

REVERSE SETTLEMENTS AS PATENT INVALIDITY SIGNALS

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TABLE OF CONTENTS

I. INTRODUCTION	282
II. THE HATCH-WAXMAN ACT	286
<i>A. The Structure and Purposes of the Act</i>	286
<i>B. The Mechanics of the Hatch-Waxman Act</i>	290
III. REVERSE SETTLEMENTS	293
<i>A. Cardizem</i>	294
<i>B. Hytrin</i>	296
<i>C. Tamoxifen</i>	297
<i>D. Ciprofloxacin I</i>	299
<i>E. Ciprofloxacin II</i>	301
<i>F. Schering-Plough</i>	301
<i>G. Provigil</i>	303
IV. THE LEGISLATIVE, EXECUTIVE, JUDICIAL, AND ACADEMIC RESPONSE	305
<i>A. The Legislative Reaction</i>	305
<i>B. The Executive Reaction</i>	309
<i>C. The Judicial Response</i>	311
<i>D. The Academic Debate</i>	312
V. SOLVING A PATENT PROBLEM THROUGH PATENT LAW	318
<i>A. Patent Reexamination</i>	319
<i>B. Utilizing the Reexamination Process</i>	322
<i>C. The Proposed Procedure</i>	324
VI. RESPONSES TO COUNTER-ARGUMENTS.....	326
<i>A. Limited Reexamination Trigger</i>	326
<i>B. Non-infringement Paragraph IV Certification</i>	328

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<i>C. Undermining Settlements</i>	330
<i>D. Amendments in Reexamination</i>	331
VII. CONCLUSION	333

I. INTRODUCTION

Over the last decade, a new type of settlement emerged in litigation over patents covering pharmaceutical products. This phenomenon passed largely unnoticed in most other litigation contexts, but in the very specific world of pharmaceutical patent litigation, it has resulted in high-profile cases involving the Federal Trade Commission (“FTC”), the Department of Justice (“DOJ”), 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. Traditionally, the alleged trespasser on someone else’s rights pays the rights holder to settle the litigation. In these new settlements, however, it is the rights holder that pays the alleged trespasser. For these reasons, such settlements have been termed “reverse payment settlements” or simply “reverse settlements.”¹

In this Article, I propose a new approach and argue that 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,² the FTC,³ and a number of legislators⁴ 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 FTC⁵ — simply is not designed

1. See, e.g., David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1315 (2010) (referring to the agreements both as “reverse payment settlements” and “reverse settlements”); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 141, 156 (2010) (same). Sometimes these settlements are also referred to as “pay-for-delay” settlements, or “exit payment” settlements. See, e.g., C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 632 (2009); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 18 (2004).

2. See *infra* Part IV.D.

3. See *infra* Part IV.B.

4. See *infra* Part IV.A.

5. See, e.g., *In re Schering-Plough Corp.*, 136 F.T.C. 956, 968 (2003), *vacated sub nom. Schering-Plough Corp. v. FTC*, 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

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 the 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.⁶ On the other hand, by permitting the challenger to retain the exclusivity period irrespective of the litigation's outcome,⁷ the Act encourages the challenger to enter into a settlement agreement which would permit market entry prior to the 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.⁸

The patentee is also incentivized to settle on similar terms because a settlement assures monopoly rents for some defined time into the future.⁹ 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 earlier than what the settlement agreement would provide.¹⁰

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.”¹¹ On the surface, these settlements may look like traditional horizontal agreements between competitors — agreements that have long been held per se illegal

million”); FED. TRADE COMM’N., PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (recommending that Congress ban such settlements).

6. 21 U.S.C.A. § 355(j)(5)(B)(iv) (West 2011); see also *infra* notes 41–45 and accompanying text.

7. See *infra* note 61 and accompanying text.

8. See Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494–502 (2007) (defining reverse settlement agreements).

9. See Laura J. Grebe, Comment, *Generic Entry in a Rough Economy — Proposed Legislation May Ease Health Care Costs*, 14 MARQ. INTELL. PROP. L. REV. 167, 174–75 (2010) (citing *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209–10 n.24 (2d Cir. 2006)).

10. See James F. Ponsoldt & W. Hennen Ehrenclou, *The Antitrust Legality of Pharmaceutical Patent Litigation Settlements*, 2006 U. ILL. J.L. TECH. & POL’Y 37, 52.

11. Holman, *supra* note 8, at 495.

under the antitrust laws.¹² The thrust of the antitrust argument is that these agreements are detrimental to consumers because they allow the patentee to unjustifiably maintain monopoly pricing.¹³ 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.¹⁴ Consequently, the antitrust argument goes, reverse settlement agreements are not just horizontal restraints on trade as between the settling parties, but are in effect 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. These settlements serve to prevent market entry for generic manufacturers and therefore force consumers to pay higher, monopoly rents for longer periods than they would have had the suits gone to judgment and the generic manufacturers prevailed. On the other hand, if the patentee would have prevailed, then the consumers benefit from a reverse settlement, as it allows for the generic's entry prior to the expiration of the patent. Thus, consumers obtain lower, non-monopolistic prices earlier than they otherwise would have. It is difficult for antitrust law to distinguish between these two situations. To the extent that the antitrust approach could take this distinction into account (for instance, by applying the rule of reason analysis to the settlement), it would transform 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 settlements, such an approach would undermine the *raison d'être* for these settlements.

Additionally, the antitrust approach may undermine patent law uniformity, as presumably whatever findings a district court would make on 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 courts of appeals,¹⁵ which would then

12. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 905–08 (6th Cir. 2003) (holding that reverse settlements are “naked, horizontal restraint[s] of trade and, as such, *per se* illegal”).

13. See Sandoval, *supra* note 1, at 147 (stating the FTC's view “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”).

14. See Uché Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 249 n.223 (2005) (quoting FAMILIES USA, GETTING ACCESS TO GENERIC DRUGS: A TIMELINE (2002), available at <http://www.familiesusa.org/assets/pdfs/genericstimelinef9a4.pdf>).

15. See 28 U.S.C. § 1291 (2006). The Supreme Court has held that when patent law is relevant only to the defenses raised, the case does not “arise under” the patent laws, and

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. A different solution must then be used in order to differentiate between pro- and anti-competitive reverse settlements. This solution is found in the patent law itself.

Part II of this Article focuses on the structure, purpose, and mechanics of the Hatch-Waxman Act, the understanding of which is necessary in order to appreciate how the problem of reverse settlements arises. Part III discusses several leading reverse settlement cases, each of which has been challenged under antitrust law. This 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.

Part IV describes the response to the reverse settlement issue from the judicial, executive, and legislative branches. It discusses academic commentary and offers criticism of the proposals advanced thus far.

Part V presents a solution to the problem of reverse settlements by arguing that reverse settlements should trigger the Patent Office-conducted reexamination proceedings. Part V further outlines what conditions must be satisfied to order the patent into reexamination and what the scope of the reexamination should be.

Part VI identifies and addresses potential counterarguments to this approach, and Part VII concludes.

therefore is to be appealed to the regional circuit. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988). 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.* (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 14 (1983)) (internal quotation marks 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 was the strength of the patent; any appeals would be heard by the appropriate regional circuit court of appeals.

16. *See* 28 U.S.C.A. § 1295 (West 2011).

17. *See* S. REP. NO. 97-275, at 5 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 15 (stating that “[t]he creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of the law”).

II. THE HATCH-WAXMAN ACT

A. The Structure and Purposes of the Act

In 1984, Congress passed a new law that streamlined the approval process for generic drugs. This law 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 principal sponsors in the Senate and the House of Representatives.²⁰ The Act had several purposes. First, the Act sought to bring lower-cost generic equivalents of patented drugs to market on an expedited basis and thus make these drugs more widely available to the general public.²¹ On the other hand, the Act sought to provide adequate incentives to the manufacturers and developers of pioneer drugs.²² Finally, the Act, through encouraging litigation over the patents that covered these drugs, sought to clear the landscape of invalid patents

18. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

19. See, e.g., Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 727 (2005) (“In 1984, 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.’”).

20. See Joel Graham, *The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription?*, 84 WASH. U. L. REV. 429, 429 n.2 (2006) (“This Act is typically referred to as the Hatch-Waxman Act because of the congressional sponsors, Senator Orrin Hatch and Representative Henry Waxman.” (quoting Larissa Burford, Note, *In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 BERKELEY TECH. L.J. 365, 365 n.2 (2004)) (internal quotation marks omitted)).

21. See *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing Before the S. Comm. on Labor and Human Res.*, 98th Cong. 1 (1984) (statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor and Human Res.) (“On the one hand, lower drug prices — tens of millions of dollars a year in total savings — will flow from increased generic competition made possible by a new abbreviated new drug application which we will refer to as ANDA, for off-patent drugs approved after 1962.”); see also Ian Jaquette, Comment, *Merck KGaA v. Integra Lifesciences I, Ltd: Implications of the Supreme Court’s Decision for the People Who Matter Most . . . the Consumer*, 33 AM. J.L. & MED. 97, 101–02 (2007) (“Title I of the Act created an abbreviated new drug application . . . process designed to expedite the arrival of generic drugs to the pharmaceutical marketplace by amending the FDA approval process.”).

22. See 130 CONG. REC. 24,430 (daily ed. Sept. 6, 1984) (statement of Rep. Henry 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.”). As further explained by Jaquette:

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 manufactures and thereby ensure continued innovation in the pharmaceutical and medical device industries.

Jaquette, *supra* note 21, at 102.

by providing a “bounty” to generics firms that challenged the validity or enforceability of the patents covering brand-name drugs.²³

Prior to the passage of the Act, a generic drug manufacturer faced two hurdles in getting the drug on the market. First, the Food, Drug, and Cosmetic Act required the generic manufacturer 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.²⁴ The generic applicant could not rely on data already compiled by the brand-name manufacturer.²⁵ The Food and Drug Administration (“FDA”) then had to conduct its usual evaluation of the application in much the same way as when the pioneer drug was approved.²⁶ Second, under the Patent Act and case law interpreting the same, generic manufacturers were not permitted to use the pioneer drug as a template for designing their own generic equivalents. Such a

23. See WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., 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”) 27 (2005). As Schacht and Thomas put it:

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.

Id.; see also Elizabeth H. Dickinson, *FDA’s Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 199 (1999) (“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 extends to challenges to the infringement allegations. 21 U.S.C.A. § 355(j)(5)(B)–(C) (West 2011). However, successful challenges to validity or enforceability are especially important because these challenges 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, 332–33 (1971); *In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 536 F.3d 1343, 1349 (Fed. Cir. 2008).

24. See Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 371 (2010) (“Before Hatch-Waxman, the FDA also required generic manufacturers to conduct their own safety and efficacy studies”); Jeff Thomas, *Schering-Plough and In re Tamoxifen: Lawful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13, 18 (2007) (stating that prior to the passage of the Hatch-Waxman Act, “the generic manufacturer was required to undertake full clinical trials to prove safety and efficacy”).

25. Matthew Avery, Note, *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 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.”); 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 (“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.”).

use was considered to be actionable infringement.²⁷ Thus, the manufacturer of the generic drug was essentially forced to wait — or risk costly litigation — until the patent on the generic drug expired before even beginning to formulate its own equivalent, and then continue to wait while the FDA acted on the application to approve the generic.²⁸ This, of course, provided the patentee with a de facto extension of the patent's life by allowing the patentee to remain the 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 usually 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 both 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 a 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 the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*³³ In *Roche*, the court held that using the patented product to conduct bioequivalency experiments constituted infringement and could, consistent with

27. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 858 (Fed. Cir. 1984).

28. See Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 0018, ¶ 2, <http://www.law.duke.edu/journals/dltr/articles/pdf/2003DLTR0018.pdf> (“[U]ntil the early 1980s, manufacturers wishing to develop generic counterparts to patented drugs had no choice but to wait for the original patents to expire before they could begin the application process to obtain FDA approval, which significantly delayed the market entry of generic drugs.”).

29. See Joyce Wing Yan Tam, Note, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 540 (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.”).

30. Janet A. Gongola, *Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787, 816 (2003).

31. See 21 U.S.C.A. § 355(j)(2)(A)(iv) (West 2011).

32. See *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1325–26 (Fed. Cir. 2001). As the *Mylan* court explained:

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.

Id.

33. 733 F.2d 858 (Fed. Cir. 1984).

general rules of equity, be enjoined.³⁴ The Hatch-Waxman Act abolished that rule.³⁵ Under Section 271 of the Patent Act, it is no longer “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 a Federal law which regulates the manufacture, use, or sale of drugs.”³⁶ Thus, any experimentation with a patented drug that is undertaken for the purposes of submitting an ANDA is no longer considered infringement.³⁷ These two sections in combination were meant to spur the process of bringing lower cost generic drugs to market.³⁸

To counter-balance the benefit conferred on the generics, and to continue to promote the development of pioneer drugs, Congress enacted rules, as part of the Hatch-Waxman Act, 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.³⁹ Thus, the Act sought to eliminate the unwarranted de facto extension of the patent term stemming from the inability of the generic to enter 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.⁴⁰

The Act also encouraged generic manufacturers to litigate the validity, enforceability, and infringement of the patents covering brand-name drugs.⁴¹ The Hatch-Waxman Act provides that any generic manufacturer that successfully challenges any of those issues in litigation will enjoy a 180-day period of exclusivity.⁴² 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 from the

34. *See id.* at 865–67.

35. 35 U.S.C.A. § 271(e)(1) (West 2011).

36. *Id.*

37. *See id.*

38. *See supra* note 21 and accompanying text.

39. 35 U.S.C. § 156 (2006). 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.

40. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260–61 (Fed. Cir. 2008) (discussing the distortions and their elimination by the Hatch-Waxman Act).

41. *See* Steven W. Day, Note, *Leaving Room for Innovation: Rejecting the FTC’s Stance Against Reverse Payments in Schering-Plough v. FTC*, 57 CASE W. RES. L. REV. 223, 228 (2006) (“Through the Act, Congress sought to lower prices of prescription drugs by encouraging generic drug manufacturers to challenge patented brand-name drugs and enter the market.”); Sarah Sorscher, Note, *A Longer Monopoly for Biologics?: Considering the Implications of Data Exclusivity As a Tool for Innovation Policy*, 23 HARV. J.L. & TECH. 285, 296 (2009) (“The Hatch-Waxman Act encourages such challenges by rewarding the first generic firm to submit an ANDA challenging the patent.”); *see also* H.R. REP. NO. 98-857, at 71 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2681 (minority views of Mr. Bliley).

42. *See* 21 U.S.C.A. § 355(j)(5)(B)(iv) (West 2011).

first generic's market entry.⁴³ For the generics companies that successfully challenge existing patents, this provision is very lucrative,⁴⁴ often worth hundreds of millions of dollars.⁴⁵

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, this Part provides an overview of a typical litigation between manufacturers of generic pharmaceuticals and brand-name pharmaceuticals.

When the FDA approves any new brand-name drug for marketing, the manufacturer is required to submit to the FDA the patent number and expiration date of every patent that covers the brand-name drug being submitted for approval.⁴⁶ 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."⁴⁷ Whenever a generic manufacturer seeks approval for a drug via the ANDA process, it must certify that one of four conditions is met:

- (I) no patent related to the pioneer drug has been filed;
- (II) the relevant patent has expired;
- (III) the patent will expire on a certain date; or

43. See *id.*; see also Christopher S. Ponder, Comment, *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." (footnote omitted)).

44. 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. See Matthew J. Higgins & Stuart J. H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370 (2009) (noting that the 180 days of exclusivity is worth, on average, \$60 million per drug); see also Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 8 n.26 (2004).

46. 21 U.S.C.A. § 355(b)(1) (West 2011); see also Gongola, *supra* note 30, at 794.

47. See Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 638.

- (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug entity.⁴⁸

If the manufacturer makes the certification under Paragraphs (I)–(III), no issue of patent law arises, as either there is no valid unexpired patent in existence, or there is a patent, but the manufacturer of the generic is asking that 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 litigation of the underlying patent.⁴⁹

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.⁵⁰ The patentee then has forty-five days in which to respond.⁵¹ If the patentee chooses not to respond to the notification, the FDA can proceed to the approval of the ANDA application.⁵² 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 invalid, 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.⁵³ The Hatch-Waxman Act makes the filing of the ANDA a constructive act of infringement,⁵⁴ thus permitting the patent holder to sue for an injunction against the approval and marketing of the generic drug.⁵⁵

48. See 21 U.S.C.A. § 355(j)(2)(A)(vii).

49. John Fazzio, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property and Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POL’Y 1, 10 (2006) (“The filing of a patent infringement action by the brand name manufacturer is virtually guaranteed.”).

50. 21 U.S.C.A. § 355(j)(2)(B).

51. *Id.* § 355(j)(5)(B)(iii).

52. *Id.* However, the filing of a suit by the patentee is “virtually guaranteed.” See Fazzio, *supra* note 49, at 10.

53. See Fazzio, *supra* note 49, at 10.

54. 35 U.S.C.A. § 271(e)(2) (West 2011).

55. See *id.* § 271(e)(4) (discussing the injunctive remedy available). Recall that prior to the Hatch-Waxman Act, a patentee could sue as soon as the generic manufacturer began experimenting in order to produce a competitive product. See *supra* notes 27–28 and accompanying text. With the passage of the Act, this avenue for litigation was closed. See 35 U.S.C.A. § 271(e)(1). 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 pre-generic entry levels, even if the generic is ultimately withdrawn. See Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of “Authorized Generics,”* 62 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, FENWICK & WEST LLP, AUTHORIZED GENERICS: ANTITRUST ISSUES AND THE HATCH-WAXMAN ACT 1

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.⁵⁶ The stay remains in effect for thirty months or until the resolution of the lawsuit, whichever comes first.⁵⁷ As a result of the 2003 amendments to the Hatch-Waxman framework,⁵⁸ only a single thirty-month stay is available.⁵⁹ Once litigation is concluded in favor of the ANDA filer or once the ANDA application has been effectively approved as a result of the expiration of the thirty-month stay (whichever is later), the ANDA filer has seventy-five days to begin to market its product or it must forfeit its 180-day exclusivity period.⁶⁰ The exclusivity period is available to any first

(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”).

56. 21 U.S.C.A. § 355(j)(5)(B)(iii) (West 2011).

57. *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. Fazzio, *supra* note 49, at 10–11 (citing 21 U.S.C.A. § 355(j)(5)(B)(iii)). 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.A. § 355(j)(5)(B)(iii).

58. The Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”) of 2003, Pub. L. No. 108-173, §§ 1101–02, 117 Stat. 2066 (2003), amended the Hatch-Waxman Act to, *inter alia*, limit thirty-month stays, and to adjust the requirements for the exercise of the 180-day exclusivity period.

59. 21 U.S.C.A. § 355(c)(3)(C). 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 thirty-month stay. *See* FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 43–44 (2002) [hereinafter FTC, GENERIC DRUG ENTRY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. The MMA eliminated this possibility by limiting the NDA holder to a single thirty-month stay. *See* Natalie Pous, *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-month period is enough time to complete litigation, as the average length of a Hatch-Waxman patent case is twenty-nine months. S. Peter Ludwig et al., *Hatch-Waxman in the Federal Courts: From 1994–2004*, 31 DRUG DEV. & INDUS. PHARMACY 215, 221 (2005). This time does not include appellate review, which takes, on average, another year. *Id.* The expiration of the thirty-month automatic stay does not necessarily enable the generic manufacturer to launch the drug, as the NDA holder may seek a preliminary injunction against the ANDA filer. 35 U.S.C.A. § 271(e)(4)(B) (stating that “injunctive 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 or veterinary biological product”). Furthermore, studies show that generic companies are reluctant to enter the market absent a final decision in their favor, as that opens them up to financial liability. *See* FTC, GENERIC DRUG ENTRY, *supra*, at 22.

60. Liu, *supra* note 44, at 453. Liu further explains:

Under the new provisions, the 180-day exclusivity period is forfeited if the first ANDA filer fails to market the generic version by the later of: (1) seventy-five days after the effective approval of its application, or thirty months after it was submitted, whichever is earlier; or (2) seventy-five days after the date on which a court decision has held that the NDA holder’s patent is invalid or is not being infringed upon, a settlement has been approved by the court, or the NDA holder has withdrawn its patent information.

filer, regardless of success on the merits of a Paragraph IV claim.⁶¹ 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 patent litigation (which average \$5 million)⁶² are avoided, while the benefits are enjoyed.

III. REVERSE SETTLEMENTS

As with any litigation, settlement of patent suits is not unusual. Indeed, about 80% of such suits are settled.⁶³ The rate of settlement in the specific context of pharmaceutical patent litigation under the Hatch-Waxman Act is actually lower— 38%.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 the patentee to the infringer.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 preserving its patent monopoly. Furthermore, unlike usual patent litigation where the dispute touches on products that are already on or about to enter the market, Hatch-Waxman litigation occurs prior to the generic drug actually entering the market.

Id.

61. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (holding that success on the merits is not 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. Compare *id.* (requiring only the filing of Paragraph IV certification for 180-day exclusivity period) with MMA § 1102 (codified in 21 U.S.C.A. § 355(j)(5)(D)(i)(III)) (imposing forfeiture of 180-day exclusivity period upon withdrawal of certification, as of 2003). The MMA changed that and now requires forfeiture of exclusivity if the Paragraph IV certification is withdrawn. See Liu, *supra* note 44, at 453. This change in law, however, was not sufficient to preclude all reverse settlements. See *infra* Part IV.A.

62. See Higgins & Graham, *supra* note 45, at 370 (contextualizing the costs of challenging a patent in relation to the larger “potential payoff” of \$60 million in the first 180 days).

63. Matthew B. Zisk, *Mediation and Settlement of Patent Disputes in the Shadow of the Public Interest*, 14 OHIO ST. J. ON DISP. RESOL. 481, 489 (1999). Although this figure is an estimate only, and is “based on anecdotal evidence or on only a few studies,” it is largely in line with the settlement rate of other civil suits, which is about 85–90%. *Id.*

64. FTC, *GENERIC DRUG ENTRY*, *supra* note 59, at 16.

65. *Id.* at 17 (stating that nine out of twenty settled cases, or 45%, involved payments from the patentee to the generic). This number may be an underestimate as noted by the Second Circuit in *Ciprofloxacin II*, 604 F.3d 98, 109 (2d Cir. 2010) (noting that “there is evidence that the practice of entering into reverse exclusionary payment settlements has increased”).

Consequently, in the Hatch-Waxman litigation there are no damages (other than the cost of litigation for each party) to be had. Yet under a reverse settlement the patentee often pays amounts far exceeding the cost of litigation to the challengers.

While each settlement obviously has different terms, the general parameters are quite similar across all settlements. This Part outlines several settlements that have been subject to judicial challenges. The goal of this Part is not so much to describe every settlement in great detail, but to show the common features of reverse settlements.

A. Cardizem

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 and angina.⁶⁶ Hoechst Marion Roussel, Inc. held a patent directed towards the dissolution profile of Cardizem CD.⁶⁷ 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.⁶⁸ About a year after Andrx filed its initial application, the FDA issued preliminary approval and stated that final approval would issue once the thirty-month stay expired or the court ruled in favor of Andrx.⁶⁹

Almost immediately after the FDA issued the preliminary approval, Hoechst and Andrx entered into a settlement agreement.⁷⁰ The agreement provided that Hoechst (the patentee) would pay Andrx \$40 million per year until Andrx received a final favorable court ruling.⁷¹ 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 thirty-month stay expired prior to such a ruling.⁷² In other words, Andrx agreed to remain off the market even after receiving a final approval from the FDA (which would issue upon the expiration of the thirty-month period). Andrx also agreed not to waive its 180-day exclusivity period.⁷³

Several pharmaceutical companies challenged the settlement as a violation of the antitrust laws and argued that, but for the agreement

66. See *La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.)*, 332 F.3d 896, 901–02 (6th Cir. 2003).

67. *Id.* at 902. Hoechst also held a patent directed to the active ingredient in Cardizem (diltiazem hydrochloride); however, that patent expired in 1992. *Id.* at 901.

68. *Id.* at 902.

69. *Id.*

70. *Id.*

71. *Id.* at 902 n.3.

72. *Id.* at 902.

73. *Id.*

between Hoechst and Andrx, the generic version would have come on the market earlier, and that the agreement “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.”⁷⁴

The Sixth Circuit addressed the question of whether such an agreement was a per se antitrust violation.⁷⁵ It concluded that it was.⁷⁶ 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,”⁷⁷ 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 [Hoechst]’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.”⁷⁸ Because the court concluded that this was a classic horizontal agreement to restrain trade, it applied a per se rule and refused to consider any pro-competitive arguments advanced by Andrx and Hoechst.⁷⁹

The same Cardizem settlement described above was also subject to litigation in the U.S. Court of Appeals for the District of Columbia Circuit.⁸⁰ The D.C. Circuit found that a “payment flowing from the innovator to 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.”⁸¹ 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 was therefore in violation of the antitrust laws.⁸² The court concluded that the agreement was a per se violation of the Sherman Act.⁸³

74. *Id.* at 904.

75. *Id.* at 905–06.

76. *Id.* at 908.

77. *Id.*

78. *Id.* at 907.

79. *Id.* at 906–08.

80. *See* *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (D.C. Cir. 2001).

81. *Id.* at 809 (quoting David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 *FOOD & DRUG L.J.* 321, 335 (2000)) (internal quotation marks omitted).

82. *Andrx*, 256 F.3d at 810.

83. *Cardizem*, 332 F.3d at 915 (affirming the grant of “summary judgment [because] the defendants had committed a per se violation of the antitrust laws”).

B. Hytrin

At about the same time as the Cardizem settlement litigation in the Sixth Circuit, the Eleventh Circuit was considering *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁸⁴ This case involved settlement agreements between several generic companies and Abbott Laboratories, which held a patent on Hytrin, a drug used to treat hypertension and prostate hyperplasia.⁸⁵

Following the filing of an ANDA with a Paragraph IV certification by two generic companies, Abbott filed suits, eventually settling both cases.⁸⁶ Both agreements required Abbott to pay several million dollars in exchange for the generics forbearing from market entry until a specified date, until some other generics firm successfully brought a generic equivalent of Hytrin to market, or until a final unappealable ruling holding the patents in question invalid.⁸⁷ Each settlement thus postponed the date of entry beyond the 30-month stay, but did not end the litigation between the generics and Abbott. Additionally, the generics agreed not to waive their 180-day exclusivity period.⁸⁸

Ultimately, Abbott lost the suit when the Federal Circuit affirmed the judgment of invalidity during an interlocutory appeal.⁸⁹ This outcome would have resulted in termination of the agreements but for the fact that they were terminated earlier in response to an investigation by the FTC.⁹⁰

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 Section 1 of the Sherman Act.⁹¹ The Eleventh Circuit, in rejecting the per se approach, stated that “[i]f 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.”⁹² The court reasoned that because patents carry with them the right to exclude, any agreements

84. 344 F.3d 1294 (11th Cir. 2003).

85. *See id.* at 1298. Abbott’s patent was directed to crystalline forms of terazosin hydrochloride, which is the active ingredient in Hytrin. As was the case with Cardizem, there also existed a patent on the terazosin hydrochloride itself, but it had expired by the time the first ANDAs were filed. *Id.*

86. *Id.* at 1300–01. In both cases the generic companies conceded infringement and argued only that the patent was invalid. *Id.*

87. *Id.*

88. *Id.* at 1300.

89. *Id.* at 1301.

90. *Id.*

91. *Id.*

92. *Id.* at 1304.

that protect that right cannot be per se illegal, but must be analyzed in light of the patentee's right to exclude others from making, using, or selling the patented product.⁹³ 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."⁹⁴ After additional years of litigation the case ultimately settled.⁹⁵

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,⁹⁶ 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.⁹⁷

In response to Barr's Paragraph IV filing, Zeneca sued, but lost in the district court because the patent was ruled invalid, the consequence of intentional withholding of clinical test results.⁹⁸ While the appeal was pending in the Federal Circuit, Zeneca and Barr entered into a settlement agreement.⁹⁹ 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, attesting that it would not market its own version of tamoxifen until Zeneca's patent expired.¹⁰⁰ Additionally, the parties agreed that should another lawsuit challenging Zeneca's tamoxifen patents be filed and result in an unappealable judgment that its patents are either invalid or not enforceable, Barr could default to its Paragraph IV certification.¹⁰¹ 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 been had it prevailed in its own case.¹⁰² Pursuant to the settlement, the district court's judgment of unenforceability was vacated.¹⁰³

93. *Id.* at 1311.

94. *Id.* at 1310.

95. *United Wis. Servs., Inc., v. Abbott Labs. (In re Terazosin Hydrochloride Antitrust Litig.)*, No. 99MDL1317SEITZKLEIN, 2005 WL 2451960, at *6 (S.D. Fla. July 8, 2005) (approving the settlement).

96. *Joblove v. Barr Labs. Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 193 (2d Cir. 2006). Zeneca marketed its version of tamoxifen under the brand name Nolvadex. *Id.*

97. *Id.* at 190.

98. *Id.* at 193.

99. *Id.*

100. *Id.* at 193–94.

101. *Id.* at 194. This would, of course, permit Barr to reclaim its first filer status and with it the 180-day exclusivity period.

102. *Id.* Recall that Zeneca and Barr settled while Zeneca's appeal of the unfavorable district court judgment was pending in the Federal Circuit. This case was settled before the

Subsequently, three other companies filed ANDAs with Paragraph IV certifications to produce a generic version of tamoxifen.¹⁰⁴ However, because of Barr's first filer status, no other manufacturer was able to enter the tamoxifen market until Barr exhausted its exclusivity period.¹⁰⁵

While the various claims on Zeneca's patent validity continued to be litigated, consumers filed an antitrust challenge to the Barr-Zeneca 1993 agreement.¹⁰⁶ The plaintiffs alleged that the settlement agreement violated the antitrust laws because it enabled Zeneca's continuing monopolization of the market for tamoxifen by resurrecting a patent already adjudged to be invalid, thus stifling competition from other generic manufacturers.¹⁰⁷ Unlike the plaintiffs in *Valley Drug* and *Cardizem* litigation, though, the plaintiffs here did not push the theory that the settlements were per se illegal. Rather, they argued that the payments offered by Zeneca to Barr were "excessive" and therefore anti-competitive.¹⁰⁸

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 they are necessarily lawful."¹⁰⁹ Nevertheless, the court "doubt[ed] the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it."¹¹⁰ 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 finds 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 the antitrust laws.¹¹¹ 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, arguing for a less deferential totality-of-the-circumstances standard,¹¹² rather than the majority's standard of "absent an extension of the monopoly beyond the patent's scope . . .

Supreme Court decided *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.

103. *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (Fed. Cir. 1993) (unpublished table decision).

104. *Tamoxifen*, 466 F.3d at 194–95.

105. *Id.* at 195.

106. *Id.* at 196.

107. *Id.* at 196–97.

108. *Id.* at 208.

109. *Id.* (citation omitted) (internal quotation marks omitted).

110. *Id.* at 210.

111. *Id.* at 212–13 (internal quotation marks omitted).

112. *Id.* at 228 (Pooler, J., dissenting).

and absent fraud.”¹¹³ While Judge Pooler was not prepared to declare such settlements illegal per se — a theory that was not advanced by the plaintiffs — she argued that the case ought to be remanded to the district court for further fact-finding in light of the standard she proposed.¹¹⁴

D. Ciprofloxacin I

The Federal Circuit, which has near-exclusive jurisdiction over the 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 that held a patent on the active ingredient in ciprofloxacin, and Barr Laboratories.¹¹⁵ Bayer filed suit in response to Barr’s filing of ANDA with a certification that Bayer’s patent was both invalid due to obviousness and unenforceable due to the patentee’s inequitable conduct before the Patent Office.¹¹⁶

In a pre-trial settlement, Barr dropped its challenge and agreed to convert its Paragraph IV certification to a Paragraph III certification, in exchange for payments from Bayer totaling \$398.1 million, including a \$49.1 million initial payout.¹¹⁷ Following the settlement, Barr and Bayer entered into a consent judgment where Barr admitted infringement and the patent’s validity and enforceability.¹¹⁸

113. *Id.* at 213 (majority opinion).

114. *Id.* at 232 (Pooler, J., dissenting).

115. Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re Ciprofloxacin Hydrochloride Antitrust Litig.*) (*Ciprofloxacin I*), 544 F.3d 1323, 1327 (Fed. Cir. 2008). Ciprofloxacin is an antibiotic used to treat a variety of bacterial infections. The antibiotic was in the news in 2002 when several anthrax-laden letters were sent out to a number of U.S. officials. Ciprofloxacin, which Bayer markets under the trade name Cipro, is the only drug that can treat anthrax infection. See Jennifer A. Lazo, Note, *The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme Will Fail To Export Any Medicines or Save Any Lives*, 33 BROOK. J. INT’L L. 237, 248–49 (2007) (noting that Cipro is “the only anthrax antibiotic [approved by] the U.S. Food and Drug Administration”). Needless to say, the patent on this drug is quite valuable. See Robert H. Trudell, *Food Security Emergencies and the Power of Eminent Domain: A Domestic Legal Tool to Treat a Global Problem*, 33 SYRACUSE J. INT’L L. & COM. 277, 317 (2005) (“Bayer is reported to earn \$1 billion per year on Cipro.”).

116. See *Ciprofloxacin I*, 544 F.3d at 1328.

117. *Id.* at 1328–29 & n.5. Under a separate supply agreement, Bayer could supply Barr with Bayer-made ciprofloxacin or make quarterly payments to Barr. *Id.* at 1329. Bayer also entered into agreements covering Hoechst, Rugby, and Apotex, another generic drug manufacturer that is controlled by Barr’s principal shareholder. See *id.* at 1327–28.

118. *Id.* at 1329. In 1997, Bayer filed for patent reexamination with the Patent Office, during which some of the original claims were cancelled and some were amended, and *mutatis mutandis*, the patent was reaffirmed. Following the reissue, four more generic companies filed Paragraph IV certification on the reissued patent. Bayer sued each of the companies and prevailed in three of the suits, while the fourth one was dismissed when the company withdrew the Paragraph IV certification. See *id.*

In 2000 and 2001, several plaintiffs filed suit against Bayer alleging, inter alia, that Bayer's settlement violated the antitrust laws under the *Walker Process*¹¹⁹ 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."¹²⁰ 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."¹²¹

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."¹²² 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."¹²³ The court stated that the "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 validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."¹²⁴ Importantly, the Federal Circuit rejected the argument that one must "evaluate the strength of the patent in determining whether reverse payments are unlawful."¹²⁵ 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."¹²⁶

119. See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177–78 (1965) (holding that enforcement of a patent procured by fraud on the Patent Office may be a violation of the Sherman Act).

120. *Ciprofloxacin I*, 544 F.3d at 1330.

121. *Id.* at 1329.

122. *Id.* at 1333.

123. *Id.* at 1333 n.11.

124. *Id.* at 1336.

125. See *id.* at 1334–35.

126. *Id.* at 1337.

E. Ciprofloxacin II

In the part of the ciprofloxacin case that remained with the Second Circuit,¹²⁷ 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.¹²⁸ The panel, however, went to great lengths to disparage the reasoning of *Tamoxifen*.¹²⁹ 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.”¹³⁰ Despite the panel's invitation, the Second Circuit declined to reconsider its jurisprudence.¹³¹ Nonetheless, at least three judges on that court are now on record — through their opinion in this case — expressing their views that reverse settlements are likely illegal as a matter of antitrust law.

F. Schering-Plough

The government directly challenged a reverse settlement between a brand-name manufacturer and a generic in one case: *Schering-Plough Corp. v. FTC*, heard by the Eleventh Circuit in 2005.¹³² It is the reasoning of this case that was adopted by the Federal Circuit and the Second Circuit, in the *Ciprofloxacin I* and *Tamoxifen* cases, respectively.¹³³ Because of the government's involvement, this case also figures prominently in the debates over the propriety of reverse settlements.¹³⁴

The dispute in *Schering-Plough* concerned a coating for potassium chloride.¹³⁵ The pill was marketed under the brand name K-

127. See Ark. Carpenters Health & Welfare Fund v. Bayer AG (*Ciprofloxacin II*), 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 issues of patent law).

128. See *id.* at 106.

129. See *id.* at 108–10.

130. *Id.* at 110.

131. Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir. 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. The Second Circuit is notorious for declining to sit en banc even in the most extraordinary cases. See, e.g., Ricci v. Destefano, 530 F.3d 88, 89–90 (2d Cir. 2008) (Katzmann, J., concurring in the denial of rehearing en banc).

132. 402 F.3d 1056 (11th Cir. 2005).

133. See *Ciprofloxacin I*, 544 F.3d 1323, 1335–36 (Fed. Cir. 2008); Joblove v. Barr Labs. Inc. (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 202 (2d Cir. 2006).

134. A quick Lexis search conducted on March 26, 2011 revealed that this case was cited in 105 law review articles, 37 treatises, and 35 judicial decisions.

135. *Schering-Plough*, 402 F.3d at 1058. The active ingredient itself, potassium chloride, is a common salt and obviously unpatentable. *Id.* Schering, however, held a patent (with an

Dur and was used as a supplement for treatment of high blood pressure and/or congestive heart failure.¹³⁶ Two generics filed an ANDA certifying that Schering's patent on the coating was invalid and unenforceable,¹³⁷ and Schering sued for infringement.¹³⁸ Prior to trial, the parties entered into a settlement agreement, in which Schering agreed to multi-million dollar payments to generics in exchange for the generics' agreement to split the patent term with Schering and license to Schering some of their own intellectual property.¹³⁹ As expected, the generics agreed not to waive or transfer the 180-day exclusivity period.¹⁴⁰

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."¹⁴¹ The full Commission did not hold that the settlements were illegal per se; rather, it concluded that Schering paid the challengers in order to delay the entry of the generic products onto the market,¹⁴² and that such delay injures competition and consumers:

[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 arbitrary 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.¹⁴³

The Eleventh Circuit reversed the FTC's finding, holding that "the Commission manufactured a rule that would make almost any

expiration date in 2006) on the pill's coating that allowed for extended release of the active ingredient. *Id.*

136. *Id.*

137. *Id.* at 1059 n.2, 1060 n.5.

138. *See id.* at 1058–60.

139. *Id.* at 1083.

140. *See In re Schering-Plough Corp.*, 136 F.T.C. 956, 1084 (2003) ("[T]he settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.").

141. *Schering-Plough*, 402 F.3d at 1061. The FTC also claimed that Schering "monopolized and conspired to monopolize the potassium supplement market." *Id.*

142. *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. *Id.*

143. *Id.*

settlement involving a payment illegal,” directly contrary to the court’s opinion in *Valley Drug*.¹⁴⁴ The court concluded:

[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetries [sic] 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. 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.¹⁴⁵

G. Provigil

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

In early 2010, the U.S. District Court for the Eastern District of Pennsylvania considered a reverse settlement agreement between Cephalon — a holder of a patent on Provigil — and four generic companies.¹⁴⁶ Although the court’s opinion only addressed Cephalon’s motion to dismiss,¹⁴⁷ it is instructive of the court’s views on reverse settlements.

Cephalon’s patent did not cover the active ingredient in Provigil, but instead was directed to the particle size of the active ingredient.¹⁴⁸ Four generic manufacturers filed an ANDA for the generic version of Provigil, and all four certified that the patent was either invalid or would not be infringed.¹⁴⁹ Ultimately, Cephalon entered into a

144. *Id.* at 1075.

145. *Id.* at 1075–76 (footnote & citation omitted) (internal quotation marks omitted).

146. *See King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010).

147. *Id.* at 517.

148. *Id.* at 521.

149. *Id.* The MMA allows for multiple “first filers” to share the 180-day exclusivity period. *See* 21 U.S.C.A. § 355(j)(5)(B)(iv)(II)(bb) (West 2011) (defining “first applicant” as any applicant that submits a “substantially complete” application “on the first day on which a[nother] substantially complete application” was submitted); John M. Rebman, *Dr. Strange*

settlement with each challenger, involving large payments in exchange for an agreement that the generic would manufacture the active ingredient in Provigil and sell it back to Cephalon at a fixed price.¹⁵⁰ The agreements also called for a number of cross-licenses between Cephalon and each generic.¹⁵¹ Each of the generics agreed not to market their own version of Provigil until a certain agreed-upon date.¹⁵² As usual, the generics also agreed not to relinquish the 180-day exclusivity period.¹⁵³

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 that additional proceedings were in order.¹⁵⁴ It thus 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, rather than the Federal Circuit.¹⁵⁵ Thus, plaintiffs such as the FTC, who have little understanding of — or interest in — the intricacies of patent law,¹⁵⁶ will be litigating the case, and judges who have little experience in adjudicating patent disputes will be deciding it. This is far from an ideal outcome.¹⁵⁷

Thus, the basic parameters of a reverse settlement are these: In exchange for a payment of significant sums of money from the patentee to the challenger, the challenger agrees to forbear from entering the market. The challenger generally agrees to preserve and not transfer its 180-day 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. These licenses make it drastically harder to figure out whether the payments are being made simply to induce the generic to delay market entry, or whether they

Drug, or: How I Learned To Stop Worrying and Love Authorized Generics, 12 DEPAUL J. HEALTH CARE L. 159, 166–67 (2009).

150. *King Drug*, 702 F. Supp. 2d at 522–23.

151. *Id.*

152. *Id.* at 522.

153. *Id.* at 530.

154. *Id.* at 533–36.

155. *Cf. id.* at 534–35 (noting that similar appeals in *Valley Drug* went from the District Court to the Eleventh Circuit).

156. 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 the 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, it creates worse patent law outcomes.

157. Such an appellate route would run counter to the congressional intent of creating uniformity in patent law. *See supra* note 17 and accompanying text.

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 reverse settlements between generic and brand-name manufacturers increasing,¹⁵⁸ it is no surprise that the issue has not escaped the attention of politicians, judges, and academics. This Part reviews these groups' reactions 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 2001,¹⁵⁹ which required all settlements between generic and brand-name manufacturers involving agreements over “the 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 the FTC and the DOJ.¹⁶⁰ Ultimately, a version of this bill was incorporated into the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹⁶¹ The Act, however, conferred no new enforcement authority on either the FTC or the DOJ. Indeed, the only purpose of the bill seems to have been “to enhance the effectiveness and efficiency of the enforcement of the antitrust laws”¹⁶² which was to be accomplished “by providing timely notice.”¹⁶³ Given the consistent judicial rejection of the FTC's attempts to rein in 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”¹⁶⁴ beyond the pre-2003 status quo.

Other proposed remedies go much further. In the 109th, 110th, and 111th Congresses, Senator Herb Kohl (together with between four and nine co-sponsors from both parties) introduced the Preserve

158. *See supra* note 65.

159. S. 754, 107th Cong. (as reported by S. Comm. on the Judiciary, June 20, 2002).

160. *Id.* § 5(a)(2).

161. MMA, Pub. L. No. 108-173, §§ 1111–18, 117 Stat. 2066 (2003).

162. S. 754 § 3.

163. *Id.*

164. *Id.*

Access to Affordable Generics Act.¹⁶⁵ 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 not to research, develop, manufacture, market, or sell the ANDA product for any period of time.”¹⁶⁶ The 109th and 110th Congress versions of the bill contained no exceptions to the ban.¹⁶⁷ 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 reasonable litigation expenses” would not be covered by the prohibition.¹⁶⁸ Second, the settlements would be presumptively unlawful and anti-competitive, but the settling parties would be permitted to rebut the presumption “if the parties to such agreement demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement.”¹⁶⁹ 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

165. S. 369, 111th Cong. (as introduced in Senate, Feb. 3, 2009); S. 316, 110th Cong. (as introduced in Senate, Jan. 17, 2007); S. 3582, 109th Cong. (as introduced in Senate, June 27, 2006).

166. S. 369 § 3; S. 316 § 3; S. 3582 § 2.

167. S. 316 § 3; S. 3582 § 2.

168. S. 369, 111th Cong. § 3(d)(2) (as reported by S. Comm. on the Judiciary, Oct. 15, 2009).

169. *Id.* § 3(a)(2).

- (7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.¹⁷⁰

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 settlements.¹⁷¹ Representative Rush introduced an identical bill in the 111th Congress.¹⁷² These proposals would brook no exception to the flat ban on reverse settlements.¹⁷³ While most of 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 2010.¹⁷⁴ The provision, however, was removed in the Senate.¹⁷⁵

These legislative efforts, though mostly unsuccessful thus far, are predicated on several proposed congressional findings, some of which are debatable. For instance, the Waxman bill states that prohibiting settlements would ultimately result in “lower prices [and] greater innovation,”¹⁷⁶ 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.”¹⁷⁷ That is a debatable proposition, for if banning the settlements would simply result in longer, more protracted litigation, prices may well increase.¹⁷⁸ Additionally, innovation may suffer if companies are unable to protect their financial investments by avoiding the vagaries of litigation.¹⁷⁹ The

170. *Id.*

171. H.R. 1902, 110th Cong. (as introduced by Rep. Rush, Apr. 17, 2007); H.R. 1432, 110th Cong. [hereinafter Waxman Bill] (as introduced by Rep. Waxman, Mar. 9, 2007). Congressman Waxman co-sponsored Congressman Rush’s bill. H.R. 1902.

172. H.R. 1706, 111th Cong. (as introduced by Rep. Rush, Mar. 25, 2009).

173. *See id.* § 2.

174. *See* H.R. 4899, 111th Cong. §§ 4201–07 (2010) (House Amendment to the Senate Amendment), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4899eah.txt.pdf.

175. *Compare* Supplement Appropriations Act of 2010, Pub. L. No. 111-212, 124 Stat. 2302 (missing Title IV of the House bill), with H.R. 4899 §§ 4201–07.

176. Waxman Bill, *supra* note 171, § 2(a)(5).

177. *Id.* § 2(a)(11).

178. *See* Andrew Kopelman, Note, *Addressing Questionable Business Method Patents Prior to Issuance: A Two-Part Proposal*, 27 CARDOZO L. REV. 2391, 2403–04 (2006) (noting that the costs of the litigation are passed on to the public in the form of increased prices).

179. *See* 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 Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005))).

latest Kohl bill — which was adopted almost verbatim by the House¹⁸⁰ — also rests on questionable findings. That bill suggests that “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,”¹⁸¹ and that such agreements “*unduly* delayed the marketing of low-cost generic drugs.”¹⁸²

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 the NDA holder’s patent. It could be just as plausibly argued that such settlements advance the goals of the Hatch-Waxman Act, especially when the settlements permit generics to enter the market prior to the expiration date of a valid patent. 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 issue. Therefore, legislative proposals remain open to the same line of intellectual attack as the FTC’s position.¹⁸³ The approach proposed *infra* in Part V avoids this problem.

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 the Medicare Prescription Drug, Improvement, and Modernization Act, Congress passed two provisions affecting 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

180. Compare S. 369, 111th Cong. § 3(d)(2) (as reported by S. Comm. on the Judiciary, Oct. 15, 2009), with H.R. 1902, 110th Cong. (as introduced by Rep. Rush, Apr. 17, 2007), and Waxman Bill, *supra* note 171.

181. S. 369, 111th Cong. § 2(a)(6)(A) (as reported by S. Comm. on the Judiciary, Oct. 15, 2009).

182. *Id.* § 2(a)(6)(B) (emphasis added).

183. Of course, courts have rejected the FTC’s stance based on the law as it currently stands. 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, and does not address 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.

the exclusivity period if, inter alia, it withdraws the Paragraph IV certification.¹⁸⁴ Under this new rule, the generics in the Ciprofloxacin and tamoxifen settlements would have lost their exclusivity periods, thus making these settlements much less worthwhile than before 2003.¹⁸⁵

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.¹⁸⁶ In order to permit the policing of such agreements, Congress enacted a second provision — requiring the parties who enter into a reverse settlement to file copies of the agreement with the FTC.¹⁸⁷

The 2003 Act, however, does not eliminate reverse settlements.¹⁸⁸ Even the forfeiture provisions may be circumvented simply by parties structuring their settlements differently, such that the generic firm does not withdraw its Paragraph IV certification. Companies remain free to enter into settlements that “divide the life” of a patent while recognizing the patent’s validity, enforceability, and infringement.¹⁸⁹

B. 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 have come to divergent conclusions about the legality of reverse settlements. The FTC took a hard line, adopting an approach that would have made all such settlements illegal per se in all but name.¹⁹⁰ 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 11th Circuit.¹⁹¹ The FTC, however, continued to press its view in the Supreme Court, seeking certiorari in *Schering-Plough*, and in other courts of appeal.¹⁹² Despite being rejected in

184. 21 U.S.C.A. § 355(j)(5)(D)(i)(III) (West 2011).

185. Recall that the generic applicants in the Ciprofloxacin and tamoxifen settlements agreed to withdraw their Paragraph IV certifications and replace them with Paragraph III certifications. *See supra* notes 100, 117 and accompanying text.

186. 21 U.S.C.A. § 355(j)(5)(D)(i)(V).

187. MMA, Pub. L. No. 108-173, § 1112, 117 Stat. 2066 (2003).

188. *Cf. Ciprofloxacin II*, 604 F.3d 98, 109 (2d Cir. 2010) (noting that since 2005 there have been at least twenty reverse settlements).

189. 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 might not be required to withdraw the Paragraph IV certification.

190. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1061–62 (11th Cir. 2005) (describing FTC’s position); *see also supra* note 141 and accompanying text.

191. *Schering-Plough*, 402 F.3d at 1065.

192. *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (order denying certiorari). While the FTC sought certiorari, the DOJ, through the Solicitor General, opposed the

nearly every court, the FTC continues to adhere to this view.¹⁹³ 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.”¹⁹⁴ In the same statement, the Chairman also announced the FTC’s support for the congressional bills described in the preceding subsection.¹⁹⁵

On the other hand, the Antitrust Division of the DOJ until recently took a very different approach. When the FTC filed its petition for a writ of certiorari in *Schering-Plough*, the DOJ 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*.”¹⁹⁶

Recently, however, the DOJ executed 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 II* case,¹⁹⁷ and for the first time asserted that reverse settlements “should be treated as presumptively unlawful under Section 1 of the Sherman Act.”¹⁹⁸ 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

petition. Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), available at <http://www.justice.gov/atr/cases/f216300/216358.pdf>.

193. The FTC pressed its position in an amicus brief to the Federal Circuit. Brief of Amicus Curiae Federal Trade Commission, *Ciprofloxacin I*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097), available at <http://www.ftc.gov/os/2008/01/080129cipro.pdf>. The Federal Circuit rejected the FTC’s approach. *Ciprofloxacin I*, 544 F.3d 1323, 1337 (Fed. Cir. 2008). The FTC also filed amicus briefs in the Second Circuit. Brief Amicus Curiae of Federal Trade Commission, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F. 3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)), available at <http://www.ftc.gov/os/2010/05/051202amicuscarpentershealth.pdf>; Brief of Amicus Curiae Federal Trade Commission, *Joblove v. Barr Labs. Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2006) (No. 03-7641), available at <http://www.ftc.gov/os/2005/12/051202amicustamoxifen.pdf>. The Second Circuit also rejected the FTC’s views. *Ciprofloxacin II*, 604 F.3d 98, 105 (2d Cir. 2010); *Tamoxifen*, 466 F.3d 187, 208 (2d Cir. 2006).

194. Jon Leibowitz, Chairman, Fed. Trade Comm’n, Address at the Center for American Progress: “Pay-for-Delay” Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution) 1 (June 23, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

195. *Id.* at 5 (stating that the FTC “strongly supports legislation to eliminate pay-for-delay deals”).

196. Brief for the United States as Amicus Curiae, *supra* note 192, at 11

197. *Ciprofloxacin II*, 604 F.3d 98 (2d Cir. 2010).

198. Brief for the United States in Response to the Court’s Invitation at 10, *Ciprofloxacin II*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)), available at <http://www.justice.gov/atr/cases/f247700/247708.pdf>.

contemporaneous evaluations of the likelihood of an invalidity judgment.”¹⁹⁹ This position is still more generous to the settling parties than what the FTC would prefer, but it is a stark reversal from the previous position that essentially endorsed the Eleventh Circuit’s approach in *Schering-Plough*.

Additionally, it is likely that the DOJ position will continue evolving toward a more restrictive view. President Obama, during his service as a U.S. Senator, was a co-sponsor of Senator Kohl’s bill that sought to ban reverse settlements altogether.²⁰⁰ 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.²⁰¹ Given that the Obama Administration generally takes a much stricter view of what constitutes permissible conduct under antitrust laws than its predecessor,²⁰² 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.

C. The Judicial Response

Not much more needs to be said about the judicial response to reverse settlements beyond what was noted in Part III, *supra*. However, as more reverse settlements are entered into, more courts, at both the district and appellate levels, will have to wrestle with the antitrust issues such settlements raise. 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,²⁰³ possibly leading to further debate — and perhaps confusion.

199. *Id.* at 28 (citations omitted) (internal quotation marks omitted).

200. See S. 316, 110th Cong. (as introduced in Senate, Jan. 17, 2007). For a list of co-sponsors, see *Thomas*, THE LIBRARY OF CONGRESS, <http://thomas.loc.gov/home/LegislativeData.php?&n=Browse&c=110> (last visited May 6, 2011).

201. See Leibowitz, *supra* note 194.

202. See, e.g., *Corporate Reform in America: A Chill in the Boardroom*, THE ECONOMIST, Dec. 12, 2009, at 69–70, available at http://www.economist.com/node/15065509?story_id=15065509 (“[T]he Department of Justice has promised to be more aggressive in its enforcement of antitrust laws.”); Editorial, *Music Inc. Gets Bigger*, N.Y. TIMES, Feb. 9, 2010, at A26, available at <http://www.nytimes.com/2010/02/09/opinion/09tue2.html> (stating that the Obama administration’s “Department of Justice and the Federal Trade Commission have become more aggressive about questioning mergers and challenging monopolies and anticompetitive behavior”).

203. 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, the 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 Seventh Circuit), Amgen and Genentech are in California (in the Ninth Circuit), and other companies are similarly

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 lie Mr. Cristofer Leffler and Professor Keith Leffler, who argue that all reverse settlements should be per se illegal.²⁰⁴ According to 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 the 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.²⁰⁵

spread 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.

204. See Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, in ANTITRUST LAW AND ECONOMICS 475 (John B. Kirkwood ed., 2004).

205. *Id.* at 491; see also Herbert Hovenkamp et al., *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,” essentially adopting the FTC’s per se rule); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (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.²⁰⁶ Lemley and Shapiro argue that patents do not, as conventionally thought, grant “the right to exclude but rather a right to *try* to exclude.”²⁰⁷ According to this thinking, unless a patentee obtains a court order allowing him to exclude a competitor by proving that the competitor is infringing a valid patent, an agreement that excludes that competitor both enlarges the scope of the patent and increases harm to consumers.²⁰⁸ Lemley and Shapiro do suggest that agreements to delay entry unaccompanied by a reverse payment may indeed be pro-competitive,²⁰⁹ 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 the position espoused by Messrs. Leffler.

Professor Michael Carrier takes a somewhat more moderate approach.²¹⁰ His approach is very similar to the one proposed by the DOJ in its Second Circuit brief in the *Ciprofloxacin II* case. Professor Carrier argues that while a complete ban on reverse settlements is over-inclusive and prohibits lawful activity,²¹¹ allowing unchecked (or nearly unchecked) reverse settlements is under-inclusive and permits unlawful restraints on trade.²¹² 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,²¹³ but that the patentee be given an opportunity to show, by “introduc[ing] arguments that have been offered in the economic literature”²¹⁴ that the settlement appropriately “reflect[ed] an objective assessment of the patent’s strength.”²¹⁵ 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”²¹⁶ should “judicial experience demonstrate[] that these arguments [from the economic literature] do not in fact justify the payments.”²¹⁷

206. See Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75 (2005).

207. *Id.* at 75.

208. *See id.* at 93.

209. *See id.* at 93–94.

210. *See* Carrier, *supra* note 179, at 62.

211. *See id.* at 67–68.

212. *See id.*

213. *Id.*

214. *Id.* at 76.

215. *Id.*

216. *Id.*

217. *Id.*

Yet another approach is offered by Marc G. Schildkraut, who criticizes the “probabilistic patent” approach of Lemley and Shapiro as well as the per se analysis of the FTC.²¹⁸ 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.²¹⁹

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.²²⁰ 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.²²¹ 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 essentially to try the validity of the

218. Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

219. *Id.* at 1058 (footnote omitted).

220. *See id.* at 1052–55.

221. *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 Railroad 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* note 218, at 1057 (describing the doctrine).

patent — an approach that Schildkraut rejects.²²² 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 holding the very trial that the settling parties seek to avoid.

Professor Daniel Crane seeks to address the problem identified above.²²³ He also proposes an inquiry into the *ex ante* expectations of settling parties but suggests a tiered approach.²²⁴ 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.²²⁵ In the absence of a preliminary injunction, Crane argues that a court should take a “quick look” into the strength of the patentee’s case — akin to a preliminary injunction hearing — and approve a settlement if the court concludes that the patentee was likely to succeed.²²⁶ Presumably, most settlements in the Hatch-Waxman context would fall in the latter category despite the presence of a preliminary injunction. After all, in the Hatch-Waxman context, a 30-month preliminary injunction on FDA approval is automatic²²⁷ and does not reflect any judicial determination of the 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.”²²⁸ 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.²²⁹

Of particular relevance to the Hatch-Waxman settlements, Crane proposes that agreements that impose barriers to third parties’ ability

222. See Schildkraut, *supra* note 218, at 1054 (agreeing with the *Valley Drug* court that “after-the-fact analysis of a settlement . . . would undermine patent incentives”).

223. See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002).

224. See *id.* at 779–96.

225. *Id.* at 783–85.

226. *Id.* at 785–88.

227. See 21 U.S.C.A. § 355(j)(5)(B)(iii) (West 2011).

228. Crane, *supra* note 223, at 788.

229. *Id.* This is indeed the same argument advanced by Lemley and Shapiro. See Lemley & Shapiro, *supra* note 206, at 94. *But see* Thomas, *supra* note 24, at 37–38 (arguing that the existence of reverse payments does not necessarily raise doubts about patent validity).

to enter the market should receive enhanced scrutiny.²³⁰ 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” it, 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 during the 180-day period or from selling its exclusivity rights.

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 article. Under Crane’s proposal, a court would approve a settlement if it concludes that the patentee had demonstrated a likelihood of success on merits.²³¹ 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.²³²

As Schildkraut shows, reverse settlements may be pro-competitive even in the face of relatively low likelihood of success in litigation.

230. See Crane, *supra* note 223, at 792–96.

231. See *id.* at 783–88 (suggesting that the courts evaluate success on the merits either through the preliminary injunction proceedings or through the “quick look” proceedings).

232. Schildkraut, *supra* note 218, at 1054–55.

Under Crane's approach, though, such settlements are likely to be disallowed by the courts.

Some scholars, in particular Mark Lemley, Mark Janis, Herbert Hovenkamp, and Scott Hemphill, have recognized the difficulty with an 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 prevail.²³³ Although this approach is certainly theoretically interesting, I am skeptical that it offers much help. 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 per se illegal, even if the authors disclaim the per se approach. In response to this objection, Professor Hemphill makes a more narrow argument. According to Hemphill, any payment — whether a side deal as in the Provigil litigation, or a pure money exchange, or even merely an agreement allowing the first filer to retain exclusivity — results in a delayed market entry as compared to what would be achieved without payment.²³⁴ The problem is that all settlements involve some exchange of benefits, as Hemphill himself recognizes.²³⁵ If that alone were enough to condemn settlements, then very few would survive an antitrust attack.²³⁶ Ultimately, Hemphill's argument, much like that of Lemley, Shapiro, Hovenkamp, and Janis, is predicated on the idea that patent validity is merely “probabilistic.”²³⁷ 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.²³⁸ For these reasons, Hemphill's supposedly more nuanced approach is also, in my view, not up to the task of solving the reverse settlement problems.

Although the above discussion is not an exhaustive compendium of various academic views and approaches to the problem of reverse settlements, it is a fair representation of the divergent positions taken

233. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557 (2006) [hereinafter Hemphill, *Paying for Delay*]; Hovenkamp et al., *supra* note 205, at 1722 (“[T]he outcome of a settlement agreement that would otherwise produce an antitrust violation might be no more anticompetitive than the outcome of litigation.”).

234. See Hemphill, *Paying for Delay*, *supra* note 233.

235. See *id.* at 1576–77.

236. See *id.*; Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68, 68–69.

237. See Hemphill, *Paying for Delay*, *supra* note 233, at 1589; Lemley & Shapiro, *supra* note 206; see also Hovenkamp et al., *supra* note 205, at 1759.

238. See McDonald, *supra* note 236, at 71.

by some eminent scholars. This lack of agreement in academia, Congress, the courts, and the Executive Branch leads me to conclude 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,”²³⁹ it is equally true that “the essence of a patent grant is the right to exclude others.”²⁴⁰ Of course, to be legitimate, the exclusion must be only of a product that infringes a valid patent.²⁴¹ The question then ultimately turns on the validity of a patent, not on any payment from the patentee to the challenger. Even those 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.²⁴² The reason 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 could be an invalid patent.²⁴³ If the worry 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 both to promote innovation by extending the terms of the patents on pharmaceuticals and to promote competition from lower cost generic alternatives.²⁴⁴ 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.”²⁴⁵ Presuming, as canons of statutory construction require, that Congress legislated with full knowledge of the state of the law then extant,²⁴⁶ it follows that one of

239. *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948).

240. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

241. *See* Lemley & Shapiro, *supra* note 206, at 93.

242. Of course, if that were to occur, there would no longer be any need for such payments. Regardless, none of the reverse settlement critics have advanced the antitrust argument so far as to say that a hypothetical patentee with a judicially “confirmed” patent would be prohibited from paying a generic manufacturer whatever sums he wishes.

243. *See, e.g.*, Lemley & Shapiro, *supra* note 206, at 93.

244. *See supra* Part II.A.

245. *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892).

246. *See, e.g.*, *United States v. Wilson*, 290 F.3d 347, 356–57 (D.C. Cir. 2002) (“Congress is presumed to preserve, not abrogate, the background understandings against

the purposes for which 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. Some of the patents would likely be invalidated, thus serving the Hatch-Waxman Act’s “clearing” goal. Others would be upheld, and the entry of the generic drug would be delayed beyond the time that could have been agreed upon between the parties, thus failing the Act’s goals of increased competition and reduced prices. Simply put, the antitrust solution is 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.²⁴⁷ The presumption, however, can be overcome during litigation by the accused infringer.²⁴⁸ 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 PTO. Reexamination is exactly what it sounds like — an examination of the patent anew.²⁴⁹ The major difference between a district court trial and a reexamination by the PTO is that the patent does not enjoy any presumption of validity during a reexamination process.²⁵⁰ Rather, the reexamination departs from the same starting point as the original examination:

which it legislates. . . . Congress is presumed to be aware of established practices and authoritative interpretations of the coordinate branches.”).

247. 35 U.S.C. § 282 (2006).

248. See *Enzo Biochem, Inc. v. 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.” (citation omitted)).

249. See 35 U.S.C. § 305 (2006) (stating that “reexamination will be conducted according to the procedures established for initial examination”); *Ethicon, Inc. 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.’” (quoting *In re Etter*, 756 F.2d 852, 857 (Fed. Cir. 1985))).

250. *Ethicon*, 849 F.2d at 1427 (“In a reexamination proceeding, on the other hand, there is no presumption of validity . . .”).

[T]he 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 a preponderance of evidence²⁵¹

There are two types of reexamination procedures: *ex parte* reexamination²⁵² and *inter partes* reexamination.²⁵³ The major difference between the two procedures is that during an *inter partes* reexamination, the third party that requested the patent be reexamined can participate in the process and appeal an unfavorable decision to the Board of Patent Appeals and Interferences (“BPAI”), and then to the U.S. Court of Appeals for the Federal Circuit.²⁵⁴ In other words, the *inter partes* reexamination is in many ways similar to a proceeding in the district court and may be used in lieu thereof.²⁵⁵ 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. The following discussion thus focuses on the *ex parte* reexamination. However, the availability of an *inter partes* exam is important and will be discussed in Part VI.D, *infra*.

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.”²⁵⁶ The person must identify the prior art that he believes is relevant to the question of patentability and explain why the cited art raises a “substantial new question of patentability.”²⁵⁷ If the Director of the Patent Office determines that a “substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for

251. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

252. *See* 35 U.S.C. §§ 301–07 (2006).

253. *See id.* §§ 311–18.

254. *Id.* § 315(b). In an *ex parte* reexamination, only the applicant is entitled to appeal an adverse decision. *See id.* § 306.

255. *See id.* § 314 (describing the requirement of serving each document on the 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).

256. *Id.* § 302.

257. *Id.* § 303; *see also id.* § 302.

reexamination of the patent for resolution of the question.”²⁵⁸ The examination proceeds much like the initial examination, except it is generally conducted by senior examiners who were uninvolved with the original examination.²⁵⁹ Once the examiner makes a final decision, a patent owner may appeal any unfavorable ruling to the BPAI or the Federal Circuit (as he would have been able to do during the original examination).²⁶⁰ 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.²⁶¹

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.²⁶² “Such reexamination may be ordered at any time during the period of enforceability of the patent.”²⁶³ 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.”²⁶⁴ If the decision is made, the reexamination proceeds as any other reexamination would.

It is important to understand that reexamination is ordered only when there is a “substantial new question of patentability.” That is a threshold inquiry.²⁶⁵ The inquiry, however, is not limited to focusing on prior art that was unavailable to the PTO during the initial examination. The statute permits for reexamination “on the basis of any prior art.”²⁶⁶ 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

258. *Id.* § 304.

259. See MPEP § 2236 (8th ed. Rev. 8, July 2010).

260. 35 U.S.C. § 306.

261. 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.”); *id.* § 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.”).

262. See *id.* § 303(a) (“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 C.F.R. § 1.520 (2010).

263. MPEP § 2239 (8th ed. Rev. 8, July 2010).

264. *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, Note, *Harmonizing the Exclusionary Rights of Patents with Compulsory Licensing*, 50 WM. & MARY L. REV. 1395, 1407–08 (2009) (describing the Patent Office’s sua sponte reexamination and ultimate rejection of patents that were involved in the controversial Blackberry litigation).

265. See 35 U.S.C. §§ 303–04.

266. *Id.* § 302.

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.

B. Utilizing the Reexamination Process

The reason patentees choose to enter into reverse settlements with the accused infringers is because of a chance that at trial the patent may be found invalid.²⁶⁷ If a patentee had a 100% chance of winning in court, there would be no reason at all to settle,²⁶⁸ except in those cases where the cost of litigation itself exceeds the value of injunctive relief. 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.”²⁶⁹ Although courts have rejected an approach through which the size of the settlement would be considered an admission of the patent’s invalidity, they agree that the relative strength of the patent is one of the important considerations in deciding whether and on what terms to settle the litigation.²⁷⁰

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 require either the courts or administrative agencies to engage in post hoc evaluations of patents’ strengths or parties’ *ex ante* expectations. Instead, reverse settlements that involve payments of more than 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, that there exists in the minds of the parties a “substantial new question of patentability” of the patent in

267. See *supra* notes 9–10 and accompanying text.

268. See Graham, *supra* note 20, at 445 n.143; Hovenkamp et al., *supra* note 205, at 1758–59.

269. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309–10 (11th Cir. 2003).

270. See, e.g., Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1073–74 (“It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. . . . Assuming the patent is reasonably strong, and the parties then settled under this scenario, the money most probably would flow from the infringers to Schering. . . .”).

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-nonexistent patent, the market would become open to any other generic manufacturer that wished to enter it. All a generic manufacturer would need to do is file an ANDA with Paragraph I certification, certifying that no patent covers the drug in question.²⁷¹ Assuming that the generic would be able to satisfy the bioequivalence requirements,²⁷² nothing would stand in the way of the FDA approving the generic version and that version entering the market to the benefit of consumers.²⁷³ In this way, the consumer-protection purposes of antitrust law would be served. So too would be 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*²⁷⁴ 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."²⁷⁵ 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.

271. See 21 U.S.C.A. § 355(j)(2)(A)(vii) (West 2011).

272. See *id.* § 355(j)(2)(A)(iv).

273. 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 MMA. 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 MMA'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.A. § 355(j)(5)(D).

274. As discussed earlier, there is a provision of *inter partes* reexamination, but it need not be utilized in order to engage in the reexamination. See *supra* notes 253–55 and accompanying text.

275. See U.S. CONST. art. III, § 2.

C. The Proposed Procedure

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, 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 beneficial to the settling parties and to consumers, but do not betray any doubt on the part of the patentee about the patent's strength.²⁷⁶ 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" regarding the patents in suit. Additionally, the presence of a "substantial new question" is a statutory requirement for reexamination.²⁷⁷ Even the FTC, with its uncompromising position, realizes that some reverse settlements do not point to any doubts about patent validity.²⁷⁸

At the same time, judging the appropriateness of a settlement's 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 these considerations 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 cross-licenses that are part of the agreement should 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 the 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,²⁷⁹ albeit in a different context — presuming that every settlement above a certain amount is 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 enough substantial new questions

276. See Thomas, *supra* note 24, at 37–38.

277. 35 U.S.C. §§ 303–04 (2006).

278. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062 (11th Cir. 2005) (describing the FTC's position that settlements which do not exceed the cost of litigation are not anti-competitive, as long as such litigation costs are below \$2 million).

279. See *id.* (stating that FTC would presume all settlements over \$2 million to be in violation of antitrust laws); Hemphill, *supra* note 1, at 636.

of patentability to trigger the reexamination request.²⁸⁰ 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 anti-competitive settlement.²⁸¹ To police against that, I would suggest that a second-level presumption be created: that any reverse settlement involving a cross-licensing side deal also be presumed to raise a substantial new question of patentability if the payments under the side agreement exceed some specified amount.²⁸²

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 “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 a 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.”²⁸³ 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 must be prepared in good faith,²⁸⁴ would identify a relevant basis for invalidating the patent.

280. The actual dollar amount can be adjusted as needed if and when the average cost of litigation changes.

281. See Hemphill, *supra* note 1, at 632.

282. 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, *Paying for Delay*, *supra* note 233, at 1588–94. 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.* at 1560. The problem is that in such a 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.

283. 21 U.S.C.A. § 355(j)(2)(B)(iv)(II) (West 2011).

284. See *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 21 F. Supp. 2d 366, 375 (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

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 FTC.²⁸⁵ 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 on either party. 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 a full reexamination should be ordered.

In short, the system that I propose would utilize the 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, have identified as raising substantial new questions of patentability. As I describe in the following Part, my proposal would broaden the scope of reexamination, so that all questions of validity — not just those based on prior art — could be addressed.

VI. RESPONSES 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, this approach is not free of 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.²⁸⁶ In other words,

is applied in determining if one such as Schein had an objective good faith basis for such action.” (citation omitted)).

285. MMA, Pub. L. No. 108-173, §§ 1111–18, 117 Stat. 2066 (2003).

286. See Scope of Reexamination in Ex Parte Reexamination Proceedings, 37 C.F.R. § 1.552 (2010); MPEP § 2258 (8th ed. Rev. 8, July 2010).

reexamination covers only § 102 (anticipation)²⁸⁷ and § 103 (obviousness)²⁸⁸ 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),²⁸⁹ double patenting,²⁹⁰ or inequitable conduct²⁹¹ in front of the PTO during the original prosecution. None of these grounds are cause for reexamination in the PTO,²⁹² 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 should no longer matter *why* it did so. During the process it would be treated like every other patent application and subjected 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 Act permits correction of a patent through a reissue “[w]henver any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee

287. 35 U.S.C. § 102 (2006).

288. *Id.* § 103.

289. *Id.* § 112; *see, e.g.*, *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 943 (Fed. Cir. 2010) (affirming lower court finding that a patent was invalid due to lack of enablement).

290. *See, e.g.*, *Sun Pharm. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385–86 (Fed. Cir. 2010) (discussing the prohibition on double patenting).

291. *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.”).

292. MPEP § 2258 (8th ed. Rev. 8, July 2010) (“Issues other than those indicated in paragraphs (a) and (b) of this section [both dealing only with printed prior art] will not be resolved in a reexamination proceeding.”).

claiming more or less than he had a right to claim in the patent.”²⁹³ The patentee can correct a written description or enablement problem through a reissue.²⁹⁴ Moreover, until 1988, the PTO examined reissue applications for conformance with the duty of disclosure.²⁹⁵ This shows that the PTO is fully capable of addressing inequitable conduct issues in post-grant review.

The current statutory scheme governing reissue applications only permits the patent owner himself to request such proceedings.²⁹⁶ 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 can currently be reviewed in the reexamination proceedings. Congress is presently considering such an authority, albeit in a different context. 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).”²⁹⁷ If this same mechanism, together with resumption of review for compliance with the duty of disclosure, is adopted for the settlement 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 a shield against a 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.²⁹⁸ Submitting an ANDA with either claim puts the first entrant in the position of claiming the

293. 35 U.S.C. § 251.

294. See *In re Amos*, 953 F.2d 613, 618 (Fed. Cir. 1991) (noting that the reissue application was examined for compliance with the enablement and written description requirements, and that those requirements were satisfied).

295. U.S. PATENT & TRADEMARK OFFICE, PATENT AND TRADEMARK OFFICE IMPLEMENTATION OF 37 CFR 1.56, 1095 Off. Gaz. Pat. & Trademark 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 Patent Office has abandoned the practice and now treats as dispositive the applicant’s affidavit that the mistake sought to be corrected in the reissue process was not a result of a deceptive intent. MPEP § 1448 (8th ed. Rev. 8, July 2010) (explaining that “[t]he Office no longer investigates or rejects reissue applications under 37 CFR 1.56,” which imposes a duty of disclosure).

296. 35 U.S.C. § 251.

297. Patent Reform Act of 2009, S. 515, 111th Cong. § 5(f)(1) (as reported by S. Comm. on the Judiciary, Apr. 2, 2009) (emphasis added).

298. 21 U.S.C.A. § 355(j)(2)(A)(vii)(IV) (West 2011).

180-day exclusivity period.²⁹⁹ Yet, if the basis for the approval of the generic drug is only a finding of non-infringement, then the patent remains valid as against future entrants. If a Paragraph IV certification on the basis of invalidity is followed by a reverse settlement, there would be no advantage for subsequent entrants to challenge the patent, for they will not be entitled to the 180-day exclusivity period. Neither would 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. Such an outcome arguably 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. Even though the same consequences flow from certification of non-infringement and certification of invalidity, I suggest that the fundamental problem with reverse settlements is not a delay in the market entry of certain generic drugs, but that settlements may stifle innovation by permitting continued occupation of the public sphere by worthless patents.³⁰⁰ No such problem presents itself when the generic manufacturer does not challenge the validity of the patent, but rather certifies non-infringement only. Furthermore, it is likely that the majority of challenges contest validity rather than non-infringement.³⁰¹ Because any ANDA filer has to show that the generic drug it seeks to market is bioequivalent — 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 anti-competitive reverse settlements. At the same

299. *Id.* § 355(j)(5)(B)(iv)(I).

300. To be sure, the delay in market entry for lower cost generics 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. See Tracy L. Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930, 946 (“While it is reasonable to expect that a branded drug’s price would be higher than those of its generic competitors, branded firms are often able to maintain, or in some instances even to raise, their prices when confronted with generic entry into their market.”).

301. Although the collection and analysis of data on the types of Paragraph IV challenges being pursued is not within the scope of this Article, I intend to collect and analyze such data in a follow-up piece to the present Article.

time, the question of such certifications' frequency certainly bears more investigation.

C. Undermining Settlements

Another possible objection to my approach is that it would dissuade parties from entering into settlements, thus undermining the judicial policy of favoring out-of-court settlements.³⁰² 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.³⁰³ This practice suggests that the prospect of reexamination does not necessarily inhibit or undermine the conclusion of settlements between patentees and generic manufacturers. There is little reason to believe then that the mechanism I am proposing would change this dynamic.

Fundamentally, the threat of patent reexamination 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 upon concluding that there exists a substantial new question of patentability in light of prior art.³⁰⁴ All patents, including pharmaceutical patents, are subject to this threat of reexamination.³⁰⁵ The presence or absence of a settlement agreement does not affect the Director's ability to exercise 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. Access to this 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

302. See *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1072 (11th Cir. 2005) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.")

303. See U.S. PATENT & TRADEMARK OFFICE, *EX PARTE* REEXAMINATION FILING DATA 1 (2010) [hereinafter REEXAMINATION FILING DATA], available at <http://reexamcenter.com/wp-content/uploads/2009/08/2010-06-30-Ex-Parte.pdf> (noting that 34% of all requests are filed by the applicants themselves).

304. 35 U.S.C. § 304 (2006).

305. *Id.*

patentee, as all of the information that the ANDA filer gathers is presumably public. In essence, granting the PTO access to such research is no different than the 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 almost never chooses to exercise it.³⁰⁶

The second change in the Director's authority to order reexamination would be slightly more significant. Under my proposal, the authority would be moderately expanded to permit reexamination not just on the basis of prior art, but on any basis that would raise new and substantial questions of patentability.³⁰⁷ 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, to reject claims — whenever there is a substantial new question of patentability of whatever variety.³⁰⁸ 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 not based on the fact that two parties reached a settlement, but on the patent's compliance with the legal requirements of the Patent Act.

D. Amendments in Reexamination

Most of the patents that enter reexamination do not emerge from the process unchanged. Of the patents that enter reexamination, less than a quarter exit with all their claims confirmed, and twelve percent of reexaminations result in all claims being cancelled.³⁰⁹ The vast majority of reexaminations (65%) result in changes to the claims.³¹⁰ This tendency potentially presents a problem. If a patent subjected to a reexamination is neither fully confirmed nor fully cancelled, but

306. See *supra* notes 262–64 and accompanying text.

307. See *supra* Part VI.A.

308. Indeed, the currently pending Patent Reform Act would confer such power on the Patent Office, albeit limited to the first nine months post-issuance. Patent Reform Act of 2009, S. 515, 111th Cong. § 5(f)(1) (as reported by S. Comm. on the Judiciary, Apr. 2, 2009).

309. REEXAMINATION FILING DATA, *supra* note 303, at 2.

310. *Id.* These numbers do not depend significantly on who requested the reexamination — whether the patentee, the Director, or a third party.

rather reissued with different claims, the reexamination may not have served the purposes of the Hatch-Waxman Act, but merely replaced one questionable patent with another. 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. Such a situation would result in no improvement over the current condition 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. An additional examination inherently 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,³¹¹ and therefore presumably better at evaluating and assessing patent applications. An application that has gone through the rigorous reexamination process is much less likely to be vulnerable to an invalidity challenge, especially if the reexamination evaluates not just novelty, but full compliance with the requirements of the Patent Act, as I propose. 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. Since the claims can only be narrower in scope, and because narrower claims necessarily sweep less prior art into their ambit, they will more likely survive a validity challenge.

Furthermore, 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 ways 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. Any interested member of the public could be allowed to comment on the reexamination process following a reverse settlement. Much of the information is already publicly available through the PTO's Patent Application Information Retrieval ("PAIR") system.³¹² 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 then issues the claims anyway, it would provide considerable evidence that the

311. See MPEP § 2236 (8th ed. Rev. 8, July 2010).

312. See *id.* § 2232.

amended claims are indeed valid and that the goals of Hatch-Waxman are satisfied. Similar approaches have been proposed for all patent examination proceedings.³¹³ 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 any concern, to the extent that such concern exists, that the patent reexamination procedure following a reverse settlement might be gamed in such a way as to maintain invalid patents in the public sphere.

VII. CONCLUSION

Reverse settlements between pharmaceutical companies present a challenge to the goals of the Hatch-Waxman Act. Settlements that seek to insulate an invalid patent from challenge prevent consumers from benefiting from reduced 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 members of Congress. 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. Antitrust law is also an imperfect solution to the problem, as it either imposes 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 to patent law to fix a problem in patent law. Since its original enactment, the new problem of reverse settlement has arisen. Up until now, the courts, the Executive Branch, Congress, and academia have all tried to resolve the issue through the application of ill-fitting antitrust law. This approach is poorly suited for what ultimately is a patent law problem. By expanding the scope of the 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 the 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 would derive the most benefit.

313. See S. 23, 112th Cong. § 5 (as passed by Senate, Mar. 8, 2011) (providing for post-grant review that can be initiated by any member of the public on any invalidity grounds).