Reverse Settlements as Patent Invalidity Signals

Gregory Dolin, *Northwestern University*
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ABSTRACT

Over the last decade a new type of settlements, commonly referred to as “reversed payment settlements” or simply “reverse settlements,” emerged in litigation over patents covering pharmaceutical products. What differentiates these new settlements from their traditional counterparts is that whereas traditionally, the alleged trespasser on someone else’s rights pays the rights-holder to settle the litigation, in these new settlements it is the rights holder that pays the alleged trespasser. These settlements are a direct consequence of the various incentives provided by the Hatch-Waxman Act – an Act designed to increase competition between brand name and generic manufactures of pharmaceutical products.

In this Article, I propose a new approach and argue the proper way to police these agreements is not by subjecting them to an antitrust analysis, but by ordering a reexamination of any patent involved in a reverse settlement. The question of whether any reverse settlement is pro- or anti-competitive, turns on the strength of the patent and the likely conclusion of the litigation. The antitrust analysis is simply not designed to address the patent scope and validity issues, and therefore cannot properly differentiate between pro- and anti-competitive settlements.

The patent law, on the other hand, is designed to evaluate the strength of the patent, and is therefore an obvious candidate to police reverse settlements. By employing the Patent Office’s existing (but broadened) reexamination authority, weak patents can be invalidated and removed from the marketplace, thus opening up the market for new
generic entrants. Additionally, if patentees know that their patents may be subject to reexamination, they will be less likely to enter into anti-competitive settlements. By expanding the scope of Patent Office’s reexamination authority, and by assigning the task of evaluating the ultimate validity of questionable patents to the agency with expertise in patent law, the ability of parties to enter into beneficial and legitimate settlements, as well as consumer access to lower cost drugs and medical devices will both be preserved.
**Reverse Settlements as Patent Invalidity Signals**

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I. **Introduction**

Over the last decade a new type of settlements emerged in litigation over patents covering pharmaceutical products. This phenomenon would pass largely unnoticed in most other litigation contexts, but in the very specific world of pharmaceutical patent litigation it has resulted in high-profile litigation involving the Federal Trade Commission, the Department of Justice, and numerous private plaintiffs. Congress has attempted (thus far unsuccessfully) to provide a legislative solution, and numerous law professors have debated the issue on the pages of various law journals. What differentiates these new settlements from their traditional counter-parts is that, whereas traditionally, the alleged trespasser on someone else’s rights pays the rights-holder to settle the litigation, in these new settlements it is the rights holder that pays the alleged trespasser. For these reasons these settlements have been termed “reversed payment settlements” or simply “reverse settlements.”

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* Frank H. Marks Visiting Associate Professor of Law, George Washington University School of Law. B.A., Johns Hopkins University; J.D., Georgetown University Law Center; M.D., State University of New York at Stony Brook.

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In this Article, I propose a new approach and argue the proper way to police these agreements is not by subjecting them to an antitrust analysis, but by ordering a reexamination of any patent involved in a reverse settlement. Although the reverse settlements have been attacked by some commentators, the FTC, and a number of legislators as anti-competitive, anti-consumer, and an abuse of the patent, in my view the question of whether the settlement is pro- or anti-competitive turns on the strength of the patent and the likely conclusion of the litigation. The antitrust analysis (especially under the per se approach advocated by the FTC) simply is not designed to address patent scope and validity issues, and therefore cannot properly differentiate between pro- and anti-competitive settlements. Instead, because the patent law is designed to address this very question, it should be relied on to police reverse settlements.

The rise of reverse settlement agreements is a direct consequence of the incentives created by the Hatch-Waxman Act. On one hand, the Act creates an incentive for generic manufacturers to challenge existing patents without much regard for their strength. As a reward for such challenges, Hatch-Waxman bestows a 180 day marketing exclusivity period on the first challenger. On the other hand, by permitting the challenger to retain the exclusivity period irrespective of the litigation’s outcome, the Act encourages the

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2 See infra Part IV.D.
3 See infra Part IV.B.
4 See infra Part IV.A.
5 See, e.g., FTC Staff, Fed. Trade Comms’n., Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (recommending that Congress ban such settlements) (hereinafter “FTC, Pay for Delay Report”): In re Schering-Plough Corp., 136 F.T.C. 956, 968 (2003) rev’d by 402 F.3d 1056 (11th Cir. 2005) (while declining to apply a per se label and purporting to utilize a “rule of reason” analysis, the FTC sought to prohibit all reverse settlements “except[ing] payments that are limited to litigation costs up to $2 million . . .”).
7 See infra n. 60 and accompanying text.
challenger to enter into a settlement agreement which would permit market entry prior to patent’s expiration. Such agreements would provide for payments from the patentee to the generic until the date of actual market entry, while allowing the generic to maintain the economic benefits of the exclusivity period when the market entry finally occurs.  

The patentee is also incentivized to settle on similar terms because a settlement assures monopoly rents for some defined time into the future. While that time may be shorter than the length of the patent, the settlement insures the patentee against the possibility of losing the suit, and thus losing its monopoly altogether and earlier than what the settlement agreement would provide.

In other words, the Act incentivizes the patentee and the challenger to enter a settlement "involv[ing] a negotiated market entry date for the generic product that ... typically occurs later than would have likely occurred if the generic company had prevailed in the patent dispute [but earlier than the patent expiration date] i.e., the parties split the remaining patent term." On the surface, these settlements may look like traditional horizontal agreements between competitors – agreements that have long been held *per se* illegal under the antitrust laws. The thrust of the antitrust argument is that these agreements are detrimental to consumers, for they allow the patentee to

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11 Holman, supra n. 8 at 494-95.

12 See In re Cardizem CD Antitrust Litig., 332 F.3d 896, 905-15 (6th Cir. 2003) (holding that reverse settlements are “a naked, horizontal restraint of trade and, as such, *per se* illegal . . . .”).
unjustifiably maintain monopoly pricing. Further, because the Hatch-Waxman Act precludes the entry of other generic companies until the 180 day exclusivity period has expired, settlements that delay the entry of the first generic also necessarily delay the entry of other generic manufacturers. Consequently, the antitrust argument goes, reverse settlement agreements are not just horizontal restraints on trade as between the settling parties, but in effect are a restraint on trade as between all market participants.

What is missing from the antitrust analysis is the recognition that settlements are detrimental to consumers only if the generic challenger would have prevailed in litigation. If the generic were to prevail then the settlement serves to prevent market entry for the generic manufacturers and therefore forces consumers to pay higher, monopoly rents for longer periods than they would have had the suit gone to judgment. On the other hand, if the patentee were to prevail, then the consumers benefit, because reverse settlements allow generic entry prior to the expiration of the patent. Thus, consumers obtain lower, non-monopolistic prices earlier than they otherwise would. Antitrust law makes no distinctions between these two situations, nor can it. To the extent that the antitrust approach does seek to take that issue into account (for instance by applying the rule of reason analysis to the settlement), it transforms the traditional economic arguments into patent litigation – the very litigation that the settlement between the patentee and the generic sought to avoid. Thus, even assuming that the rule of reason antitrust analysis could differentiate between the pro- and anti-competitive reverse

13 See Sandoval, supra n. 1 at 147 (stating that FTC believes “that such reverse payment settlements maintain high prices by averting generic competition with a patented drug, unduly allowing the patent holder to charge monopoly profits.”).
settlements, the utilization of this approach would undermine the *raison d'être* for these settlements.

What is more, the antitrust approach may wreak havoc in patent law, as presumably whatever findings a district court would make on the antitrust liability could (and would) be appealed. The appeals, like any other appeal on issues of antitrust law, would likely be heard by the regional circuit court of appeals,\(^{15}\) which would then be tasked with evaluating the validity and strength of the patents underlying the antitrust litigation. This could put the regional circuits on a collision course with the U.S. Court of Appeals for the Federal Circuit which is a specialist court with exclusive jurisdiction over patent disputes.\(^{16}\) Such an outcome would put complicated technical patent questions in the hands of non-specialist judges, and would run directly contrary to the congressional desire for uniformity of patent law throughout the country.\(^{17}\)

In short, the antitrust approach is not a promising solution to the very real problems raised by reverse settlements. Other options must then be used in order to differentiate between pro- and anti-competitive reverse settlements. Those options are found in the patent law itself.

In Part II of this Article, I will focus on the structure, purpose, and the mechanics of the Hatch-Waxman Act, understanding of which is necessary in order to appreciate

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\(^{15}\) See 28 U.S.C. § 1291 (2006). The Supreme Court in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988) held that when patent law is relevant only to the defenses raised, the case does not “arise under” the patent laws and therefore is to be appealed to the regional circuit. That is true “even if the defense is anticipated in the plaintiff’s complaint, and even if both parties admit that the defense is the only question truly at issue in the case.” *Id.* at 826 (internal citations and quotations omitted). Thus, if the complaint against a reverse settlement sounded in antitrust, it would be irrelevant that the only salient question to the outcome of litigation would the strength of the patent, and any appeals would have to be heard by the appropriate regional circuit court of appeals.


how the problem of reverse settlements arose. Part III will discuss several leading reverse settlement cases, each of which has been challenged under antitrust law. Although I will not go into great details about each case, the discussion will illustrate features that are common to such settlements, as well as the struggle that lawyers and judges face in attempting to shoehorn the problem of reverse settlements into an antitrust-based solution.

Thereafter, in Part IV, I will describe the response to the reverse settlement from the judicial, executive, and legislative branches. I will discuss academic commentary and offer my criticism of the proposals advanced thus far. In Part V, I will present my solution to the problem of reverse settlements, by arguing that reverse settlements should result in the Patent Office commencing reexamination proceedings. I will outline what conditions must be satisfied to order the patent into reexamination and what the scope of the reexamination should be. Part VI will be dedicated to identifying and addressing potential counter-arguments to my approach. The Article will conclude in Part VII.

II. The Hatch-Waxman Act

A. The Structure and Purposes of the Act

In 1984, Congress created a new procedure that streamlined the approval process for generic drugs. This procedure was officially titled “The Drug Price Competition and Patent Term Restoration Act of 1984,”18 but is commonly referred to as the Hatch-Waxman Act19 after its two principle sponsors in the Senate and the House of

Representatives. The Act had several purposes. First, the Act sought to bring lower-cost generic equivalents of patent drugs to market on an expedited basis and thus make these drugs more widely available to the general public. On the other hand, the Act sought to provide adequate incentives to the manufacturers and developers of pioneer drugs. Third, the Act, through encouraging litigation of the patents, sought to clear the landscape of invalid patents by providing a “bounty” to those generics that challenged the validity or enforceability of the patents covering the brand-name drugs.

Congress added two more provisions for FDA-administered market exclusivity in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the “Hatch-Waxman Act.”


130 CONG. REC. 24430 (1984) (statement of Rep. Waxman) (“The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor.”); see also Jaquette, supra n. 21 at 102 (“Congress enacted Title II of the Hatch-Waxman Act as a means of mitigating the distortion to the patent term created by the FDA regulatory process. . . . Congress reasoned that restoring some of the lost patent life would maintain profit incentives for pioneering drug manufacturers and thereby ensure continued innovation in the pharmaceutical and medical device industries.”).

Wendy Schacht & John Thomas, CRS Report for Congress, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (“The Hatch-Waxman Act”) (2005) at 27. available at http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/r13075601102005.pdf (“The 1984 Act provides prospective manufacturers of generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical. The reward consists of a 180-day generic drug exclusivity period awarded to the first generic applicant to file a paragraph IV certification. This provision is intended to encourage generic applicants to challenge a listed patent for an approved drug product.”); elizabeth h. Dickinson, FDA’s Role in Making Exclusivity Determinations, 54 FOOD DRUG L.J. 195, 199 (“The 180-day exclusivity provision is intended as an incentive for the first generic applicant to challenge a listed patent for the innovator drug product.”). The same “bounty” also extended to challenges to the infringement allegations. 21 U.S.C. § 355(j)(5)(B)(iv) (2006). However, because successful challenges to validity or enforceability permanently remove the patentee’s ability to litigate on that patent, see Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 333 (1971); In re Cygnus Telecomms. Tech., LLC, Patent Litig., 536 F.3d 1343 (Fed. Cir. 2008), these challenges are more important.
Prior to the passage of the Act, a manufacturer of a generic drug faced two hurdles in getting the drug on the market. First, under the Food, Drug, and Cosmetic Act, the generic manufacturer needed to conduct its own separate tests and studies to prove that its drug was safe and efficacious, even if the drug was an exact copy of the brand-name counterpart. The generic applicant could not rely on the data already compiled by the brand-name manufacturer. The Food and Drug Administration then had to conduct its usual evaluation of the application, much the same way it did when the pioneer drug was approved. Second, under the Patent Act, and case law interpreting same, the manufacturer of the generic was not permitted to use the pioneer drug as a template for designing his own generic equivalent. Such a use was considered to be actionable infringement. Thus, the manufacturer of the generic drug was essentially forced to wait (or risk costly litigation) until the patent on the generic drug expired prior to even beginning to formulate his own equivalent, and then wait some more while the FDA acted on his application to approve the generic.


25 Matthew Avery, Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments, 60 HASTINGS L.J. 171, 174-75 (2008)(“Generic manufacturers could not use the NDA holder's data to demonstrate safety and efficacy, and were forced to conduct their own clinical trials.”).

26 See Patcharin Pisut, Freedom to Research: Room for Trial and Error in Drug Development After Merck KGAA v Integra Lifesciences I, Ltd., 2005 U. ILL. J.L. TECH. & POL’Y 339, 342 (2005) (“As with newly patented drugs, a competitor's generic copy of a name-brand drug is subject to FDA regulatory review before it is approved for sale in the United States.”); M. Howard Morse, Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules, 10 GEO. MASON L. REV. 359, 383 (2002) (“Prior to the passage of the Hatch-Waxman Act, manufacturers of generic drugs were required to file a new NDA and duplicate the safety and efficacy studies already conducted by the original applicant.”).


with a *de facto* extension of the patent’s life, for he could remain exclusive provider of the drug for the period between the expiration of the patent and the submission and approval of the generic’s application.\(^{29}\) As a result, generic competition generally did not begin until three to five years after the expiration of the underlying patent.\(^{30}\)

The Hatch-Waxman Act solved this problem by amending the Food, Drug, and Cosmetic Act and the Patent Act. With respect to the former, Congress created a new process called the Abbreviated New Drug Application (“ANDA”) whereby a manufacturer of a generic drug can certify that the drug it seeks to market is bioequivalent to the drug that has already been approved by the FDA.\(^{31}\) This process obviates the need for the manufacturer of the generic drugs to run duplicative tests to show, for the second time, that its drug is “safe and efficacious.”\(^{32}\) With respect to the Patent Act, Hatch-Waxman essentially overruled Federal Circuit’s decision in *Roche v. Bolar*. In *Roche*, the court held that using the patented product to conduct bioequivalency experiments constituted infringement and could (consistent with general rules of equity) be enjoined.\(^{33}\) The Hatch-Waxman Act abolished that rule.\(^{34}\)

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\(^{29}\) Joyce Wing Yan Tam, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 541 (2010) (Pharmaceutical research firms “argued that forcing generic drug makers to wait until after patent expiration to commence the lengthy FDA approval process, in effect, created a de facto term extension that further inhibited the public’s access to affordable medicine.”).


\(^{32}\) See Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1325-26 (Fed. Cir. 2002) (“An ANDA offers an expedited approval process for generic drug manufacturers. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug.”).

\(^{33}\) 733 F.2d at 865.

Act, it is not “an act of infringement to make, use, or sell a patented invention … solely for uses reasonably related to the development and submission of information under federal law which regulates the manufacture, use, or sale of drugs.” Thus, any experimentation with a patented drug that is undertaken for the purposes of submitting ANDA is no longer considered infringement. These two sections in combination were meant to spur the process of bringing lower cost generic drugs to market.

To counter-balance the benefit conferred on the generics, and to continue to promote the development of pioneer drugs, as part of the Hatch-Waxman Act, Congress enacted rules that were meant to benefit brand-name manufacturers. Specifically, the Act provided for the extension of the life of the patent to account for the delays associated with the FDA approval process. Thus, the Act sought to eliminate the unwarranted *de facto* extension of the patent term stemming from the inability of the generic to come on the market, but cushioned that blow by allowing the patentees to collect profits on their labors for as long as they would have been able to absent the FDA approval process.

The Act also encouraged generic manufacturers to litigate the validity, enforceability and infringement of the patents covering the brand-name drugs. The Hatch-Waxman Act provides that any generic manufacturer that successfully challenges

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35 *Id.*
36 *Id.*
37 *See supra* n.22 and accompanying text.
38 Pub. L. 98-417 § 201 codified in 35 U.S.C. § 156. This provision is what gave the Act the second half of its title, as this portion of the Act “restored” the time lost to the FDA approval process.
any of those issues in litigation will enjoy a 180 day period of exclusivity. In other words, the FDA will not approve any other generic drug to compete with the brand-name or the first to file generic until 180 days elapses from the first generic’s market entry. For the generic companies that successfully challenge existing patents, this provision is very lucrative, often worth hundreds of millions of dollars.

B. The Mechanics of the Hatch-Waxman Act

In order to understand how reverse settlements came about, it is first necessary to understand the mechanics of litigation under the Hatch-Waxman Act. To that end, I will provide an overview of a typical generic vs. brand-name pharmaceutical patent litigation.

When any new brand-name drug is approved for marketing by the FDA, the manufacturer is required to submit to the FDA patent number and expiration date of every patent that covers the brand-name drug being submitted for approval. If the FDA approves the drug, each patent is then listed in Approved Drug Products with Therapeutic Equivalence Evaluations commonly known as the “Orange Book.” Whenever a generic manufacturer seeks approval for his drug via the ANDA process, it must certify that one of four conditions is met:

42 Id.; see also Christopher S. Ponder, The Dubious Value of Hatch-Waxman Exclusivity, 45 Hous. L. Rev. 555, 560-61 (2008) (“The Act shields the “first applicant” of an ANDA who makes a paragraph IV certification against competition from other ANDA applicants by delaying the FDA’s approval of competing applications until 180 days after the first applicant begins to commercially market the drug.”).
43 See Wansheng Jerry Liu, Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases, 18 Alb. L.J. Sci. & Tech. 441, 450 (2008) (“During the 180-day market exclusivity period, the first ANDA applicant enjoys a market duopoly along with the NDA holder; therefore, the market exclusivity is a “highly lucrative” reward for the generic drug company.”).
45 21 U.S.C. § 355(b)(1) (2006); see also Gongola, supra n. 30 at 794.
(I) no patent related to the pioneer drug has been filed;
(II) the relevant patent has expired;
(III) the patent will expire on certain date; or
(IV) the patent is invalid or will not be infringed by the
manufacture, use, or sale of the generic drug entity.\textsuperscript{47}

If the manufacturer makes the certification under Paragraphs (I)-(III), no issue of
patent law arises, as there is either no valid unexpired patent in existence, or there is a
patent, but the manufacturer of the generic is asking that the approval begin upon the
expiration of that patent. If, however, the manufacturer of the generic substitute provides
what is referred to as “Paragraph IV certification,” it sets in motion a series of events that
usually lead to the litigation of the underlying patent.\textsuperscript{48}

Once the Paragraph IV certification is filed, the ANDA applicant must notify the
holder of the patent rights of his application and certification under Paragraph IV.\textsuperscript{49} The
patentee then has forty-five days in which to respond.\textsuperscript{50} If the patentee chooses not to
respond to the notification, the FDA can proceed to the approval of the ANDA
application.\textsuperscript{51} In that situation, again, no issue of patent law arises because the patentee
chooses not to contest the generic manufacturer’s assertion that the relevant patents are
either invalid or not infringed or both. In the more likely scenario, however, the patentee
files suit within forty five days of the receipt of the generic’s notification.\textsuperscript{52} The Hatch-
Waxman Act makes the filing of ANDA a constructive act of infringement\textsuperscript{53} thus

\textsuperscript{48} John Fazzio, Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property
of a patent infringement action by the brand name manufacturer is virtually guaranteed.”).
\textsuperscript{50} Id. § 355(j)(5)(B)(iii).
\textsuperscript{51} Id. However, the filing of a suit by the patentee is “virtually guaranteed.” See Fazio, supra n. 48 at 10.
\textsuperscript{52} See Fazio, supra n. 48 at 10.
permitting the patent holder to sue for an injunction against the approval and marketing of the generic drug.\textsuperscript{54}

Should the patent holder choose to exercise his right to sue the ANDA filer, the Hatch-Waxman Act provides for an automated stay of the ANDA process.\textsuperscript{55} The stay remains in effect for 30 months or until the resolution of the lawsuit, whichever comes first.\textsuperscript{56} As a result of the 2003 amendments to the Hatch-Waxman framework,\textsuperscript{57} only a single thirty month stay is available.\textsuperscript{58} Once litigation is concluded in favor of the ANDA

\textsuperscript{54}See id. § 271(e)(4) (discussing remedies that are available). Recall that prior to Hatch-Waxman Act, a patentee could sue as soon as the generic began experimenting in order to produce its own product. See supra nn. 27-28 and accompanying text. With the passage of the Act, this avenue for litigation was closed. 35 U.S.C. § 271(e)(1) (2006). However, Congress chose not to require the patentee to wait until the generic actually entered the market. Instead, it permitted a patentee to file suit prior to the approval of the generic’s ANDA. The reason for this is rather straightforward. Multiple studies have shown that once the generic enters the market, the value of the patent drops considerably and can never be recovered to the pre-generic entry levels (even if the generic is ultimately withdrawn). See Saami Zain, \textit{Sword or Shield? An Overview and Competitive Analysis of the Marketing of “Authorized Generics”}, 62 \textit{FOOD \\& DRUG L.J.} 739, 746 (2007) (stating that “generic entry often causes branded companies to quickly lose between 50 and 80 percent of their pre-generic sales”); see also Narinder S. Banait, \textit{Authorized Generics: Antitrust Issues and the Hatch-Waxman Act}, (Fenwick \\& West LLP, 2005), available at http://www.fenwick.com/docstore/publications/IP/Authorized_Generics.pdf (stating that authorized generics allow “branded companies to maintain cash flow, albeit at a lowered rate, once generic competition starts”).


\textsuperscript{56}Id. The stay does not affect the FDA’s evaluation of the application. However, no approval can be granted until either the expiration of the patent, or the resolution of the litigation in favor of the generic manufacturer. Fazio, supra n. 48 at 10. The stay can be extended (or shortened) by a court as a penalty against a party that “failed to reasonably cooperate in expediting the action.” 21 U.S.C. § 355(j)(5)(B)(iii).

\textsuperscript{57}Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [hereinafter “MMA”], Pub. L. No. 108-173, §§ 1101-04, 117 Stat. 2066, amended the Hatch-Waxman Act to, \textit{inter alia}, limit 30 months stays, and to adjust the requirements for the exercise of the 180 day exclusivity period. 21 U.S.C. § 355(c)(3)(C) (2006). Previously, an NDA holder could amend its Orange Book entries to list new patents. Such an amendment would require new Paragraph IV certifications, which would in turn trigger a new 30 month stay. See FTC, \textit{Generic Drug Entry}, supra n. 64 at 43-44. The MMA eliminated this possibility by limiting the NDA holder to a single 30 month stay. See Natalie Pous, \textit{Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch Waxman Past, Present, and Future}, 19 Fed. Cir. B.J. 301, 309-10 (2009). On average, the thirty months period is enough time to complete litigation, as the average length of Hatch-Waxman patent case is 29 months. S. Peter Ludwig, Kristin Behrendt Kosinski, and Jonathan Harris, \textit{Hatch-Waxman in the Federal Courts: From 1994—2004}, 31 \textit{DRUG DEV. AND INDUS. PHARM}. 215, 221 (2005). This time does not include appellate review, which takes, on average, another year. Id. The expiration of the 30 months automatic stay does not necessarily enable the generic to launch the drug, as the NDA holder may seek a preliminary injunction against the ANDA filer. 35 U.S.C. § 271(e)(4)(B) (“[I]njective relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product.”). Furthermore, studies show that generic companies are reluctant to enter the market absent a final decision.
filer or once the ANDA application has been effectively approved as a result of the expiration of the thirty months stay (whichever is later), the ANDA filer has 75 days to begin to market its product or it must forfeit its 180 day exclusivity period.\textsuperscript{59} The exclusivity period is available to any first filer whether or not they ultimately prevailed on the merits of its Paragraph IV claim.\textsuperscript{60} It is this provision that permits ANDA filers to settle suits with patentees while simultaneously keeping the benefits of the exclusivity period. In this way, the costs of litigation (which average over $5 million)\textsuperscript{61} are avoided, while the benefits are enjoyed.

\section*{III. Reverse Settlements}

As with any litigation, settlement of patent suits is not unusual. Indeed, about 80\% of such suits are settled.\textsuperscript{62} The rate of settlement in the specific context of pharmaceutical patent litigation under the Hatch-Waxman Act\textsuperscript{63} is actually lower and

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\textsuperscript{59} Liu, \textit{supra} n. 43 at 453. “The first ANDA applicant also forfeits the 180-day exclusivity period if it: (1) ‘withdraws its application’; (2) ‘withdraws its paragraph IV certification’; (3) ‘does not receive [the] approval of its ANDA within thirty months after [the ANDA] was filed’; or (4) ‘enters into an agreement with another party, such as the patent holder,’ and the agreement is found by the FTC or a court to be in violation of the federal antitrust laws.” \textit{Id.} (quoting and citing the MMA).
\textsuperscript{60} See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998) (holding that success on the merits is not a required to obtain 180 days of exclusivity by the first Paragraph IV filer). The system in place between 1998 and 2003 allowed an ANDA filer to certify its application under Paragraph IV, and then withdraw such certification and change it to Paragraph III, all without losing its period of exclusivity. The MMA changed that and now requires forfeiture of exclusivity if the Paragraph IV certification is withdrawn. \textit{See supra} n. 59. This change in law, however, was not sufficient to preclude all reverse settlements. \textit{See infra} Part IV.A.
\textsuperscript{61} Higgins & Graham, \textit{supra} n. 44 at 370.
\textsuperscript{62} Matthew B. Zisk, \textit{Mediation and Settlement of Patent Disputes in the Shadow of the Public Interest}, 14 OHIO ST. J. ON DISP. RESOL. 481, 489 (1999). This is largely in line (though a bit lower) with the settlement rate of other civil suits which is about 85-90\%. \textit{Id.}
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stands at 38%.\textsuperscript{64} Most of these settlements do not present any unusual problems. However, about 45% of settlements (or 17% of cases) result in payments flowing not from the accused infringer to the patentee, but from patentee to the infringer.\textsuperscript{65} Such an arrangement would not be particularly unusual if the payments were accompanied by the patentee’s agreement not to assert the patent in the future. In that situation, the patentee would essentially be reimbursing the challenger for the cost of litigation and then permitting the challenger to enter the market. The reverse settlements are unusual in that the patentee pays the challenger while simultaneously holding on to its patent monopoly. Furthermore, unlike usual patent litigation where the dispute touches on the products that are already on or about to enter the marketplace, Hatch-Waxman litigation occurs prior to the generic drug actually entering the market. Consequently, in the Hatch-Waxman litigation there are no damages (other than cost of litigation for each party) to be had. Yet, under the reverse settlement the patentee often pays to the challengers amounts far exceeding the cost of litigation.

While each settlement has (unsurprisingly) different terms, the general parameters are quite similar across all settlements. In this section, I will outline several settlements that have been subject to judicial challenges. The goal of this section is not so much to describe every settlement in great detail, but to show the common features to reverse settlements.

\textbf{A. Cardizem}


\textsuperscript{65} Id. at 17 (stating that nine out of 20 settled cases (which equals to 45%) involved payments from the patentee to the generic). This number may be an underestimate as noted by the Second Circuit in \textit{Ark. Carpenters Health & Welfare Fund v. Bayer AG}, 604 F.3d 98, 109 (2d Cir. 2010) (“there is evidence that the practice of entering into reverse exclusionary payment settlements has increased. . . [Since 2005] twenty of twenty-seven Hatch-Waxman settlements [or 74%] have involved reverse payments.”).
One of the first reverse settlements (or at least one of the first that attracted significant public scrutiny) involved Cardizem CD – a brand name prescription calcium channel blocker used to treat several heart ailments such as hypertension, angina, and some arrhythmias.\textsuperscript{66} Hoechst Marion Roussel, Inc. held a patent directed towards the dissolution profile of Cardizem CD. Andrx Pharmaceuticals – a generic manufacturer – filed an ANDA seeking to manufacture a generic equivalent of Cardizem CD and certified, under Paragraph IV, that none of the patents covering Cardizem CD would be infringed by its product.\textsuperscript{67} About a year after Andrx filed its initial application, the FDA issued preliminary approval, and stated that final approval would issue once the thirty months stay expired or the court ruled in favor of Andrx.\textsuperscript{68}

Almost immediately after the FDA issued the preliminary approval, Hoechst and Andrx entered into a settlement agreement.\textsuperscript{69} The agreement provided that Hoechst (the patentee) would pay Andrx $40 million per year until Andrx received a final favorable court ruling.\textsuperscript{70} In exchange, Andrx agreed not to enter the market with its generic version of the drug until there was such a final unappealable ruling in its favor, even if the 30 month stay expired prior to such a ruling. In other words, Andrx agreed to stay off the market even after receiving a final approval from the FDA (which would issue upon the expiration of the 30-month period).\textsuperscript{71} Andrx also agreed not to waive its 180 day exclusivity period.\textsuperscript{72}

\textsuperscript{66} In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 902 (6th Cir. 2003). Hoechst also held a patent directed to the active ingredient in Cardizem (diltiazem hydrochloride); however, that patent expired in 1992. \textit{Id.}
\textsuperscript{67} \textit{Id.}
\textsuperscript{68} \textit{Id.}
\textsuperscript{69} \textit{Id.}
\textsuperscript{70} \textit{Id.}
\textsuperscript{71} \textit{Id.} at 902.
\textsuperscript{72} \textit{Id.}

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Several pharmaceutical companies challenged the settlement as a violation of antitrust laws and argued that, but for the agreement between Hoechst and Andrx, the generic version would have come on the market earlier, and that “protected [Hoechst] from competition from both Andrx and other potential generic competitors because Andrx’s delayed market entry postponed the start of its 180-day exclusivity period . . . .”\textsuperscript{73}

The U.S. Court of Appeals for the Sixth Circuit addressed the question of whether such an agreement was a \textit{per se} antitrust violation.\textsuperscript{74} It concluded that it was.\textsuperscript{75} In the court’s view, the agreement “was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States,”\textsuperscript{76} because it “guaranteed to [Hoechst] that its only potential competitor at that time, Andrx, would . . . refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval, protecting [Hoecht]’s exclusive access to the market” while simultaneously “delay[ing] the entry of other generic competitors, who could not enter until the expiration of Andrx’s 180-day period of marketing exclusivity . . . .”\textsuperscript{77} Because the court concluded that this was a classic horizontal agreement to restrain trade, it refused to consider any pro-competitive arguments advanced by Andrx and Hoechst.\textsuperscript{78}

The same Cardizem settlement described above was also subject to litigation in the U.S. Court of Appeals for the District of Columbia.\textsuperscript{79} On the same facts (but with a different plaintiff) the D.C. Circuit found that “a payment flowing from the innovator to

\textsuperscript{73} Id. at 904.  
\textsuperscript{74} Id. at 905.  
\textsuperscript{75} Id. at 908.  
\textsuperscript{76} Id. at 908.  
\textsuperscript{77} Id. at 907.  
\textsuperscript{78} Id. at 906 (stating that pro-competitive justifications are not considered where the \textit{per se} rule applies).  
\textsuperscript{79} Andrx Pharms., Inc. v. Biovail Corp. Int’l, 256 F.3d 799 (D.C. Cir. 2001).
the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement.” In the court’s view, although Andrx was entitled to bar other generic manufacturers from entering the market under the 180-day exclusivity provision, “Andrx’s manipulation of the exclusivity period trigger date extended” its legal rights beyond those authorized by the Hatch-Waxman Act, and therefore in violation of antitrust laws. Although the court never used the words “per se,” the logic of the opinion suggests that it views any reverse settlement agreement to be anticompetitive and an unlawful extension of the generic’s legal rights to the exclusivity period.

B. Hytrin

At about the same time that the Sixth Circuit was considering the Cardizem settlement, the Eleventh Circuit was considering another case involving a reverse settlement. Valley Drug Co. v. Geneva Pharmas., Inc., involved settlement agreements between Abbott Laboratories, which held a patent on Hytrin – a drug used to treat hypertension and prostate hyperplasia, and several generic companies.

Following the filing of ANDA with a Paragraph IV certification by two generic companies, Abbott filed suits, but eventually settled both cases. Both agreements required Abbott to pay the generic several million dollars in exchange for the generics...
forbearing from market entry until a certain date, or until some other generic successfully brought a generic equivalent of Hytrin to market, or until there were a final unappealable ruling holding the patents in question invalid.\textsuperscript{86} The settlement thus postponed the date of entry beyond the 30 months stay, but did not end the litigation between the generics and Abbott. Additionally, the generics agreed not to waive their 180 day exclusivity period.\textsuperscript{87}

Ultimately, Abbott lost the suit when the Federal Circuit affirmed the judgment of invalidity.\textsuperscript{88} This outcome would have resulted in termination of the agreements, but for the fact that they were in fact terminated earlier in response to the investigation by the Federal Trade Commission.\textsuperscript{89}

Following these events, a group of plaintiffs filed an antitrust action against Abbott, Geneva, and Zenith alleging that the agreements were a per se illegal restraint of trade in violation of § 1 of the Sherman Act.\textsuperscript{90} The Eleventh Circuit, in rejecting the per se approach stated, “If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court’s order. This is not such a case, however, because one of the parties owned a patent.”\textsuperscript{91} The court reasoned that because patents carry with them the right to exclude, any agreements that protect that right cannot be per se illegal, but must be analyzed under the rule of reason and in light of the patentee’s right to exclude others from making, using or selling the patented product.\textsuperscript{92}

\textsuperscript{86} \textit{Id.}  
\textsuperscript{87} 344 F. 3d at 1301.  
\textsuperscript{88} \textit{Id.}  
\textsuperscript{89} \textit{Id.}  
\textsuperscript{90} 344 F. 3d at 1301.  
\textsuperscript{91} \textit{Id.} at 1305.  
\textsuperscript{92} \textit{Id.} at 1309.
years of litigation the case ultimately settled. The court also observed that “[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”

C. Tamoxifen

In 2006, it was the Second Circuit’s turn to review an alleged antitrust violation following a settlement between Zeneca, Inc., a manufacturer of tamoxifen— a drug used in the treatment of breast cancer and Barr Laboratories, a generic manufacturer that sought to produce a generic version of this drug.

In response to Barr’s Paragraph IV filing, Zeneca sued, but lost in the district court on Barr’s claim that the patent was unenforceable. While the appeal was pending in the Federal Circuit, Zeneca and Barr entered into a settlement agreement. In return for payment and a non-exclusive license to manufacture tamoxifen, Barr agreed to withdraw its Paragraph IV certification and refile its ANDA with a Paragraph III certification, certifying to the FDA that it would not market its own version of tamoxifen until Zeneca’s patent expired. Additionally, the parties agreed that should another lawsuit challenging Zeneca’s tamoxifen patents be filed and result in an unappealable judgment that the patents are either invalid or not enforceable, Barr would be permitted to revert to the Paragraph IV certification. In other words, if a third party were to prevail in its challenge to Zeneca’s patents, Barr would be in the same position as it would have

93 Id. at 1310.
94 In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 193 (2d Cir. 2006). Zeneca marketed its version of tamoxifen under the brand name Nolvadex. Id.
95 Id. at 190.
96 Id. at 193.
97 Id.
98 Id.
99 Id.
100 Id. at 194. This would, of course, permit Barr to reclaim its first filer status and with it the 180 day exclusivity.
been had it prevailed in its own case.\textsuperscript{101} Pursuant to the settlement, the district court’s judgment of unenforceability was vacated.\textsuperscript{102}

Subsequently, three other companies filed ANDAs with a Paragraph IV to produce a generic version of tamoxifen.\textsuperscript{103} However, because of Barr’s first filer status, no other manufacturer was able to enter the tamoxifen market until Barr exhausted the exclusivity period.\textsuperscript{104}

While the various claims on Zeneca’s patent validity continued to be litigated, consumers filed an antitrust challenge to the Barr-Zeneca 1993 agreement.\textsuperscript{105} The plaintiffs alleged that the settlement agreement violated the antitrust laws because it enabled Zeneca’s continuing monopolization of the market for tamoxifen by resuscitating a patent that the district court had already held to be invalid and unenforceable, thus preventing competition from other generic manufacturers of tamoxifen.\textsuperscript{106} Unlike the plaintiffs in Valley Drug and Cardizem litigation, though, the plaintiffs here did not push the theory that the settlements were \textit{per se} illegal. Rather, they argued that the payments offered by Zeneca to Barr were “excessive,” and anticompetitive for that reason.\textsuperscript{107}

The Second Circuit disagreed. The court conceded that “even if ‘reverse payments are a natural by-product of the Hatch-Waxman process,’ it does not follow that

\begin{footnotes}
\footnotetext[101]{Recall that Zeneca and Barr settled while Zeneca’s appeal of unfavorable district court judgment was pending in the Federal Circuit. This case was settled before the Supreme Court decided \textit{U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership}, 513 U.S. 18 (1994) which held that appellate courts should not vacate judgments below in the face of a settlement. Consequently, Zeneca was able to convince the Federal Circuit to vacate the unfavorable district court judgment and avoid the preclusive effect of the unenforceability finding.}
\footnotetext[102]{Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co., 991 F.2d 811 (Fed. Cir. 1993).}
\footnotetext[103]{466 F.3d at 194-95.}
\footnotetext[104]{\textit{Id}.}
\footnotetext[105]{\textit{Id}.}
\footnotetext[106]{\textit{Id}. at 196-97.}
\footnotetext[107]{\textit{Id}. at 208.}
\end{footnotes}
they are necessarily lawful.”108 The court “doubt[ed] the wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.”109 Thus, according to the court, the patent remained valid and gave the authority to the patent holder to exclude others from the market. Consequently, unless a court were to find that “the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent’s protection’” the agreement must be found to be within the patentee’s rights and therefore not a violation of antitrust laws.110 In short, because Zeneca’s patent was not finally adjudged to have been invalid or unenforceable, in the Second Circuit’s view, Zeneca had a right to continue its monopoly.

Judge Pooler dissented. In her dissent she argued that the majority’s standard for judging the settlement agreements was wrong, and that an inquiry into “reasonableness” under the totality-of-circumstances was the proper inquiry.111 In Judge Pooler’s view, the majority’s “[a]bsent an extension of the monopoly beyond the patent’s scope . . . and absent fraud” standard was too deferential to the patentee (and the other settling party).112 While Judge Pooler was not prepared to declare such settlements to be illegal per se (then again, the plaintiffs did not advance that theory), she argued that the case ought to be remanded to the district court for further fact-finding in light of the standard she proposed.113

D. Ciprofloxacin I

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108 Id.
109 Id. at 210.
110 Id. at 212-13.
111 Id. at 228.
112 Id. at 223-24.
113 Id. at 232.
The Federal Circuit – a unique court that is vested with an almost exclusive jurisdiction over patent laws – also addressed the legality of reverse settlements in the context of Hatch-Waxman litigation. The case involved a settlement between Bayer – a German pharmaceutical manufacturer\textsuperscript{114} which held a patent on the active ingredient in ciprofloxacin, and Barr Laboratories.\textsuperscript{115} In response to Barr’s filing of ANDA with a certification that Bayer’s patent was both invalid for obviousness and unenforceable due to the patentee’s inequitable conduct before the Patent Office, Bayer launched suit.\textsuperscript{116}

The matter never came to trial as Bayer and Barr entered into a settlement agreement.\textsuperscript{117} Barr dropped its challenge and also agreed to convert its Paragraph IV certification to a Paragraph III certification in exchange for multi-million dollar payments from Bayer.\textsuperscript{118} The total amount of payments thus promised to Barr (including the $49.1 million initial payout) was $398.1 million.\textsuperscript{119} Following the settlement, Barr and Bayer entered into a consent judgment where Barr admitted infringement and the patent’s validity and enforceability.\textsuperscript{120}
In 2000 and 2001, several plaintiffs filed suit against Bayer alleging, *inter alia* that Bayer’s settlement violated antitrust laws under the *Walker Process*\textsuperscript{121} doctrine and that “Bayer unlawfully monopolized the ciprofloxacin market in violation of state antitrust laws by enforcing a patent obtained by fraud. Specifically, they alleged that Bayer violated state antitrust and/or consumer protection laws through fraud on the PTO and sham litigation in enforcing the [] patent against Barr.”\textsuperscript{122} The plaintiffs also alleged that the settlement “constituted an illegal market allocation in violation of the prohibition on contracts in restraint of trade contained in sections 1 and 2 of the Sherman Act and in violation of various state antitrust and consumer protection laws.”\textsuperscript{123} Because one of the claims involved a question of the patent validity, the appeal was taken to the Federal Circuit.\textsuperscript{124}

In rejecting the plaintiffs’ arguments, the Federal Circuit held that “[s]ettlement of patent claims by agreement between the parties--including exchange of consideration--rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.”\textsuperscript{125} The court noted that “a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed.”\textsuperscript{126} The court stated that “[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent,” and concluded that “in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the

\begin{footnotes}
\begin{itemize}
\item[121] See *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965) (holding that enforcement of a patent procured by fraud on the patent office may be a violation of the Sherman Act).
\item[122] 544 F.3d at 1329-30.
\item[123] *Id.* at 1329.
\item[124] *Id.* at 1330.
\item[125] *Id.* at 1333.
\item[126] *Id.* at 1333 n. 11.
\end{itemize}
\end{footnotes}
validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”

Importantly, the Federal Circuit rejected the argument that one “need to evaluate the strength of the patent in determining whether reverse payments are unlawful.” Accordingly, the court rejected the notion that in evaluating reverse settlements an “analysis of patent validity is appropriate in the absence of fraud or sham litigation.”

E. Ciprofloxacin II

Part of the Ciprofloxacin case remained with the Second Circuit and was not addressed by the Federal Circuit’s decision. The underlying facts were the same as those addressed by the Federal Circuit. The panel ruled that it was constrained by the prior panel’s ruling in Tamoxifen, and therefore declined to adopt a per se rule against the reverse settlements. The panel, however, went to great length to disparage the reasoning of Tamoxifen. At the end of its opinion, the panel stated that it “believe[s] there are compelling reasons to revisit Tamoxifen with the benefit of the full Court’s consideration of the difficult questions at issue and the important interests at stake. [The panel] therefore invite[s] the plaintiffs-appellants to petition for rehearing in banc.”

Despite the panel’s invitation, on September 7, 2010, the Second Circuit declined to

127 Id. at 1336.
128 Id. at 1334-35.
129 Id. at 1337.
130 See Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 103 n.10 (2d Cir. 2010) (noting that only Walker Process claims were transferred to the Federal Circuit, as the resolution of those claims depended on issue of patent law).
131 See supra Part III.C.
132 Id. at 106.
133 See id. at 108-10.
134 Id. at 110.
reconsider its jurisprudence. Nonetheless, at least 3 judges on that court are now on record expressing their views that reverse settlements are likely illegal as a matter of antitrust law.

F. Schering Plough

The one case where the government directly challenged the reverse settlement between a brand name manufacturer and a generic was Schering Plough v. FTC and was heard by the Eleventh Circuit in 2005. It is the reasoning of this case that was adopted by the Federal and the Second Circuits in the Ciprofloxacin and Tamoxifen cases respectively. Because of the government’s involvement, and subsequent loss, it is also the case that figures most prominently in the debates over the propriety of reverse settlements.

The dispute in Schering Plough concerned a formulation of potassium chloride. The pill was marketed under the brand name K Dur and was used as a supplement for treatment of high blood pressure and/or congestive heart failure. Two generics filed an ANDA certifying that Schering’s patent on the coating was invalid and unenforceable, and Schering sued for infringement. Prior to trial, the parties entered into settlement agreement. Schering agreed to multi-million dollar payments to generics in exchange for the generics splitting the patent term with Schering and licensing to Schering some of the

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135 Ark. Carpenters Health and Welfare Fund v. Bayer AG, --- F.3d ----, 2010 WL 3464382 (2nd Cir. Sep 07, 2010) (denying petition to rehear the case en banc). This decision, however, should not be necessarily taken as an indication that the rest of the Second Circuit agrees with the panel’s decision. Second Circuit is notorious for declining to sit en banc even in most extraordinary cases. See Ricci v. Destefano, 530 F.3d 88, 89-90 (2d Cir. 2008) (Katzmann, J., concurring in the denial of rehearing en banc).

136 See Cipro, 544 F.3d at 1335; see also Tamoxifen, 466 F.3d at 202.

137 Schering Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005). The active ingredient itself – potassium chloride – is a common salt and obviously unpatentable. Id. Schering, however, held a patent (with an expiration date in 2006) on the pill’s coating that allowed for extended release of the active ingredient. Id.

138 Id.

139 Id. at 1058 n.2.

140 See id. at 1058-60.
generics’ own intellectual property. As expected, the generics agreed not to waive or transfer the 180 day exclusivity period.\textsuperscript{141}

The FTC filed a complaint against all of the parties alleging that the agreements were “illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.\textsuperscript{142} The full Commission did not hold that the settlements were illegal \textit{per se}, rather, it concluded that Schering paid the challengers in order to delay the entry of the generic products onto the market,\textsuperscript{143} and that such delay injures competition and consumers.\textsuperscript{144}

\textit{[T]he Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one exception for payments to the generic: beyond a “simple compromise” to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties need not worry about a later antitrust attack.}\textsuperscript{145}

The Eleventh Circuit reversed the FTC’s finding, holding that “the Commission manufactured a rule that would make almost any settlement involving a payment illegal,” directly contrary to the court’s opinion in \textit{Valley Drug}.\textsuperscript{146} The court concluded that neither

\begin{quote}
The size of the payment, [n]or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetries of risk and large profits at stake, even a patentee
\end{quote}

\begin{footnotes}
\item[141] See \textit{In re} Schering-Plough Corp., 136 F.T.C. 956, *12 (“[T]he settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.”).
\item[142] Id. at 1061. The complaint also charged that Schering “monopolized and conspired to monopolize the potassium supplement market.” \textit{Id.}
\item[143] Id. at 1062. The Commission concluded that payments that Schering made in order to obtain licenses from Upsher and ESI did not represent legitimate consideration for those licenses. \textit{Id.}
\item[144] \textit{Id.}
\item[145] \textit{Id.}
\item[146] \textit{Id.} at 1075.
\end{footnotes}
confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.” An exception cannot lie, as the Commission might think, when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements). The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.147

G. Pro vig il

As the volume of criticism of naked cash payments from brand name manufacturers to the generic challengers has increased, the companies have become more creative in structuring the settlements. Two recent cases exemplify the new complexities with reverse settlements.

In early 2010, the District Court for the Eastern District of Pennsylvania considered a reverse settlement agreement between Cephalon – a holder of a patent on Prov igil – and four generic companies. Although the court’s opinion only addressed Cephalon’s motion to dismiss, it is instructive of the court’s views on reverse settlements.148

Cephalon’s patent covered not the active ingredient in Provigil, but instead was directed to the particle size of the active ingredient.149 Four generic manufacturers filed an ANDA for the generic version of Provigil, and all four certified that the patent is either invalid or will not be infringed.150 Ultimately, Cephalon entered into a settlement with

147 Id. at 1075-76.
149 Id. at *27.
150 Id. at *28. The Medicare Modernization Act allows for multiple “first filers” to share the 180 day exclusivity period. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2006) (defining as “first applicant” any applicant that submits a “substantially complete” application “on the first day on which [another] substantially complete application” was submitted.”); John M. Rebman, Dr. Strange Drug, or: How I Learned to Stop Worrying and Love Authorized Generics, 12 DEPAUL J. HEALTH CARE L. 159, 166-67 (2009).
each challenger. Each settlement involved a large payment from the patentee to the challenger.\textsuperscript{151} Each of the settlements involved an agreement that the generic would manufacture the active ingredient in Provigil and sell it back to Cephalon at a fixed price. The agreements also called for a number of cross-licenses between Cephalon and each generic.\textsuperscript{152} Each of the generics agreed not to market their own version of Provigil until a certain agreed-upon date.\textsuperscript{153} As usual, the generics also agreed not to relinquish the 180-day exclusivity period.\textsuperscript{154}

The District Court, in denying Cephalon’s motion to dismiss various antitrust claims by the FTC and other plaintiffs concluded that the settlement may have enlarged the scope of the patent, and therefore additional proceedings were in order.\textsuperscript{155} It then appears, that in further adjudications, the District Court will be tasked with evaluating the patent’s validity, enforceability, and scope for the purposes of infringement – the very determinations that the settlements sought to avoid. The appeal will then likely lie with the U.S. Court of Appeals for the Third Circuit,\textsuperscript{156} rather than the Federal Circuit. Thus, plaintiffs such as the FTC, who have little understanding of and interest in the intricacies of patent law,\textsuperscript{157} will be litigating the case, and judges who have little experience in adjudicating patent disputes will be deciding it. I submit that this is far from an ideal outcome.

\textsuperscript{151} King Drug, 2010 U.S. Dist. LEXIS 29905, *28-34.
\textsuperscript{152} Id.
\textsuperscript{153} Id. at 28.
\textsuperscript{154} Id. at 54.
\textsuperscript{155} Id. at 63-72.
\textsuperscript{156} Cf. id. at 64-66 (noting that similar appeals in Valley Drug went from the District Court to the Eleventh Circuit).
\textsuperscript{157} I do not suggest that the attorneys at the FTC (or the commissioners) are somehow not capable enough to understand patent law. However, patent law is not FTC’s primary concern – antitrust law is. For this reason, I do not expect the FTC to be particularly alarmed if in pursuing better antitrust outcomes, they create worse patent law outcomes.
The basic parameters of reverse settlement then are these. In exchange for a payment of significant sums of money from the patentee to the challenger, the challenger agrees to forbear entering the market. The challenger generally agrees to preserve and not transfer its 180 exclusivity period and the patentee agrees to split the life of the patent with the challenger. Agreements may be complicated and payments obscured by the challenger licensing some of its own intellectual property to the patentee. In these cases, it makes it drastically harder to figure out whether the payments are being made simply to induce the generic to delay market entry, or whether they constitute consideration for the licenses. This difficulty, in turn, significantly clouds the antitrust analysis.

IV. The Legislative, Executive, Judicial and Academic Response

With the number of settlements between generic and brand-name manufacturers increasing,\textsuperscript{158} it is no surprise that the issue has not escaped the attention of politicians, judges, and academics. In this section, I will review these groups’ reaction to the reverse settlements.

A. The Legislative Reaction

The legislative branch has been particularly unhappy with reverse settlements and the judicial tolerance thereof. While no explicit ban on reverse settlements has been enacted, a number of such bills have been proposed.

The first efforts to address reverse settlements began in 2002 when the U.S. Senate unanimously passed the Drug Competition Act of 2002\textsuperscript{159} which required all settlements between the generics and branded drugs that involved agreements over “the

\textsuperscript{158} See supra n. 65.

\textsuperscript{159} S.754 (107\textsuperscript{th} Cong., 2d Session, 2002).
manufacture, marketing or sale of the brand name drug . . . [or] of the generic drug” or “the 180-day [exclusivity] period” to be disclosed to both FTC and the Department of Justice. Ultimately, a version of this bill was incorporated into the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Act, however, conferred no new enforcement authority on either the FTC or the Department of Justice. Indeed, the only purpose of the bill seems to have been “to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws” which was to be accomplished “by providing timely notice.” Given the consistent judicial rejection of FTC’s attempts to rein in the reverse settlements under the present antitrust law, it is rather hard to see how this Act would achieve its stated goal of “enhanc[ing] the effectiveness and efficiency of the enforcement of the antitrust and competition laws” beyond what was the pre-2003 status quo.

Other proposed remedies would go much further. In the 109th, 110th, and 111th Congresses, Senator Herb Kohl (together with between 4 and 9 co-sponsors from both parties) has introduced the Preserve Access to Affordable Generics Act. The Act would make it unlawful for the brand-name manufacturer and the generic ANDA filer to enter into any agreement where “(i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.” The 109th and 110th Congress version of the bill made no exceptions to the ban. In the newest version,
Senator Kohl’s bill would only make two exemptions. First, any payments, not to exceed $7,500,000, meant to reimburse the ANDA filer for “for reasonable litigation expenses” would not be covered by the prohibition. 167 Second, the settlements presumptively unlawful and anticompetitive, but would permit the settling parties to rebut the presumption “if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.” 168 In deciphering whether or not the parties have carried their burden, the trier of fact would be able to consider:

(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;
(2) the value to consumers of the competition from the ANDA product allowed under the agreement;
(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;
(4) the revenue the ANDA filer would have received by winning the patent litigation;
(5) the reduction in the NDA holder’s revenues if it had lost the patent litigation;
(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and
(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection. 169

Similar legislation has been introduced in the House of Representatives. In the 110th Congress, Representatives Bobby Rush and Henry Waxman introduced two separate, yet nearly identical bills each of which would flatly prohibit reverse

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167 S. 369 (111th Cong.) (as reported in the Senate) § 3(d)(2).
168 Id. § 3(a)(2)(B).
169 Id. § 3(b).
settlements. Representative Rush introduced an identical bill in the 111th Congress. These proposals would brook no exception to the flat ban on reverse settlements. While these bills have been languishing in committees, the House did take up a version identical to the latest Senate bill, and passed it as part of the Supplemental Appropriations Act of 2010. The provision, however, was removed in the Senate.

These legislative efforts, though mostly unsuccessful thus far, are predicated on several proposed Congressional findings, some of them debatable. For instance, the Waxman bill would find that prohibiting settlement would ultimately result in “lower prices [and] greater innovation,” and that as a result “settlements which include a payment from a brand name manufacturer to a generic manufacturer to delay entry by generic drugs are anti-competitive and contrary to the interests of consumers.” That is a debatable proposition, for if banning the settlements would simply result in longer, more protracted litigation, prices may well increase. Additionally, if the ability of companies to protect their financial investments by avoiding the vagaries of litigation is undercut, innovation may suffer as well. The latest Kohl bill (which was adopted

170 H.R. 1432 (110th Cong.) (Waxman bill); H.R. 1902 (110th Cong.) (Rush bill). Congressman Waxman co-sponsored Congressman Rush’s bill.
171 H. R. 1706 (111th Cong.)
172 Id. § 2.
174 See Pub. L. 111-212 (missing Title IV of the House bill).
175 H.R. 1432 (110th Cong.) § 2(a)(5).
176 Id. § 2(a)(11).
177 Andrew Kopelman, Addressing Questionable Business Method Patents Prior to Issuance: A Two-Part Proposal, 27 CARDOZO L. REV. 2391, 2404 (2009) (noting that the costs of the litigation are passed on to the public in the form of increased prices).
178 Michael A. Carrier, Unsettling Drug Patent Settlements: A Framework For Presumptive Illegality, 108 MICH. L. REV. 37, 62 (2009)(stating that “[the caustic environment of patent litigation] could reduce innovation by increasing the uncertainty around the drug manufacturer’s ability to research, develop, and market the patented product.”) (quoting Schering-Plough, 402 F.3d at 1075).
almost verbatim by the House)\textsuperscript{179} also rests on questionable findings. That bill suggests that the “the intent of the 1984 [Hatch-Waxman] Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make ‘reverse payments’ which are payments by the brand company to the generic company,”\textsuperscript{180} and that such agreements “unduly delayed the marketing of low-cost generic drugs.”\textsuperscript{181} Of course, it is unclear whether the Hatch-Waxman Act has been “subverted” by agreements that would permit a generic to enter the market prior to the patent’s expiration without the need to actually prove, by clear and convincing evidence, the invalidity of NDA holder’s patent. It could be just as plausibly argued that such settlements advance the goals of the Hatch-Waxman Act. Similarly, one cannot say that the entry of the generics is unduly delayed absent some showing that but for these settlements, the ANDA filers would have prevailed at trial and been able to enter the market earlier. None of this is to say that Representative Waxman and Senator Kohl are necessarily wrong in their assessment of reverse settlements’ impact. What I am suggesting is that the proposed “findings” are, without additional support, questionable.

The problem is that Congress continues to see these settlements as an antitrust problem and therefore remains open to the same line of intellectual attack as the FTC’s position.\textsuperscript{182} The approach that I propose, \textit{infra} avoids this problem.

\textsuperscript{179} \textit{See supra} n. 173 and accompanying text.
\textsuperscript{180} S. 369 (111th Cong.) (as reported in the Senate) § 2(a)(6)(A).
\textsuperscript{181} \textit{Id.} § 2(a)(6)(B).
\textsuperscript{182} Of course, courts have rejected FTC’s stance based on the law as it currently stands. \textit{See supra} Parts III.B-F. Congress has the advantage of changing the law and forcing the courts to apply the new rules, even if the courts think that such rules rest on questionable economic or intellectual analysis. But that is a question of raw power, not the question of whether such an approach actually best preserves the balance between favoring litigation settlements and protecting consumers from the collusive effects of such settlements.
Before proceeding further, it should be observed that Congress was successful in enacting legislation that essentially eliminated some types of settlements. In 2003, as part of Medicare Prescription Drug, Improvement, and Modernization Act, Congress passed two provisions that affect reverse settlements. First, Congress enacted forfeiture provisions for the 180 day exclusivity period. Under the new version of the law, the generic manufacturer can no longer retain the exclusivity period if, \textit{inter alia}, it withdraws the Paragraph IV certification.\footnote{21 U.S.C. § 355(j)(5)(D)(i)(III) (2006).} Under this new rule the generics in the Ciprofloxacin and Tamoxifen settlements would have lost their exclusivity periods, thus making these settlements not nearly as worthwhile as prior to 2003.\footnote{Recall that the generic applicants in the Ciprofloxacin and Tamoxifen cases agreed to withdraw their Paragraph IV certifications and replace them with Paragraph III certifications. \textit{See supra} nn. 99, 118 and accompanying text.}

Additionally, Congress also mandated forfeiture of exclusivity whenever the ANDA filer enters into any agreement with respect to the filing that is ultimately adjudged to be a violation of antitrust laws.\footnote{21 U.S.C. § 355(j)(5)(D)(i)(V) (2006).} In order to permit the policing of such agreements, Congress enacted the second provision – requiring the parties who enter into a reverse settlement to file copies of the agreement with the FTC.\footnote{Pub. L. 108-173 § 1112.}

At bottom, however, the 2003 Act does not eliminate reverse settlements. Even the forfeiture provisions merely result in companies structuring their settlements differently, and not withdrawing the Paragraph IV certification.\footnote{\textit{Cf.} Ark. Carpenters, 604 F.3d at 109 n. (noting that since 2005 there have been at least 20 reverse settlements).} Companies remain
free to enter into settlements that “divide the life” of a patent while recognizing patent’s validity, enforceability, and infringement.\textsuperscript{188}

\textbf{B. \textit{The Executive Reaction}}

If the Congressional response to the problem of reverse settlements has been halting and cautious, the Executive’s response has been downright schizophrenic. Two agencies charged with enforcing antitrust laws came to divergent conclusions about the legality of reverse settlements. The Federal Trade Commission took more of a hard line, adopting an approach that would have made all such settlement illegal \textit{per se} in all but name.\textsuperscript{189} As described above, the FTC attempted to adopt a rule that would bar all payments to the generic manufacturers that were the greater of $2 million or actual litigation expenses. That rule was rejected by the 11\textsuperscript{th} Circuit. The FTC though, continued to press its view in the Supreme Court, seeking certiorari, and other courts of appeal. Despite being rejected in nearly every court, the FTC continues to adhere to its view. For instance, Jon Leibowitz – the newly-appointed chairman of the Commission – recently stated that “eliminating these deals is one of the Federal Trade Commission’s highest priorities.”\textsuperscript{190} In the same statement, the Chairman also announced FTC’s support for the congressional bills described in the preceding subsection.\textsuperscript{191}

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\textsuperscript{188} Such recognition could be embodied in a settlement decree entered by a court. Faced with such a decree, a generic would not be able to launch its product, but also may not be required to withdraw the Paragraph IV certification.

\textsuperscript{189} See \textit{Schering Plough,} 402 F.3d at 1060 (describing FTC’s position); see also \textit{supra} n. 145 and accompanying text.


\textsuperscript{191} \textit{Id.} at 5 (stating that the FTC “strongly supports legislation to eliminate pay-for-delay deals.”).
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On the other hand, the Antitrust Division of the Department of Justice, until recently took a much different approach. When the FTC filed its petition for a writ of certiorari, the Department of Justice opposed the grant, and in its separate brief argued that “the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful. Rather, an appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed *ex ante.*”\(^{192}\)

Recently, though, the DOJ did a complete about-face with respect to its view of reverse settlements’ validity. On July 6, 2009, the Justice Department filed an *amicus* brief with the Second Circuit in the Ciprofloxacin case,\(^ {193}\) and for the first time asserted that reverse settlements “should be treated as presumptively unlawful under Section 1 of the Sherman Act.”\(^ {194}\) The new position would subject these settlements to a rule of reason analysis, and would permit the defendant to rebut the presumption of illegality upon showing that the “terms of the settlement did not ‘impose[] an unreasonable restraint on competition,’ in view of their contemporaneous evaluations of the likelihood of an invalidity judgment.”\(^ {195}\) This position is still more generous to the settling parties than what the FTC would have, but it is a stark reversal from the previous position which essentially endorsed the 11th Circuit’s approach in *Schering Plough.*

Additionally, it is likely that the DOJ position will continue evolving towards a more restrictive view. President Obama, during his service as a U.S. Senator, was a co-


\(^{193}\) *Ark. Carpenters*, 604 F.3d 98.


\(^{195}\) *Id.* at 28 (internal citations and quotations omitted).
sponsor of Senator Kohl’s bill that sought to ban reverse settlements altogether.\(^{196}\) Indeed, President Obama’s sponsorship of that bill was cited by Mr. Leibowitz as evidence that the executive branch is committed to increased and aggressive action against reverse settlements.\(^{197}\) Given that the Obama Administration generally takes a much dimmer view of what constitutes permissible conduct under antitrust laws than its predecessor,\(^{198}\) and given the Administration’s intense focus on health care issues, it is quite reasonable to expect that it will amplify its antitrust-grounded objections to settlements between brand name and generic drug manufacturers in the context of Hatch-Waxman litigation.

\(\textit{C. Judicial Response}\)

Not much more needs to be said about the judicial response to reverse settlements beyond what was said in Part III, \textit{ante}. However, as more settlements are entered into, more courts (district and appellate) will have to wrestle with the antitrust arguments. It is worth remembering that the majority of circuits have not yet had an opportunity to opine on the issue of reverse settlements. Their turn may yet come,\(^{199}\) possibly leading to further debate (and perhaps confusion).

\(^{196}\) \textit{See} S. 316 (110th Cong.). List of co-sponsors is available at http://thomas.loc.gov/cgi-bin/bdquery/D?d110:1:./temp/~bd5KYJ:@@@P|/home/LegislativeData.php?n=BSS;c=110| (last visited Aug. 28, 2010).

\(^{197}\) \textit{See} Leibowitz, \textit{supra} n. 190 at 9.

\(^{198}\) \textit{See}, e.g., Editorial, \textit{Music Inc. Gets Bigger}, N.Y. TIMES, Feb 9. 2010, at A26 (“President Obama[’s] . . . Department of Justice and the Federal Trade Commission have become more aggressive about questioning mergers and challenging monopolies and anticompetitive behavior.”); A chill in the boardroom; Corporate reform in America, THE ECONOMIST, Dec. 12, 2009, at 3 (“[T]he Department of Justice has promised to be more aggressive in its enforcement of antitrust laws.”).

\(^{199}\) The most obvious candidate for the next court to opine on the matter is the Third Circuit, as it will hear the appeal, if any, of the Provigil case. Furthermore, Third Circuit is home to Johnson & Johnson, Wyeth, and Merck which are all headquartered in New Jersey. Other circuits may face these questions as well. For instance, Abbott Laboratories is headquartered in Illinois and Eli Lilly is in Indiana (both in the 7th Circuit), Amgen and Genentech are in California (in the 9th Circuit), and other companies are similarly spread
D. The Academic Debate

The dispute over the proper antitrust treatment of reverse settlements has not escaped the academic world either. Much like the political establishment, the academic world is split on the question of whether these settlements can ever be anything other than anti-competitive, and if so under what conditions.

At one extreme are Mr. Cristofer and Professor Keith Leffler who argue that all reverse settlements should be per se illegal. According to the Messrs. Leffler,

A patent enjoys only a rebuttable, not a conclusive presumption of validity. This probability of invalidity has an economic value. Under the system as created by Congress, the challenger has an incentive to capture that value and that incentive creates consumer benefit. In contrast, a payment by the patent holder to the challenger captures the value of the probability of patent invalidity. The agreement between a patent holder and the challenger divides the profits from agreed validity and thereby eliminates any consumer benefit. Through an agreement not to compete, the patent holder changes the congressionally mandated rebuttable presumption of validity into a conclusive presumption. When a patent holder thus enlarges the reward granted to him by Congress, in the form of paying a potential rival to confess validity, he and his co-conspirator reduce efficiency and consumer welfare and therefore commit a per se violation of the antitrust laws.

throughout the nation and various judicial circuits. It is quite possible, given the location of these various companies, that the local circuit courts will yet have a chance to opine on any deals that these companies may enter into.


201 Id. at 491. See also Herbert Hovenkamp, Mark Janis, and Mark A. Lemley, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2003) (arguing that reverse settlements should be treated as unlawful if the amount of settlement is greater than “the expected value of litigation and collateral costs attending the lawsuit,” i.e., essentially adopting FTC’s per se rule.); cf. Carl Shapiro, Antitrust Limits To Patent Settlements, 34 RAND J. OF ECON. 391, 408 (2003) (stating that “a naked cash payment flowing from the patentholder to the challenger (in excess of avoided litigation costs) is a clear signal that the settlement is likely to be anticompetitive . . . , and that “the FTC has a sound basis for its skepticism about ‘reverse cash payments’ from the patentholder to the challenger.”).
Mark Lemley and Carl Shapiro take a similar approach, without explicitly calling for a *per se* prohibition. Lemley and Shapiro argue that patents do not, as conventionally thought, grant a right to exclude, but rather grant a right to “try to exclude.” According to this thinking, unless a patentee obtains a court order allowing him to exclude a competitor (having proved that the competitor is infringing a valid patent), an agreement that excludes enlarges the scope of the patent and harm to consumers. Lemley and Shapiro do make an allowance that agreements to delay entry unaccompanied by a reverse payment may indeed be pro-competitive, which may be somewhat at odds with how the FTC would view these agreements. On balance, though, the Lemley and Shapiro approach is similar to what Messrs. Leffler are arguing.

A somewhat more moderate approach is taken by Professor Michael Carrier. His approach is very similar to the one proposed by the Department of Justice in its Second Circuit’s brief. Professor Carrier argues that while a complete ban on reverse settlements has the disadvantage of being over-inclusive and prohibiting lawful activity, allowing unchecked (or nearly unchecked) reverse settlements has the disadvantage of being under-inclusive and permitting unlawful restraints on trade. In order to balance these considerations, and taking into account Hatch-Waxman’s competition promoting goals and regulatory structure, Carrier suggests that the payments by brand names to generics should be presumptively illegal, but that the patentee be given an opportunity to show, by “introduc[ing] arguments that have been offered in the

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203 *Id.* at 75.
204 *See id.* at 93.
205 *See id.* at 93-94.
206 Carrier, *supra* n. 178.
207 *See id.* at 67-68.
208 *See id.*
209 *Id.*
economic literature”210 that the settlement appropriately “reflect[ed] an objective assessment of the patent’s strength.”211 Although Carrier suggests his approach as a middle way, he admits that the presumptive illegality may evolve, and “per se illegality might ultimately become a more appropriate treatment”212 should “judicial experience demonstrates that these arguments [from economic literature] do not in fact justify the payments.”213

Yet another approach is offered by Marc G. Schildkraut in his article Patent-Splitting Settlements and the Reverse Payment Fallacy.214 Schildkraut criticizes the “probabilistic patent” approach of Lemley and Shapiro as well as the per se analysis of the FTC. In Schildkraut’s view

[E]xplicit or implicit reverse payments are not necessarily anticompetitive. First, there are conditions under which an explicit or implicit “reverse” payment is necessary to settle patent litigation. There may be a gap between the parties that prevents settlement. This gap may be the result of a difference in perceptions about the outcome of the litigation or a difference in risk preferences. Sometimes a reverse payment can close the gap when it is impossible to close the gap by splitting time because the time has a different value to each party while the money has the same value.

Second, the reverse payment that settled the litigation may result in entry before the probable date of entry under the litigation. Such a settlement can lead to early entry when the patent holder is risk averse and willing to accept less than it expects to obtain in litigation in order to settle. Or, the patent holder’s perceptions about the outcome of litigation could simply be wrong. Under the circumstances, settling with reverse payments may be procompetitive.215

210 Id. at 76.
211 Id.
212 Id.
213 Id.
215 Id. at 1058.
Schildkraut does argue that the settlements are extremely hard to evaluate because of the uncertainties in litigation and the subjective perceptions of the litigating parties.\textsuperscript{216} Nonetheless, instead of “simply giving up on settlements” he proposes that the parties to the settlement obtain prior court approval, and thus avail themselves of the protections of the *Noerr-Pennington* doctrine.\textsuperscript{217} While on its face a sensible proposal, it is hard to see what tools the court would use to evaluate a settlement and its pro- or anti-competitive effects. The only plausible way to do this would be to essentially try the validity of the patent – an approach that Schildkraut rejects.\textsuperscript{218} Thus, while his observations about the effects of reverse settlements may well be correct, it is not evident that courts can adjudicate the matter without the very trial that the settling parties seek to avoid.

Professor Daniel Crane seeks to address the problem identified above.\textsuperscript{219} He also proposes an inquiry into the *ex ante* expectation of settling parties but suggests a tiered approach.\textsuperscript{220} Crane suggests that whenever there is a preliminary injunction in place, a reverse settlement should be presumptively lawful, as the presence of the injunction indicates that the court believes that the patentee is likely to succeed on the merits.\textsuperscript{221} In the absence of a preliminary injunction, Crane argues that the courts should take a “quick look” into the strength of the patentee’s case (something akin to a preliminary injunction hearing) and approve a settlement if the court concludes that the patentee was likely to

\textsuperscript{216} See id. at 1052-55.
\textsuperscript{217} Id. at 1068. The *Noerr-Pennington* doctrine arises from two Supreme Court cases, *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) and *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). Under the doctrine, private parties are immune from antitrust liability for injuries that may arise out of petitioning the government and any state actions that result from such petitioning. See Schildkraut, supra n. 214 at 1057 (describing the doctrine).
\textsuperscript{218} See Schildkraut, supra n. 214 at 1054 (agreeing with the *Valley Drug* court that “after-the-fact analysis of a settlement . . . would undermine patent incentives.”).
\textsuperscript{220} Id. at 779-96.
\textsuperscript{221} Id. at 783-85.
succeed. Presumably, most settlements in the Hatch-Waxman context would fall in the latter category despite the presence of a preliminary injunction in place. After all, in the Hatch-Waxman context, a 30 months preliminary injunction on FDA’s approval is automatic and does not reflect any judicial determination of patentee’s likelihood of success. Crane’s proposal is further refined by his suggestion that there be “a cap on the percentage of the patentee's monopoly rents that it may pay the defendant to exit the market.”

According to Crane

A settlement in which the patentee is willing to pay the alleged infringer a large percentage of its monopoly rents from the patent in exchange for the alleged infringer's promise to discontinue the infringing use reflects a low probability that the patent is valid or that the defendant's use is actually infringing.

Of particular relevance to the Hatch-Waxman settlements, Crane proposes that agreements that impose barriers to third-parties’ ability to enter the market should receive enhanced scrutiny. Because a number of the reverse settlements impose precisely these barriers (via agreements not to waive or transfer the 180 day exclusivity period) they would be subject to enhanced scrutiny. However, absent the ability to enter into an agreement to “bank” the exclusivity period may undermine the ability of the parties to settle. The patentee’s incentive will be reduced because it may fear further challenges from more and more entities, while the generic’s incentive could be reduced because it would no longer be able to count on increased profits in the or the sale of the 180 day period.

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222 Id. at 785-88.
224 Crane, supra n. 219 at 788.
225 Id. This is indeed the same argument advanced by Lemley and Shapiro. See Lemley & Shapiro, supra n. 202 at 94. But see Thomas, supra n. 24 at 37-38 (arguing that “reverse payments do not necessarily connote fears of patent invalidity.”).
226 Crane, supra n. 219 at 792-96.
While Crane’s approach is quite solicitous of reverse settlements it too presents significant problems. One of the main problems is identified in the Schildkraut’s article. Under Crane’s proposal, a court would approve a settlement if it concludes that the patentee had demonstrated likelihood of success on merits. Presumably, the converse is true as well, that is the court would reject the settlement if such likelihood is not demonstrated. The problem is that a settlement may be pro-competitive even when the likelihood of success is below 50%. As Schildkraut describes it

Consider a case where the patent holder believes it has only a 40 percent chance of prevailing. Being risk averse, it settles the case without net consideration by accepting 30 percent of the patent life. Clearly, we have not violated the uncertain competition standard. Yet, under the traditional standard of proof, there is an argument that the patent holder has violated the antitrust laws. Because the patent holder is likely to lose the patent litigation, a court might find that it has no legal basis for excluding the alleged infringer, even an exclusion that only lasts for 30 percent of the remaining patent life. If the patent holder is forced to litigate, however, there is a 40 percent chance it will prevail and exclude the alleged infringer until the end of the patent life. Although consumers would vote for the compromise, we cannot honor that consumer preference under the traditional standard of proof.

As Schildkraut shows, reverse settlements may be pro-competitive even in the face of relatively low likelihood of success in litigation. Under the Crane’s approach though, such settlements are likely to be disallowed by the courts. Some scholars, notably, Mark Lemley, Mark Janis, Herbert Hovenkamp, and Scott Hemphill have recognized the difficulty with the antitrust approach that ultimately asks whether the patentee or the challenger would have prevailed at trial. In order to solve the problem, they suggest that the real question is not whether one side or another would prevail, but whether there is a loss to the public of a chance that the generic would

227 Crane, supra n. 219 at 783-88 (suggesting that the courts evaluate success on the merits either through the preliminary injunction proceedings or through the “quick look” proceedings).
228 Schildkraut, supra n. 214 at 1054-55.
Although this approach is certainly theoretically interesting, I am skeptical that it offers much help. I am willing to stipulate that almost no matter how strong a case one may have, there is always a chance that one will lose at trial. This is true not just of pharmaceutical litigation, but litigation in general. All settlements that end litigation then, extinguish these chances of loss. Thus, this method is simply a new way of arguing that all reverse settlements should be \textit{per se} illegal (even if authors disclaim the \textit{per se} approach). In response to this objection, Professor Hemphill makes a more narrow argument. According to Hemphill, any payment (whether as a side-deal \textit{a la} Provigil, or pure money exchange, or even by merely allowing the first filer to retain exclusivity) results in a delayed market-entry as compared to what would be achieved without inducement.\footnote{See generally Hovenkamp, Janis, and Lemley, supra n. 201; C. Scott Hemphill, \textit{Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem}, 81 N.Y.U. L. REV. 1553 (2006) (hereinafter \textit{``Hemphill, Pay for Delay.'''})} The problem is that at very bottom, all settlements involve some exchange of benefits, as Hemphill himself recognizes.\footnote{See Hemphill, \textit{Pay for Delay}, supra n. 229.} But if that alone were enough to condemn settlements, then very few of them would survive an antitrust attack.\footnote{Id. at 1576-77.} Ultimately though, Hemphill’s argument, much like that of Lemley, Shapiro, Hovenkamp, and Janis is predicated on the idea that patent right is merely “probabilistic.” I, on the other hand, tend to agree with Kevin McDonald that there is no reason to treat patents as any more “probabilistic” than any other form of property.\footnote{See generally Kevin D. McDonald, \textit{Hatch-Waxman Patent Settlements and Antitrust: On \textquoteleft Probabilistic\textquoteleft Patent Rights and False Positives}, ANTITRUST, Spring 2003 at 68, 71; \textit{cf.} Hemphill, \textit{Pay for Delay}, supra n. 229 at 1576-77.} For these reasons, this supposedly more “nuanced” approach is also, in my view not up to the task of solving the reverse settlement problems.
This section is not an exhaustive compendium of various academic views and approaches to the problem of reverse settlements; however, it is a fair representation of the divergent positions taken by some very eminent scholars. It is this lack of agreement in academia, as well as in Congress, courts, and the Executive branch that leads me to my conclusion that a new approach is needed – one that would be based in patent law and serve the stated goals of the Hatch-Waxman Act. It is to this proposal that I now turn.

V. Solving a Patent Problem through Patent Law

As can be seen from the above disagreements, and as the courts and scholars have explicitly and repeatedly recognized, there is inherent and constant tension between antitrust law and patent law. While it is “well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act,” it is equally true that “the essence of a patent grant is the right to exclude others.” Of course, the exclusion must be legitimate, i.e., only of an infringing product and only pursuant only to a valid patent. The question then ultimately turns on the validity of a patent, not on any payment from the patentee to the challenger. Even though who have advocated for a per se rule against reverse settlements have not suggested that such payments would be illegal if the patent were adjudged to be valid and infringed. The reason then why some seek to ban reverse settlements is because they prevent adjudication of the patents and thus allow a patentee to exclude on the basis of what

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236 See Lemley & Shapiro, supra n. 202 at 93.
237 Of course, if that were to occur, there would no longer be any need for such payments. Nonetheless, as an analytical matter it does not appear that anyone is suggesting that a patentee with a judicially “confirmed” patent would be prohibited from paying a generic manufacturer whatever sums he wishes.
could be an invalid patent.\textsuperscript{238} If the worry then is that brand name manufacturers are enforcing invalid patents through reverse settlements, the best way to address the problem is through patent law itself.

In enacting the Hatch-Waxman Act, Congress sought to both promote innovation by extending the terms of the patents on pharmaceuticals and to promote competition from lower cost generic alternatives.\textsuperscript{239} Additionally, as far back as 1892, the Supreme Court held that “[i]t is as important to the public that competition should not be repressed by worthless patents.”\textsuperscript{240} Presuming, as canons of statutory construction require that Congress legislated with full knowledge of the state of the law then extant,\textsuperscript{241} it follows that one of the purposes that Congress enacted Paragraph IV was to encourage competition through the removal of “worthless patents” on pharmaceutical products. Congress thus constructed a system where competitors who would attempt to clear “worthless patents” would be rewarded. It is with reference to these goals that the solution to the problem of reverse settlements should be crafted. Restricting or even banning settlements simply does not remove worthless patents from the field. At most, banning the settlements would push more disputes into litigation where the outcome is far from certain. While some of the patents would likely be invalidated (thus serving the “clearing” goal), others would be upheld, and the entry of the generic drug would be delayed beyond the time that could be agreed upon between the parties (thus failing the goals of increased competitions and reduced prices). Simply put, the antitrust solution is

\textsuperscript{238} See, e.g., Lemley & Shapiro, supra n. 202 at 93.
\textsuperscript{239} See supra Part II.A.
\textsuperscript{240} Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892).
\textsuperscript{241} See, e.g., United States v. Wilson, 290 F.3d 347, 357 (D.C. Cir. 2002)(“Congress is presumed to be aware of established practices and authoritative interpretations of the coordinate branches.”) and id. at 356 (“Congress is presumed to preserve, not abrogate, the background understandings against which it legislates.”).
a very imperfect tool to address the problem of reverse settlements and an even more imperfect tool to advance the goals Congress had in mind in enacting the Hatch-Waxman Act. Patent law, the very tool Congress used to create the Hatch-Waxman Act is a far better instrument to address these issues.

A. Patent Reexamination

After a patent issues, it is presumed valid. The presumption, however, can be overcome during litigation by the accused infringer. Of course, in the context of reverse settlements the litigation is avoided and that avenue is foreclosed. The other option is reexamination of the patent by the USPTO. Reexamination is exactly what it sounds like – an examination of the patent anew. The major difference between a district court trial and a reexamination at the USPTO is that the patent does not enjoy any presumption of validity during a reexamination process. Rather, the reexamination departs from the same starting point as the original examination where the Examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by preponderance of the evidence.

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243 See Enzo Biochem, Inc. Gen-Probe Inc., 424 F.3d 1276, 1281 (Fed. Cir. 2005) (“A patent is presumed to be valid, and this presumption only can be overcome by clear and convincing evidence to the contrary.”) (internal citation omitted).
244 See 35 U.S.C. § 305 (stating that “reexamination will be conducted according to the procedures established for initial examination.”); Ethicon v. Quigg, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (“In a reexamination proceeding, . . . the 'focus' of the reexamination 'returns essentially to that present in an initial examination . . . .’”).
245 Ethicon, 849 F.2d at 1427 (“In a reexamination proceeding, on the other hand, there is no presumption of validity . . . .”).
246 In re Oetiker, 977 F.2d 1443
There are two types of reexamination procedures: an *ex parte* reexamination and an *inter partes* reexamination. The major difference between the two procedures is that during an *inter partes* reexamination, the third party that requested that the patent be reexamined can participate in the process and appeal any decision unfavorable to it to the Board of Patent Appeals and Interferences, and then to the U.S. Court of Appeals for the Federal Circuit. In other words, the *inter partes* reexamination is in many ways similar to a proceedings in the district court and may be used in lieu thereof. The *inter partes* procedure presumes that there is a third party opposing the validity of the issued patent and willing to convince the PTO of the correctness of its views. Of course, if post-Paragraph IV certification parties enter into a settlement, it is unlikely that there will remain an entity interested in prosecuting the invalidity argument in the PTO. Thus, I will focus on the *ex parte* reexamination. However, the availability of an *inter partes* exam is important and will be discussed in Part VI.D.

Section 302 of the Patent Act authorizes “[a]ny person at any time [to] file a request for reexamination by the Office of any claim of a patent on the basis of any prior art . . . .” The person must identify the prior art that he believes is relevant to the question of patentability and explain why in his view the cited art raises a “substantial new question of patentability.” If the Director of the Patent Office determines that a “substantial new question of patentability affecting any claim of the patent concerned is

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248 See id. §§ 311-18.
249 See id. § 315(b). In *ex parte* reexamination, only the applicant is entitled to appeal an adverse decision. See id. § 306.
250 See id. § 314 (describing the requirement of serving each document on opposing party and allowing both the patent owner and the third party requester to file written responses and arguments with the Patent Office); id. § 315 (allowing both the patent owner and the third party requester to appeal unfavorable decisions).
251 Id. § 302.
252 Id. § 303.
raised by the request,” the Director will order reexamination of the relevant claims.\textsuperscript{253}

The examination proceeds much like the initial examination, except it is generally conducted by senior examiners who were uninvolved with the original examination.\textsuperscript{254}

Once the examiner makes his final decision, a patent owner may appeal any unfavorable ruling to the BPAI or the Federal Circuit (as he would’ve been able during the original examination).\textsuperscript{255} Ultimately, once the reexamination is concluded, a reexamination certificate is issued either confirming the claims, canceling them, amending them to narrow their scope, or a combination thereof.\textsuperscript{256}

In addition to permitting any third party to file requests, the regulations promulgated under the statute permit the Director to order reexamination on his own initiative.\textsuperscript{257} “Such reexamination may be ordered at any time during the period of enforceability of the patent.”\textsuperscript{258} Although the PTO has the authority to order a reexamination at any time, its own rules specify that “[a] decision to order reexamination at the Director's initiative is, however, rare. Only in compelling circumstances, after a review of all the facts concerning the patent, would such a decision be made.”\textsuperscript{259} If the decision is made, the reexamination proceeds as any other reexamination would.

\begin{footnotesize}
\footnotesize{\textsuperscript{253} Id. § 304. \\
\textsuperscript{254} See MPEP § 2236. \\
\textsuperscript{256} See id. § 305 (“No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter”) § 307 (“[T]he Director will issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.”). \\
\textsuperscript{257} See 35 U.S.C. § 303(a) (2006) (“On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him . . .”); 37 CFR § 1.520. \\
\textsuperscript{258} MPEP § 2239. \\
\textsuperscript{259} Id. While the Manual of Patent Examining Procedures does not delineate what constitutes “compelling circumstances,” the Director has previously ordered reexamination in high profile cases. See Troy L. Gwartney, Harmonizing The Exclusionary Rights Of Patents With Compulsory Licensing, 50 WM AND}
\end{footnotesize}
It is important to understand that the reexamination is ordered only when there is a “substantial new question of patentability.” That is a threshold inquiry.\textsuperscript{260} The inquiry however is not limited to focusing on prior art that was not available to the PTO during the initial examination. The statute permits for reexamination “the basis of any prior art.”\textsuperscript{261} This means that even if a given piece of prior art was considered during the initial application, it could still raise a “substantial new question of patentability,” if for instance the Director determines that the initial examination did not fully or properly consider that piece of evidence. In other words, no new evidence needs to be cited to the PTO in order for the reexamination to be ordered.

\textbf{B. Utilizing the Reexamination Process}

The reason patentees choose to enter into settlements with the accused infringers is because of a chance that at trial the patent may be found invalid.\textsuperscript{262} If a patentee had a 100\% chance of winning in court, there would be no reason at all to settle,\textsuperscript{263} except in those cases where the cost of litigation itself exceeds the value of judgment. Given the money at stake in pharmaceutical litigation, the cases where favorable judgment is of little worth to the patentee can be expected to be exceedingly rare. It has been conceded, even by those who find no antitrust fault with reverse settlements that “the size of the payment to refrain from competing, sometimes called a ‘reverse payment’ or an ‘exit payment,’ raises the suspicion that the parties lacked faith in the validity of the patent . . .

\textsuperscript{261} \textit{Id.} § 302.
\textsuperscript{262} \textit{See supra} nn. 9-10 and accompanying text.
\textsuperscript{263} \textit{See} Hovenkamp, Janis, and Lemley, \textit{supra} n. 201 at 1578-79; Graham, \textit{supra} n. 20 at 445 n. 143
Although courts have rejected an approach through which the size of the settlement would be considered an admission of patent’s invalidity, they agree, as do scholars that the relative strength of the patent is one of the important considerations in deciding whether and on what terms to settle the litigation.

Using the above insight, I propose a different approach to the problem of reverse settlements – one that takes into account the size of the settlement, but one that does not sound in antitrust law, nor requires either the courts or administrative agencies to do post hoc evaluations of patents’ strengths or parties’ ex ante expectations. Instead, reverse settlements that involve payments of more than just reasonable litigation expenses should be treated as a signal to the Patent Office that private parties (the patentee and the generic challenger) have some doubts about the strength of the patent at issue. If the size of the settlement exceeds reasonable litigation costs and cross-license fees, it would indicate that the doubts are “substantial;” in other words whether there exists in the mind of the parties a “substantial new question of patentability” of the patent in suit. The Patent Office can then decide whether such question indeed exists and if so, order the patent into reexamination proceedings.

If a reexamination is triggered, the Patent Office can then use its expertise to determine whether the claims are valid. If it determines that they are, it would necessarily follow that the settlement was proper, for the exclusion of the generic would not be the result of an illegal payment, but the result of the scope of a now-confirmed valid patent. Alternatively, should the PTO reject the claims, thus removing the patentee’s ability to enforce a now-non-existent patent, the market would become open to any other generic manufacturer who wishes to enter it. All that would need to be done is

\[264\] Valley Drug, 344 F.3d at 1309-10.
for that manufacturer to file an ANDA with Paragraph I certification certifying that no patent covers the drug in question.\(^\text{265}\) Assuming that the generic would be able to satisfy the bioequivalence requirements,\(^\text{266}\) nothing would stand in the way of FDA approving the generic version and that version entering the market to the benefit of consumers.\(^\text{267}\) In this way, the purposes of antitrust law, which after all concerns itself with the well-being of the consumer, would be served. So too would the goals of the Hatch-Waxman Act, as the procedure would both allow the quicker entry of the generic drugs and the removal of “worthless patents” from the public sphere.

One of the fundamental advantages of the proposed approach is that it does not depend on adversarial litigation or any particular party challenging a patent. Because the PTO conducts its reexamination *ex parte*\(^\text{268}\) upon either its own motion or following a submission from “any person,” the patentee cannot possibly contract away this procedure, unlike the judicial inquiry which can only proceed when there is a “case or controversy.”\(^\text{269}\) Consequently, it would be impossible for the patentee and the generic challenger to collude in order to keep an invalid patent on the market while splitting the supra-competitive profits.

\textit{C. The Proposed Procedure}

\(^{266}\) Id. § 355(j)(2)(A)(iv).
\(^{267}\) The first filer may still be able to enjoy a 180 day marketing exclusivity period, but even so, the market would be open at worst 180 days later rather than a number of years later. Alternatively, the 180 day period may be forfeited under the Medicare Modernization Act. If the underlying patent was invalid, it would follow that the settlement was anti-competitive, and therefore likely to have violated antitrust laws. Under the Medicare Modernization Act’s amendments, a generic that enters into a settlement that is found to violate antitrust laws forfeits its 180 day exclusivity period. 21 U.S.C. § 355(j)(5)(D) (2006).
\(^{268}\) As discussed *ante*, there is a provision of *inter partes* reexamination, but it need not be utilized in order to engage in the reexamination.
\(^{269}\) U.S. CONST. art. III, § 2.
If reverse settlements are to lead to patent reexamination, there must be a set of rules that would dictate when the settlements would trigger the reexamination and who would serve as the reviewing authority for the trigger, and what information should be available to that authority. Adopting a *per se* rule that would require a reexamination of all patents subject to reverse settlements would be inconsistent with the understanding that some settlements are not only economically beneficient to the settling parties and to consumers, but do not betray any doubt on the part of the patentee about the patent’s strength. \(^{270}\) The premise of the system that I am proposing, on the other hand, is that certain settlements do raise a “substantial new question of patentability” with regards to patents in suit. Additionally, the presence of a “substantial new question” is a statutory requirement for reexamination. \(^{271}\) Even the FTC, with its uncompromising position, realizes that some reverse settlements do not point to any doubts about the patent validity. \(^{272}\)

At the same time, judging the appropriateness of the settlements’ size can only be accomplished by reference to the value of the underlying patent – the stronger the patent, the more valuable it is, and therefore, the larger the settlement will be. If that had to be examined prior to reexamination proceedings, there would essentially be two separate inquiries into the strength of the patent making the system too unwieldy and unpredictable.

In my view, any reverse settlement where the amount of money paid to the generic challenger exceeds reasonable litigation costs plus reasonable payments for any

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\(^{270}\) *Cf.* Thomas, *supra* n. 24 at 37-38.


\(^{272}\) *See* Schering Plough, 402 F.3d at 1062 (describing FTC’s position that settlements which do not exceed the cost of litigation of $2 million are not anticompetitive).
cross-licenses that are part of the agreement would be referred to the PTO. That, however, leaves open the question of valuating the cost of litigation and side-deals. Avoiding protracted adjudication over this issue is important if reexamination solution to the reverse settlement problem is to work. Consequently, I would impose an approach similar to that advocated by the FTC and Professor Hemphill (albeit in a different context) – presuming that every settlement above a certain amount are a signal that there exists a substantial new question of patentability. I would adjust the FTC’s presumption to state that any settlement in excess of $2 million will be presumed to raise substantial new questions of patentability enough to trigger the reexamination request.

Additionally, I agree with Professor Hemphill that some (though not all) cross-licensing deals may also be little more than a convenient cover for an otherwise anticompetitive settlement. To police against that, I would suggest that a second-level presumption be created – that any reverse settlement involving a cross-licensing side-deal be also presumed to raise a substantial new question of patentability if the payments under the side agreement exceed some specified amount.

Faced with settlements that exceed the limits set in regulations, the FTC will be able to request that the PTO reexamine the patent subject to the settlement. The PTO will then be able to consider, under its regular procedure, whether there are indeed

273 See Schering Plough, 402 F.3d at 1062 (stating that FTC would presume all settlements over $2 million to be in violation of antitrust laws); Hemphill, supra n. 1
274 The actual dollar amount can be adjusted as needed if and when the average cost of litigation changes.
275 Hemphill, supra n.1.
276 I leave the actual dollar value to those more skilled in economic valuation of patents and licenses; however, a $20 million cap does not seem unreasonable. Relatedly, I would reject Hemphill’s suggestion that all settlements that allow the challenger to keep the 180 day exclusivity period be treated in the same way as other reverse settlements, even if no money exchanges hands. See Hemphill, Pay for Delay, supra n. 229. In Hemphill’s view, because the retained exclusivity confers a potentially multi-million dollar benefit on the generic, it functions in exactly the same way as a payment. Id. The problem is that in that situation, the patentee is not giving up anything of value. Consequently, a settlement where the generic is simply allowed to retain the exclusivity period does not signal that the patentee has substantial questions about the patentability of its invention.
“substantial new questions of patentability” and if so, order the patent into a full reexamination. In determining whether such questions exist, the PTO will be able to rely on the documentation compiled and arguments made by the generic manufacturer in support of its ANDA Paragraph IV filing. I would therefore propose that whenever reverse settlements are concluded, such information be turned over to the PTO. This should not place significant burden on the generic manufacturer. The Hatch-Waxman Act (as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) already requires any applicant that files an ANDA under Paragraph IV to provide “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”277 Thus, the generic manufacturer must have an opinion of counsel on the validity of the patent that is being challenged under Paragraph IV. The opinion, which after all must be prepared in good faith,278 would identify relevant basis for invalidating the patent.

The only change that my proposal would require is that the opinion be shared not just with the patentee and the FDA, but also with the PTO. The law already requires the settling parties to notify the FTC whenever they enter into reverse settlements and to file the full text of the agreement with the Commission.279 Requiring the parties to also file an already-prepared opinion of counsel identifying the basis for the claims of invalidity would not impose any additional burden (save for the cost of Xeroxing) on either party.

278 See Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc., 21 F. Supp. 2d 366 (S.D. N.Y. 1998), aff'd, 231 F.3d 1339 (Fed. Cir. 2000) (“In filing its paragraph IV certification along with its ANDA, Schein represented that “in the opinion of the applicant and to the best of its knowledge” the . . . patent was invalid. . . . However, the patent law imposes an affirmative duty of due care on one making such an assertion, and this standard is applied in determining if one such as Schein had an objective good faith basis for such action.”).
The opinion would identify for the Director the “new questions of patentability” and be buttressed by the finding that the size of the settlement exceeds the reasonable cost of litigation plus the reasonable value of any cross-licenses. Armed with this evidence, the PTO would determine, applying current statutory rules, whether it should proceed to reexamination. The PTO would make that decision aided by, but independent of, the opinion of counsel that was submitted with the initial Paragraph IV certification (and any other documents that became available to the challenger during discovery). The reexamination itself would not automatically follow a reverse settlement. Rather, the settlement would only require the PTO to consider whether the full reexamination should be ordered.

In short, the system that I propose would utilize PTO’s existing authority to reexamine patents, and would simply focus the PTO’s attention on those patents that the patentee and a competitor, through their behavior, indicate have substantial new questions of patentability. As I describe in the following section, my proposal would broaden the scope of the re-examination, so that all questions of validity (not just those based on prior art) could be addressed.

VI. Response to Counter-Arguments

The patent solution to the problem of reverse settlements is in my view a better approach than the blunt tool of antitrust law. However that does not mean that the approach is not without its own potential shortcomings. I will address a few of these shortcomings and suggest how the law should be fine-tuned in order to mitigate these problems.
A. Limited Reexamination Trigger

Currently, reexaminations may be conducted only when certain prior art can be shown to invalidate the patent.\footnote{Scope of reexamination in ex parte reexamination proceedings, 37 CFR § 1.552 (2010); MPEP § 2258.} In other words, reexamination covers only § 102 (anticipation)\footnote{35 U.S.C. § 102 (2006).} and § 103 (obviousness)\footnote{Id. § 103.} rejections. At trial, on the other hand, an issued patent can be attacked on other grounds such as § 112 (lack of written description or enablement),\footnote{35 U.S.C. § 112 (2006); see e.g. ALZA Corp. v. Andrx Pharmaceuticals, LLC, 603 F.3d 935, 943 (Fed. Cir. 2010) (affirming lower court finding that a patent was invalid due to lack of enablement).} double patenting,\footnote{See, e.g., Sun Pharm. Indus. v. Eli Lilly & Co., 611 F.3d 1381, *6-*8 (Fed. Cir. 2010) (discussing the prohibition on double patenting).} or inequitable conduct\footnote{See e.g. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1567 (Fed. Cir. 1984) (“[W]e are compelled to conclude that “inequitable conduct” occurred. Accordingly, all claims of the patent must be held unenforceable.”)} in front of the PTO during the original prosecution. None of these grounds are cause for reexamination in the PTO,\footnote{MPEP § 2258(c) (“Issues other than those indicated in paragraphs (a) and (b) [both dealing only with printed prior art] of this section will not be resolved in a reexamination proceeding.”).} yet all of these grounds would be part of the settlement calculus. A patent holder may legitimately fear losing a case on the grounds of inequitable conduct or lack of enablement and enter into a reverse settlement in order to avoid that prospect. The settlement is meant to avoid a likely invalidation of the patent, and yet, under the present law, the PTO would be powerless to reexamine the patent as it is not invalidated by any prior art. This calls for a change in the reexamination procedures. In order for reexamination to be an effective policing tool against improper settlements, the PTO must be given authority to order a patent into reexamination for any potentially invalidating reason. In determining whether the patent ought to be reexamined, it should make no difference whether the patent fails to comply with Section 102 or Section 112 of the Patent Act. Any failure to comply with the Act’s requirements should be sufficient to
remove the patent from the public sphere. The authority to order patents into reexamination for reasons other than prior art invalidation would not change the reexamination process itself. Once the patent enters the process, it no longer matters why it did so. During the process it would be treated like every other patent application and subject to the same full set of requirements.

The burden on the PTO should not noticeably increase if the scope of its authority to order a patent for reexamination is broadened. First, the PTO already has a process to “reexamine” patents that fail the written description or specification requirements. Section 251 of the Patent permits correction of a patent through a reissue “[w]henever any patent is, through error without any deceptive intention, [is] deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent . . . .”287 The patentee can correct a written description or enablement problem through a reissue.288 Moreover, until 1988, the PTO examined reissue applications for conformance with the duty of disclosure.289 This shows that the PTO is fully capable of addressing inequitable conduct issues in post-grant review.

288 See In re Amos, 953 F.2d 613, 618 (Fed. Cir. 1991) (noting that reissue application was examined for compliance with enablement and written description requirements, and that those requirement were satisfied).
289 United States Patent and Trademark Office, Patent and Trademark Office Implementation of 37 CFR 1.56, 1095 Off. Gaz. Pat. Office 16 (Oct. 11, 1988); see also Allan M. Soobert, Breaking New Grounds in Administrative Revocation of U.S. Patents: A Proposition for Opposition -- And Beyond, 14 SANTA CLARA COMPUTER & HIGH TECH. L.J. 63, 77 n.51 (1998). As of 1988, the PTO has abandoned the practice and now treats the applicant’s affidavit that the mistake sought to be corrected in the reissue process was not a result of a deceptive intent as dispositive of the issue. MPEP § 1448 (“The Office no longer investigates or rejects reissue applications under 37 CFR 1.56” which imposes a duty of disclosure).
The current statutory scheme governing reissue applications only permits the patent owner himself to request such proceedings. In contrast to the reexamination process, neither the Director of the PTO, nor a third party may request reissue proceedings. That limitation presents a serious obstacle to accomplishing full review of a pharmaceutical patent within the PTO. In order for my proposed scheme to work, the PTO must be given the authority to review the patent for all potential problems and not just those that are can currently be reviewed in the reexamination proceedings. Such an authority (albeit in different context) is presently being considered by Congress. The pending Patent Reform bill would permit any third party to request and the PTO to conduct post-grant review “on any ground that could be raised under section 282 (relating to invalidity of the patent or any claim).” If this same mechanism, together with resumption of review for compliance with the duty of disclosure, is adopted for the Hatch-Waxman review process that I am advocating, it would permit the PTO to fully examine the patent. This will preclude the possibility of reverse settlements serving as shield against the finding of invalidity on grounds other than anticipation or obviousness.

B. Non-infringement Paragraph IV Certification

The Paragraph IV certification comes in two varieties: the non-infringement claim and the invalidity claim. Submitting an ANDA with either claim puts the first entrant in the position of claiming the 180 day exclusivity period. Yet, if the basis for the approval of the generic drug is only finding of non-infringement, then the patent

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293 Id. § 355(j)(5)(B)(iv)(I).
remains valid as against future entrants. If a Paragraph IV certification on the basis of invalidity is followed by a reverse settlement then, there would be no advantage for subsequent entrants to challenge the patent (for they will not be entitled to the 180 exclusivity period) nor will there be a basis for the PTO to reexamine the patent (for there will be no opinion of counsel that the patent is in any way invalid). It can be argued that such an outcome presents a problem because it allows the parties to collude in order to avoid judicial determination of non-infringement. Avoidance, of such a determination, may improperly preserve a broader scope of exclusivity than the patent itself warrants. In other words, even though the patent claims by themselves only permit the patentee to exclude certain products, a reverse settlement that avoids the finding of non-infringement effectively permits the exclusion of additional products.

The proposal I lay out does not help solve the problem of reverse settlements following the certification of non-infringement, whereas the antitrust-based approach would. Although that is certainly a drawback to my solution, I am not convinced that it is a major one. Albeit the same consequences flow from certification of non-infringement and certification of invalidity, the fundamental problem with reverse settlements in my view, is not that certain generic drugs don’t enter the market early, but that settlements may stifle innovation by permitting continued occupation of the public sphere by worthless patents.294 No such problem presents itself when the generic manufacturer does not challenge the validity of the patent, but rather certifies noninfringement only.

294 To be sure, the delay in market entry for lower cost generic does hurt consumers as it increases the price of medical care. Nonetheless, the delay in and of itself does not have an impact on the patent and innovation system as a whole. Furthermore, the cost to consumers is not that high. According to FDA, when there is a single generic on the market, the cost of that generic is 94% of the cost of brand-name. It is only with subsequent entries that the price drops. Food and Drug Administration, Generic Competition and Drug Prices, available at http://www.fda.gov/CDER/ogd/generic_competition.htm (last visited Feb. 28, 2007)
Furthermore, it is likely that the majority of challenges are challenges to validity rather than non-infringement. Because any ANDA filer has to show that the generic drug it seeks to market is bioequivalent or, in other words, essentially the same as the patented drug, it is very likely that the generic version would read on the patent. As a result, I am not overly concerned about non-infringement Paragraph IV certifications being used as a prelude to anticompetitive reverse settlements. At the same time, the question such certifications’ frequency certainly bears more investigation.

C. Undermining Settlements

Another objection that could be raised against my approach is that it would dissuade parties from entering into settlements, thus undermining the judicially favored policy of out-of-court settlements. The argument is that if every settlement is subject to review and potential patent invalidation through the reexamination process patentees will be dissuaded from entering settlements because they will lose the certainty that their property rights will remain intact. Even though the argument is appealing on the surface, it does not withstand close scrutiny.

As an initial matter, it should be observed that some companies voluntarily request reexamination of their patents even after entering into reverse settlements. This practice suggests that the prospect of reexamination does not inhibit or undermine the conclusion of settlements between patentees and generic manufacturers. There is

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295 While at present I do not have data on the types of Paragraph IV challenges being pursued, I intend to collect and analyze such data in a follow-up piece to the present Article.

296 See Schering-Plough, 402 F.3d at 1072 (“The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”)

little reason to believe then that the mechanism I am proposing would change this
dynamic.

Fundamentally, the threat of patents being reexamined following reverse
settlements will not affect patentees’ desire to enter into settlements because my proposal
does not create any new significant threat for the patentees. Recall, that at present, the
Director can, *sua sponte*, order any patent into reexamination at any time that he
concludes there exists a substantial new question of patentability in light of prior art.\(^{298}\)

All patents (including pharmaceutical patents) are subject to this threat of
reexamination.\(^{299}\) The presence or absence of a settlement agreement does not affect the
Director’s ability to exercise the reexamination authority. My proposal would bring only
moderate changes to the Director’s ability to exercise this already-existent power. First,
the Director would have access to the research compiled by the generic applicant as part
of the ANDA application process. The access to the research, in and of itself, should not
give the patentee any qualms, for it merely eases the work that the PTO can do of its own
volition. Such access does not in any way prejudice the patentee, as all of the
information that the ANDA filer gathered is presumably public. In essence, granting the
PTO access to such research is no different than PTO hiring in-house reviewers to
continuously review issued patents, and advise the Director if a reexamination ought to
be ordered. The PTO has such authority presently, although it chooses to almost never
exercise it.\(^{300}\)

The second change in Director’s authority to order reexamination is slightly more
significant. Under my proposal, the authority would be moderately expanded to permit

\(^{299}\) *Id.*
\(^{300}\) 35 U.S.C. § 303(a) (2006); MPEP § 2239.
reexamination not just on the basis of prior art, but on any basis that would raise new and substantial questions of patentability.  

While this would extend the overall vulnerability of patents to reexamination, it would not fundamentally change the nature or strength of the patentee’s rights. Furthermore, my proposal for extending the scope of reexamination proceedings is not limited to those instances where proceedings are a result of the Hatch-Waxman process. Rather, it is my view that the Director ought to be able to order a reexamination (and, if necessary, reject claims) whenever there is a substantial new question of patentability of whatever variety. 

If that were the case, again, the presence of a reverse settlement would not in any way change the Director’s authority or ability to reexamine a patent. The reverse settlement would simply serve as a triggering event for the Director to determine whether a substantial new question of patentability exists. Whether such a question exists though, will be determined based not on the fact that two parties reached a settlement, but based on patent’s compliance with the legal requirements of the Patent Act.

D. Amendments in Reexamination

Most of the patents that enter reexamination do not exit it in the same form as they entered it. Of the patents that enter reexamination, only a quarter exit with all the claims confirmed. Eleven percent of reexaminations result in all claims being cancelled. The vast majority of reexaminations – 65% – result in changes to the

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301 See supra Part V.A.


This tendency potentially presents a problem. If a patent subjected to a reexamination is neither fully confirmed nor fully cancelled, but rather reissued with different claims, it can be argued that the reexamination did not serve the purposes of the Hatch-Waxman Act, and merely replaced one questionable patent with another one. Since the amended claims would not have been reviewed for weakness and invalidity by any opposing counsel, there is a danger that these claims would be only marginally stronger than the original claims. This would result in no improvement over the current situation where a patentee is able to pay the challenger in order to forego the challenge and preserve a questionable patent.

While there is no perfect response to the above objection, several factors mitigate the seriousness of the problem. First, a reexamined patent, even if amended, would have gone through the examination process not once, but twice. This in and of itself significantly increases the odds that the final amended claims are valid. This is particularly true given that reexaminations are conducted by senior examiners who are more experienced and therefore presumably better in evaluating and assessing patent applications. An application that has gone through the rigorous reexamination process is so much less likely to be vulnerable to an invalidity challenge, especially if the reexamination evaluates not just novelty, but as I propose, full compliance with the requirements of the Patent Act. Second, the reexamination proceedings do not permit broadening of claims; rather, the patentee is only permitted to narrow the claims further. I do not propose to change this limitation, even as I am advocating for broadening the scope of reexamination. Since the claims can only be narrower in scope, and because

304 Id. These numbers do not seem to depend on who requested the reexamination (whether the patentee, the Director, or a third party).

305 See MPEP § 2236.
narrower claims of necessity sweep less prior art into their ambit, they will more likely survive a validity challenge.

Additionally, should additional protection against issuing dubious amended claims be desired, the reexamination procedure itself can be adjusted. The Patent Office could be required to permit third parties to comment on the reexamination proceedings. There already exists an opportunity for *inter partes* reexamination that in some way resembles adversarial trial proceedings. However, in the *inter partes* proceedings as currently constituted, only the patentee and the third party that requested the reexamination can submit information and arguments to the PTO. What can be done in the context of reexamination following a reverse settlement is to allow any interested member of the public to comment on the reexamination process. Much of the information is already publicly available through the PTO’s Patent Application Information Retrieval (PAIR) system. All that would be required is to permit the public to submit arguments to the PTO as to why the claims, even as amended, should not issue. If the examiner considers the arguments and issues the claims anyway, it would provide considerable evidence that the amended claims are indeed valid, and that the goals of Hatch-Waxman are satisfied. Similar approaches have been proposed for all patent examination proceedings. The resolution of a debate over whether all examination should be opened for public input is beyond the scope of this Article. However, opening the reexamination proceedings for public participation would lessen the concern (to the extent that such concern exists) that the patent reexamination procedure following a reverse settlement would be gamed in such a way as to maintain invalid patents in the public sphere.

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306 MPEP § 2232.
VII. Conclusion

Reverse settlements between pharmaceutical companies present a challenge to the goals of Hatch-Waxman Act. Settlements that just seek to insulate an invalid patent from challenge prevent consumers from benefiting from lower generic prices and retard innovation by others. At the same time, legitimate settlements are economically efficient and have the added benefit of easing the strain on a severely overburdened judicial system. Because some of the settlements may be beneficial, it makes little sense to adopt a blanket ban on the practice as has been proposed by some Congressmen. This is especially true given that many of these settlements involve various cross-licenses, making it extraordinarily difficult to determine which settlements would be legal and which would not be. Antitrust law is also an imperfect solution to the problem, as it either works a blanket ban on such settlements or requires collateral litigation over patent validity.

The Hatch-Waxman Act has worked well for many years because it used amendments patent law to fix a problem in patent law. Since its original enactment, a new problem of reverse settlement has arisen. Up until now, the courts, the executive, Congress, and academia have all tried to resolve the issue through the application of ill-fitting antitrust law. This approach is ill suited for what ultimately is a patent law problem. By expanding the scope of Patent Office’s reexamination authority, and by assigning the task of evaluating the ultimate validity of questionable patents to the agency with expertise in patent law, the goals of Hatch-Waxman Act and the ability of parties to
enter into beneficial and legitimate settlements will both be preserved. It is through this system that consumers of drugs and medical devices will derive the most benefits.