wrong and there are procompetitive benefits to some settlements that are being made in which something of value is given to generics in addition to market entry and attorneys' fees, or if changing the law deters beneficial patent challenges from generics, then there may be more harm than good from such a change.

Regardless, I do not think it would be wise to change the burden of proof in reverse payment antitrust cases from the preponderance of the evidence standard. Preponderance is the standard that has long been used in antitrust law, and it has been effective in letting both parties make arguments for pro- and anti-competitive effects of agreements at issue. Courts and the agencies do not have experience applying other standards in antitrust cases—such as "clear and convincing" evidence, and such other standard would likely confuse matters and serve to break with normal antitrust practice and procedures. I believe that simply shifting the burden to those entering reverse payment settlements and then letting the matter be decided by a preponderance of the evidence should be enough to efficiently deter anticompetitive pay for delay practices.

III. Patent Thickets

Another area of controversy in patent law is the subject of "patent thickets." A number of academic articles have been written about patent thickets. Some argue that patent thickets are a significant problem, while others argue that they are neither new nor problematic. The initial issue is to define what is a patent thicket. Many quote Carl Shapiro who defined a "patent thicket" as "a dense web

of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[10] But when one tries to discern a clear definition of a "patent thicket," one finds that there is no canonical definition, and that different authors use the term to mean different things in different contexts.[11]

Moreover, it is generally acknowledged that however one defines a patent thicket, they are much more prominent in other industries than pharmaceuticals. Estimates of the number of patents that cover a smartphone, for instance, range from the thousands to the tens of thousands to even the hundreds of thousands. With this number of patents that need to be licensed or avoided in order to market a smart phone one might expect a significant drag on innovation. But there is no conclusive evidence that smartphone or other high-tech innovation is being retarded by the large numbers of patents that may cover these devices. Instead, market mechanisms such as patent pools have grown up and seem to provide solutions to coordinating the large number of patent rights that apply in these areas. While occasional patent litigation wars do occur, such as the one that has raged between Apple and Samsung, they do not seem to stifle innovation.

The number of patents that cover any particular drug or biologic, in comparison, are quite low, ranging from the single digits to perhaps one hundred. This is not enough patents to constitute a substantial patent thicket that will deter innovation. The problem with overlapping patents on drugs

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[10] Shapiro, Carl, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting (March 2001). Available at SSRN: https://ssrn.com/abstract=273550 or http://dx.doi.org/10.2139/ssrn.273550

[11] *See, e.g.*, Edward J. Egan and David J. Teece, *Untangling the Patent Thicket Literature*, Working Paper #7, Tusher Center for Management of Intellectual Capital (2015), available at: https://pdfs.semanticscholar.org/0b85/ea551cf0666ba09f784c01e4b92d1036f621.pdf?_ga=2.266584334.1085196487.1556745187-125093049.1556745187 (conducting a literature survey and finding that authors use the term "patent thicket" to refer to "various combinations of seven different underlying economic issues.").

is not that they are numerous and diffusely held such that licensing them will involve large transaction costs. Rather, the problem is that drug makers seek to "evergreen" their drugs with new patents and exclusivities so as to maintain their monopoly position on valuable drugs.

IV. Evergreening

Another problem often discussed with regard to drugs and drug prices is the practice of "evergreening" a drug. "Evergreening" refers to the practice of obtaining additional patents or other exclusivities so as to extend the monopoly period for a drug. It is important to note that the problem of evergreening is not a problem of patent law not fitting the pharmaceutical industry, but is rather a problem of attempts to abuse patents and other forms of exclusivity.

It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong. In addition, assertions of plainly invalid patents can subject the patent holder to antitrust claims (with treble damages), as well as Rule 11 sanctions.

New patents can be filed on different formulations of a previous drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.

Problems arise when drug owners collect a number of new(er) patents on their drugs that are of questionable validity or that they assert overbroadly. To the extent that a new patent on a method of producing a biologic is a better and cheaper way to produce the drug, such that competitors will not be able to compete without it, granting a patent on that method is not harmful "evergreening" even if the patent expires ten years after the original patent on the biologic. Rather, such a patent is the type of innovation that the patent system exists to encourage.

If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, the new patent is either invalid or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing.

Thus, the issue with patent evergreening is not an issue of patent law that fails to fit the industry, rather it is an issue of the occasional temptation of deep-pocketed drug companies with billion-dollar drugs to abuse the patent system to try to maintain their exclusivity. The solution to this problem should be in preventing such abuse rather than in changing patent law.