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Abstract

Reverse payment settlements in pharmaceutical patent litigation, also known as “pay for delay” settlements, are almost universally anticompetitive. Nonetheless, because of the current regulatory framework and a failure of courts to address the definition of patent scope, many of these settlements are upheld as legal, falling under a patent “exception” to antitrust liability. The patent “exception”, however, does not apply to pay-for-delay settlements, because paying to protect a patent is inherently beyond the scope of that patent. This note addresses the problem of reverse payment settlements and proposes a new comprehensive solution.

Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform

by WILLIAM J. NEWSOM*

Spawned and encouraged by the Hatch-Waxman Act, reverse payment settlements in pharmaceutical patent litigation, also known as “pay for delay” settlements, are almost universally anticompetitive. Nonetheless, because of the current regulatory framework and a failure of courts to address the definition of patent scope, many of these agreements are upheld as legal, falling under a patent “exception” to antitrust liability. However, the patent “exception,” while certainly a valid concern, does not apply to pay for delay settlements because paying to protect one’s patent is inherently beyond the scope of that patent. This article will address the problem, and propose a new and comprehensive solution.

I. Introduction

The Drug Price Competition and Patent Term Restoration Act of 1984, now known primarily as the Hatch-Waxman Act,¹ was intended to benefit consumers by allowing generic drug makers (“DMs”) to challenge the patents of pioneer DMs in a simple and

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¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e) (2000), 35 U.S.C. § 156 (2000), and 21 U.S.C. § 355(j) (2000)).

cost effective manner.² Further, it enabled generic DMs to piggyback on the Food and Drug Administration (“FDA”)-mandated drug testing done by the pioneer.³ The theory was that, if competition could be introduced into the prescription drug market by facilitating generic entry, drug prices would drop and consumers would better be able to afford quality healthcare. However, while the Act was noble in its purpose, and it succeeded in lowering drug prices in some cases, the Act has also created a perverse regulatory system, the manipulation of which can extend the patent monopoly owned by pioneer DMs.⁴ This unintended consequence is made worse by the fact that the regulatory scheme has cast a cloud of uncertainty over the classical intersection of antitrust and patent law, further blurring the lines between the two. By altering the normal incentive-based landscape of patent litigation, Hatch-Waxman has spawned agreements that would otherwise be *per se* antitrust violations to go forward unscathed, as a majority of courts have found them to be protected by patent law and the general policy of encouraging settlement of patent litigation, under almost any circumstance.⁵ The agreements spawned by this regulatory environment, generally referred to as reverse payment settlement agreements, are encouraged by the Hatch-Waxman Act’s regulatory regime.⁶ These agreements preserve the patentee’s monopoly power over a prescription drug market by making “exit payments” to generic DMs who have applied for FDA approval.⁷ That is, the pioneer suing the generic DM settles the case by paying the generic to cease litigation and agree not to compete in the market for the pioneer’s drug. Such payments are unquestionably anticompetitive, but have repeatedly been upheld as legal.⁸ The problem, which has been decried by members of Congress,⁹ courts,¹⁰ and many scholars,¹¹ has led to the

2. See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2000); 35 U.S.C. § 271(e)(2)(A) (2000) (“It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . .”).

3. 21 U.S.C. § 355(j)(2)(A)(ii)-(iv) (2000).

4. See, e.g., cases discussed *infra* Section II.B.

5. *Id.*

6. These type of payments are also referred to as “exit” and “exclusion” payments.

7. For an explanation of the dynamics of this type of agreement, see hypothetical *infra* at Section III.A.2.

8. See *infra* Section II.B.

9. See, e.g., 148 CONG. REC. 57,566 (daily ed. July 20, 2002) (statement of Sen. Hatch) (stating that he “find[s] these types of reverse payment collusive arrangements appalling.”).

proposition of a number of solutions and a split among circuits on the correct outcome of such cases.¹² Yet, thus far, the solutions have failed to create a consensus among the circuit courts, and none of the proposed legislation has passed.¹³

This Note will argue that a true solution to the problem posed by reverse payment settlements must involve a combination of judicial, administrative, and congressional action. Some positive steps have already been taken, such as the 2003 amendments embodied in the Medicare Prescription Drug, Improvement, and Modernization Act (hereinafter, "MMA"),¹⁴ which was intended to curtail some of the abuses of the Hatch-Waxman Act. Unfortunately, these amendments have largely failed,¹⁵ though they are a step in the right direction. For example, the fact that the Federal Trade Commission ("FTC") now reviews any reverse payment settlements, as they must be submitted

10. See *infra* Section II.B.

11. See, e.g., 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, 2 (2004) (arguing that reverse payment settlements should be banned); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *The Interface Between Intellectual Property Law and Antitrust Law: Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L.REV. 1719, 1727 (2003) (suggesting a presumption of illegality for reverse payment settlements in the Hatch-Waxman context, and limiting reverse payments in any case to litigation costs); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L.REV. 1789 (2003) (suggesting a slightly more lenient standard than the Hovenkamp article); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L.REV. 1553, 1596 (also suggesting a rebuttable presumption of illegality).

12. See *infra* Section II.B.

13. Compare *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899, 901 (6th Cir. 2003) (finding a *per se* antitrust violation), with *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 392 (2d Cir. 2005) (finding the agreement to be protected from antitrust liability by patent law). See also Preserve Access to Affordable Generics Act, S. 316, 110th Cong. § 3(2) (2007) (which would have barred settlement agreements where the "ANDA filer receives anything of value" and "agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time."); Press Release, Sen. Grassley, Kohl, Leahy and Schumer Introduce Bill to Stop 'Payoffs' That Delay Generic Drugs (June 27, 2006), available at <http://grassley.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressReleaseid=b292869c-4975-41a9-a6ad>.

14. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (effective Dec. 8, 2003).

15. See 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 (2008).

to the FTC and the Department of Justice (“DOJ”),¹⁶ ensures that such settlements will not go unnoticed, and will often be challenged if there is a legitimate antitrust concern.¹⁷ However, to be truly effective, the amendments require both a change in the predominant case law, as the current state of such decisions weigh in favor of allowing the reverse payment settlements, and a further, perhaps harsher amendment of the regulatory regime. Combined with FTC and private antitrust enforcement, the age of the reverse payment settlement can give way to a more pro-competitive, consumer-friendly era of generic drugs, one in which settlements promote earlier entry by generic DMs, thus passing the savings to consumers, rather than hoarding the monopoly profits and sharing them amongst horizontal competitors.¹⁸

This Note first analyses the current regulatory regime, and provides an extensive review of the most important case law in the area.¹⁹ Next, the Note discusses the scope of the problem and its roots, and the confusing question of the true scope of the patent.²⁰ Finally, the Note poses a multi-faceted solution, analyzing and critiquing some previous proposals before settling on this author’s recommendation.²¹

Finally, it should be noted that addressing the public interest in invalidating “bad” or weak patents, and protecting the interests of the consumer in antitrust and patent litigation are beyond the scope of this article.

II. Analysis of the Current Regime

In reviewing the current state of the law, it is important to analyze both the relevant statutes and the most relevant case law. This section will first present a short explanation of the history and context of the regulatory regime created by the Hatch-Waxman Act and its amendments. Next the section will analyze the relevant case

16. Medicare Modernization Act, *supra* note 14, § 1112.

17. In fact, the FTC challenged an agreement earlier this year in the D.C. District Court, filing suit against Cephalon for entering reverse payment settlements with four ANDA applicants. *See* Complaint for Injunctive Relief at 9, *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. Feb. 13, 2008).

18. *See, e.g.*, Hovenkamp et al., *supra* note 11, at 1762 (discussing the pro-competitive alternative of delayed entry for generics).

19. *See infra* Section II

20. *See infra* Section III

21. *See infra* Section IV

law discussing reverse-payment settlements at the circuit court level (with one notable exception in the Southern District of Florida). The case law interprets the conflicting purposes and effects of the Hatch-Waxman Act as it interacts with antitrust and patent law. The cases are resolved differently by the separate circuit courts, thus creating a circuit split, and exemplifying the two leading schools of thought on how to resolve these conflicts. Finally, the section addresses the current majority and minority rules drawn from the different Circuit Court decisions and offers some brief criticism.

A. Hatch-Waxman – A Brief Overview

To bring a new pharmaceutical product, referred to as a pioneer drug, to market, a pharmaceutical company must file a New Drug Application (“NDA”) with the Food and Drug Administration (“FDA”), and obtain approval.²² This process is exhaustive and expensive, involving extensive testing, including human clinical trials.²³ Once the FDA has approved an NDA, the pioneer DM can make and sell its drug.²⁴

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, which is now generally known as the Hatch-Waxman Act.²⁵ The purpose of the Act was two-fold: first “to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products,” and second, to enable “competitors to bring cheaper, generic copies of those drugs to market.”²⁶ To this end, the Hatch-Waxman Act allows generic DMs to avoid the expensive NDA approval process by filing an Abbreviated New Drug Application (“ANDA”). The ANDA filing allows the generic DM to obtain FDA approval upon a showing of bioequivalence.²⁷ A “bioequivalent” of a drug that has received NDA approval, essentially a copy or a different form of the same drug, is

22. See 21 U.S.C. § 355(a) (2000) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.”).

23. 21 C.F.R. § 312.23 (2005).

24. See 21 U.S.C. § 355(a) (2000).

25. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e) (2000), 35 U.S.C. § 156 (2000), and 21 U.S.C. § 355(j) (2000)).

26. *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990); see also H.R. REP. NO. 98-857, at 14-15 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647.

27. 21 U.S.C. § 355(j)(2)(A)(ii)-(iv) (2000).

known as a “generic.”²⁸ The ANDA process also requires certification that the generic drug will not infringe any patent listed in conjunction with an NDA because it falls within one of four categories: (I) there is no patent, or none on file with the FDA; (II) the patent(s) in question has expired; (III) the generic drug will not be marketed until the patent in question expires; or (IV) the patent in question is invalid or not infringed by the generic.²⁹

When a generic DM files an ANDA within the fourth category, called a paragraph IV certification (a “Paragraph IV ANDA”), the Hatch-Waxman Act defines that certification itself as an act of patent infringement.³⁰ A pioneer DM with an approved NDA then has forty-five days to sue the ANDA applicant for infringement. Otherwise the ANDA can be approved right away.³¹ However, if the pioneer sues the generic applicant within forty-five days, it triggers a thirty-month stay on FDA approval of the ANDA.³² The FDA can “tentatively approve” the ANDA,³³ but actual approval can only occur on the expiration of the stay or a district court finding of invalidity or non-infringement of the patent.³⁴

In order to incentivize generic challenges to weak patents, the first generic DM to file a Paragraph IV ANDA, and thus to risk expensive patent litigation with the pioneer DM, is rewarded with 180 days of market exclusivity upon generic entry of the market.³⁵ The FDA enforces this exclusivity by refusing to approve a subsequent ANDA for the same drug until the expiration of the 180-day exclusivity period.³⁶ Prior to 1998, the 180-day exclusivity was subject to a “successful defense” of ensuing patent litigation, but the rule now

28. In the words of the FDA, “[a] generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.” FDA, Office of Generic Drugs, <http://www.fda.gov/cder/ogd/> (last visited Mar. 30, 2009). Bioequivalence requires that the “rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.” 21 U.S.C. § 355(j)(8)(B)(i) (2000).

29. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2000).

30. 35 U.S.C. § 271(e)(2)(A) (2000) (“It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . .”).

31. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

32. *Id.*

33. *Id.* at § 355(j)(5)(B)(iv)(II)(dd).

34. *Id.* at §§ 355(j)(5)(B)(iii)(I)-(IV).

35. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

36. *Id.*

applies even without litigation.³⁷ The exclusivity period creates a duopoly, which the generic can use to garner a significant market share, while maintaining prices above the competitive level.³⁸

These provisions have been effective in promoting generic challenges to pioneer drugs,³⁹ but have also led to abuses of the system, by which pioneers are able to effectively delay generic entry even in the face of legitimate challenges.⁴⁰ For example, the first ANDA filer and the pioneer patentee can settle their lawsuit with a provision that the generic DM will not enter the market until a later date, often in exchange for a “reverse” payment from the patentee to the generic challenger.⁴¹ Thus, because the first filer does not market his product, the 180-day exclusivity period does not start, and further ANDAs cannot be approved. And while an agreement to pay a competitor not to enter the market is generally considered a *per se* violation of the Sherman Act,⁴² a majority of circuit courts have ruled that these agreements are protected as falling within the scope of the legal monopoly granted by a patent.⁴³

In response to criticism from members of Congress,⁴⁴ the FTC,⁴⁵ and even President Bush,⁴⁶ Congress enacted the MMA.⁴⁷ The MMA

37. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (overturning the FDA’s “successful defense” requirement for the 180-day marketing exclusivity).

38. See Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1 (Describing Barr’s successful challenge of Prozac, which led to Barr earning “revenue of about \$368 million from the new drug, or 31-percent of its total” during the first year it entered the market).

39. See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 10* (July 2002) (reporting challenges involving 130 drugs between 1984 and 2000); *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act” Before the S. Comm. on the Judiciary*, 108th Cong. 117 (2003) (statement of Timothy Muris, Chairman, FTC) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

40. FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, at i (July 2002).

41. Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 74 (2003).

42. See, e.g., *Klor’s, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207 (1959).

43. See *infra* Section II.B.

44. See, e.g., *supra* note 9.

45. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998).

46. See President George W. Bush, Remarks by the President on Prescription Drugs (Oct. 21, 2002), available at <http://whitehouse.gov/news/releases/2002/10/print/20021021-2.html> (proposing new FDA regulations to expedite generic drug approvals).

made significant changes to the Hatch-Waxman Act, including limiting use of the thirty-month stay to one per ANDA filer,⁴⁸ providing for forfeiture of the 180-day exclusivity period under certain conditions,⁴⁹ and requiring that reverse payment settlements and other potentially collusive types of agreements be filed with the FTC and the DOJ.⁵⁰ However, these provisions have been largely ineffective,⁵¹ though they are certainly a step in the right direction.

B. Decisions, Decisions, Decisions

To understand the extent of the problem, a detailed understanding of the most relevant case law is needed. The following case summaries are illustrative of the prevalence of reverse payment settlements and the regulatory problems that encourage them. Moreover, attention must be paid to the analyses undertaken by courts, as they reveal the best analysis, albeit through somewhat of a trial and error process.

Thus far, the Second, Sixth, Eleventh, and Federal Circuit Courts of Appeal have all ruled on antitrust challenges to reverse payment settlements of pharmaceutical patent infringement suits. The Sixth Circuit, in one of the earlier decisions, found such agreements to be a *per se* violation of the Sherman Act as not just an agreement in restraint of trade, but a naked horizontal restraint, which is always held to be *per se* illegal. Further, the Sixth Circuit rejected the notion that a naked horizontal restraint could be immunized from the antitrust laws by the mere existence of a patent. Nonetheless, the Eleventh, Second, and Federal Circuits have all rejected the *per se* treatment applied by the Sixth Circuit, and have applied some form of what now appears to be the accepted test: whether the agreement in question exceeds the scope of the patent. If the scope of the agreement and the scope of the patent are concentric, these courts have held, there is no antitrust violation. In some cases, these courts distinguished the Sixth Circuit decision by pointing out that the

47. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (effective Dec. 8, 2003).

48. 21 U.S.C. § 355(c)(3)(C) (2000) (essentially codifying *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 691 n.3 (E.D. Pa. 2004)).

49. *See* 21 U.S.C. § 355(j)(5)(D) (2000).

50. Medicare Modernization Act, *supra* note 14, § 1112.

51. *See generally* Avery, *supra* note 15. *See also* Hemphill, *supra* note 11, at 1571 (noting that in 2005 and 2006 a number of reverse payment settlements were filed with the FTC).

agreement in that case would apply to non-patented alternative generic drugs as well as those covered by the patent, and thus the agreements exceed the scope of the patent. Yet, notwithstanding these appellate decisions, at least one district court on remand nonetheless found a *per se* violation of the antitrust laws after applying the test dictated by the Eleventh Circuit.

Thus there remains a split in the Circuits, with a concurrence amongst a majority of circuits that have weighed in on these reverse payment settlements. And even amongst those in the majority, the Eleventh Circuit was not willing to go so far as to overturn the district court below when it found a *per se* antitrust violation in spite of the Eleventh Circuit's contrary prior ruling which established the "scope of the patent" test. Still, a true understanding of the case law requires an analysis of the five major decisions, as provided below, in chronological order.

I. In re Cardizem (Sixth Circuit 2003)

In one of the first major appellate decisions on the antitrust liability of reverse payment settlements of Hatch-Waxman pharmaceutical patent litigation, *In re Cardizem*,⁵² the Sixth Circuit found a *per se* violation of the Sherman Act.

In this case, Hoechst Marion Roussel ("HMR") made a heart drug, Cardizem.⁵³ A generic competitor of HMR's, Andrx, filed a paragraph IV ANDA seeking to market a generic version of Cardizem, claiming non-infringement of the listed patents.⁵⁴ Within the forty-five-day period HMR sued Andrx for infringement, enacting the thirty-month stay under Hatch-Waxman.⁵⁵ HMR's suit sought neither damages nor a preliminary injunction, and Andrx brought antitrust and misuse counterclaims.⁵⁶

After the generic competitor Andrx won tentative FDA approval for its drug, HMR and Andrx signed an agreement under which Andrx would refrain from entering the generic market, even after receiving FDA approval, but would hold on to its 180-day exclusivity period.⁵⁷ In return, HMR would make quarterly payments to Andrx

52. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

53. *Id.* at 896, 899, 901.

54. *Id.* at 902.

55. *Id.*

56. *Id.*

57. *Id.*

of \$10 million.⁵⁸ Further, HMR agreed to pay Andrx \$100 million per year, less interim payments, if the patent was judged not infringed on a final unappealable ruling, or if HMR dropped the infringement suit.⁵⁹ The agreement was terminated when Andrx formulated and got approval for a new version of the drug that didn't infringe, at which point HMR paid Andrx an additional \$50.7 million, bringing total payments to \$89.83 million.⁶⁰ Antitrust plaintiffs then sued HMR and Andrx for violations of §1 of the Sherman Act, alleging that the agreement prevented generic competition, thereby causing customers to pay higher prices for Cardizem.⁶¹ The district court granted the plaintiffs' motion for partial summary judgment that the agreement was *per se* unlawful.⁶² Notably, the district court found the agreements to be a naked horizontal restraint of trade.⁶³

Defendants appealed, and the Sixth Circuit affirmed, finding that "the agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation."⁶⁴ The court differentiated the payment here as straying from the patent right, writing that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."⁶⁵ The antitrust injury arose from the fact that the agreement also delayed the entry of other generic competitors by use of the 180-day marketing exclusivity period.⁶⁶

Of great importance to later decisions, especially in distinguishing this case, was the fact that the agreement here precluded Andrx from marketing other generic or bioequivalent versions of Cardizem not at issue in the pending litigation.⁶⁷ Yet,

58. *Id.*

59. *In re Cardizem*, 332 F.3d at 903.

60. *Id.*

61. *Id.* at 903-904.

62. *Id.* at 905. See *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 682 (E.D. Mich. 2000).

63. *In re Cardizem*, 332 F.3d at 905. See *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 682 (E.D. Mich. 2000).

64. *In re Cardizem*, 332 F.3d at 908.

65. *Id.*

66. *Id.* at 907.

67. See *id.* at 908 n.13 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 242 (E.D.N.Y. May 20, 2003)).

while later courts would rely on that fact to distinguish *In re Cardizem* from subsequent cases, the *Cardizem* court did not rely on that aspect of the agreement, but rather dismissed the idea that a naked horizontal restraint could be immunized from antitrust scrutiny simply because it arose in the context of a settlement of patent litigation.⁶⁸

2. Valley Drug (*Eleventh Circuit 2003*)

The *Valley Drug* case was a reversal of the trend towards *per se* illegality established by *In re Cardizem*. After the district court in *Valley Drug* found the agreements there to be *per se* illegal, the 11th Circuit reversed.⁶⁹ The case arose from settlements between Abbott Labs (“Abbott”), Geneva Pharmaceuticals (“Geneva”), and Zenith Goldline Pharmaceuticals (“Zenith”) regarding a hypertension drug.

Abbott manufactured and sold Hytrin, a hypertension drug with the active ingredient terazosin hydrochloride (“terazosin”).⁷⁰ Abbott had a number of patents filed with the FDA that covered various crystalline forms of terazosin and methods for its use.⁷¹ Geneva and Zenith both filed multiple paragraph IV ANDAs to sell generic versions of Hytrin in different forms.⁷² Abbott sued both for infringement.⁷³ Abbott then entered into agreements with both Zenith and Geneva, agreeing to pay them money to stay out of the market and to retain their rights to any 180-day marketing exclusivity period they may have had.⁷⁴ The Geneva agreement paid Geneva \$4.5 million a month, with the agreement to expire upon expiration of the patents, entry by another generic, or an unappealable Geneva win invalidating the patent.⁷⁵ The Zenith agreement paid Zenith \$6 million per quarter and was to expire upon expiration of the patent or the generic entry by another.⁷⁶ Both agreements entailed provisions that the generics would oppose any subsequent ANDAs filed by others.⁷⁷ The agreements ended when the FTC investigated them,

68. *In re Cardizem*, 332 F.3d at 908.

69. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1295 (11th Cir. 2003).

70. *Id.* at 1298.

71. *Id.*

72. *Id.* at 1299-1300

73. *Id.*

74. *Id.* at 1300-1301.

75. *Id.*

76. *Id.* at 1300.

77. *Id.*

resulting in a consent settlement agreement between the parties and the FTC, dissolving the agreements and resulting in a fine for the parties.⁷⁸

Plaintiffs filed suit and moved for partial summary judgment that the agreements were *per se* illegal.⁷⁹ The district court granted the motion.⁸⁰ The order issued by the district court characterized the agreements as geographic market allocations between horizontal competitors.⁸¹ Defendants filed an interlocutory appeal, claiming that the rule of reason is required and that the agreements were patent litigation settlements that must be analyzed under the rule of reason, unless they were shams.⁸²

Finding that horizontal market allocations are clearly anticompetitive, the Eleventh Circuit nonetheless distinguished this case “because one of the parties owned a patent.”⁸³ Next, the court found that the exclusionary effects of the settlement agreements may be within the potential exclusionary power of the patents in question, and thus, *per se* analysis is inappropriate.⁸⁴ The court then found that a subsequent finding of invalidity of a patent has no bearing on the antitrust analysis, because the reasonableness of an agreement in the antitrust context is evaluated at the time it is entered into.⁸⁵ Next the court disagreed with plaintiffs’ allegation that “reverse,” “exit,” or “exclusion” payments were not within the patent scope, emphasizing the importance of allowing settlements and the fact that the Hatch-Waxman statutes encourage such settlements.⁸⁶ Nonetheless, the court acknowledged that reverse payments could be “suspicious,” but that their presence alone does not demonstrate anticompetitive tendencies.⁸⁷ Finally, the court concluded by holding that any

78. *Valley Drug Co.*, 344 F.3d at 1301. See *Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000).

79. *Valley Drug Co.*, 344 F.3d at 1301.

80. *Id.*

81. *Id.* See *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340 (S.D.Fla. 2000).

82. *Valley Drug Co.*, 344 F.3d at 1303.

83. *Id.* at 1304.

84. *Id.* at 1305-1306 (noting that “the exclusion of infringing competition is the essence of the patent grant.”).

85. *Id.* at 1306-1307 (citing *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985)).

86. *Id.* at 1309-1311.

87. *Id.*

provisions of the agreements that have effects beyond the exclusionary effects of the patent may be subject to traditional antitrust analysis.⁸⁸

Thus, the Eleventh Circuit rejected the Sixth Circuit's *per se* analysis. In doing so, the Eleventh Circuit established that the appropriate analysis is to compare the provisions of the agreement to the exclusionary effects of the patent. Nonetheless, the Eleventh Circuit left the door open to a finding of antitrust liability on remand, albeit under a more thorough and stringent analysis.

3. *In re Terazosin (Valley Drug on Remand, S.D. Fla. 2005)*

On remand, the district court nonetheless found that the agreements were *per se* unlawful violations of §1 of the Sherman Act.⁸⁹ Applying the Eleventh Circuit's holding, and using Herbert Hovenkamp's suggested approach,⁹⁰ the court adopted a three-part test to determine whether the agreements violated the antitrust laws.⁹¹ Under the three-part test, the court first analyzed the exclusionary power of the patent, including the likely outcome of a preliminary injunction motion and/or a final adjudication in the underlying patent litigation.⁹² Next, the court analyzed whether, given the scope of the patent, the agreements were a reasonable implementation of the exclusionary power of the patent.⁹³ Finally, the court looked to whether any effects of the agreement that exceeded the power of the patent were subject to traditional antitrust analysis.⁹⁴ In adopting this framework, the court justified the review of the underlying patent litigation by reviewing the actual exclusionary right of the patent.⁹⁵ Most notably, the court quoted an article by Carl Shapiro, "theorizing

88. *Valley Drug Co.*, 344 F.3d at 1312.

89. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F.Supp.2d 1279 (S.D.Fla. 2005)

90. See Hovenkamp et al., *supra* note 11, at 1727 (suggesting that the analysis "ensure (1) that the parties did have a bona fide dispute, (2) that the settlement is a reasonable accommodation, and (3) that the settlement is not more anticompetitive than a likely outcome of litigation.").

91. *In re Terazosin*, 352 F.Supp.2d at 1295.

92. *Id.*

93. *Id.* at 1295-96.

94. *Id.* at 1296.

95. *Id.*

that a patent does not give the patentee the right to exclude, but the right to *try* to exclude by asserting its patent in court.”⁹⁶

Applying its new framework, the district court found that the evidence in the underlying patent litigation allowed only one conclusion—that a preliminary injunction motion would be denied and the patent would be held inval.⁹⁷ Having found that the only likely outcome of the litigation would be the invalidity of the patent at issue, the court then found that the market allocation agreements exceeded the scope of the patent and, as a naked horizontal restraint on competition, was *per se* illegal.⁹⁸ Accordingly, the court granted the plaintiffs’ renewed motions for summary judgment.⁹⁹

Here, on remand from *Valley Drug*, the district court was bold enough to tackle the question of whether the scope of the settlement agreement exceeded the exclusionary power of the patent. Although this approach was criticized in later circuit court opinions—finding evaluation of the underlying patent right impractical—this belabored opinion performed a full analysis. Thus, even in the face of a rebuttable presumption of validity, analysis of the true scope of the patent, including its strength and the likelihood that it will be upheld at trial, is possible. An although this may have been an easy analysis in light of the subsequent invalidity finding, it is nonetheless an important example that such an analysis is not beyond the ability of courts to undertake.

4. Schering-Plough (*Eleventh Circuit 2005*)

Meanwhile, the Eleventh Circuit revisited its holding in the *Valley Drug* case in yet another reverse payment settlement case, *Schering-Plough*. In this case, Schering had a patent on an extended-release coating for a potassium supplement, which it marketed as K-Dur 20.¹⁰⁰ Two competitors filed ANDAs to market generic versions

96. *Id.* (quoting Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003)). The court also quoted Herbert Hovenkamp’s article, stating that “[t]he legitimate exclusion value of a pharmaceutical patent [like the ‘207 patent] is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid.” *In re Terazosin*, 352 F.Supp.2d at 1296 (citing Hovenkamp et al., *supra* note 11, at 1761).

97. *In re Terazosin*, 352 F.Supp.2d at 1300-1307. The court also noted that the high reversal rates in patent cases did not protect the agreements. *Id.* at 1310.

98. *Id.* at 1307-1319.

99. *Id.* at 1319-1320.

100. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

of K-Dur 20, and Schering sued each of them for infringement.¹⁰¹ Both lawsuits settled during litigation, with agreements that set a time for generic entry, and gave payments from the patentee, Schering, to the proposed generics, Upsher and ESI. The Upsher agreement, signed the day before trial, provided that Upsher would stay off the market for K-Dur until September 1, 2001, five years prior to the expiration of the K-Dur patent.¹⁰² In addition, because Upsher demanded additional payment to “stay off the market,” Schering agreed to license five patents from Upsher, including one covering Niacor, a niacin supplement Schering had already sought to license from another company.¹⁰³ After Schering estimated the net present value of Niacor to be around \$250 million, it licensed the five Upsher patents in exchange for: “(1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales.”¹⁰⁴ The ESI settlement agreement allowed ESI to enter the market on January 1, 2004, but upon ESI’s demand also provided that Schering would pay ESI \$5 million for legal fees and another \$10 million, contingent upon ESI obtaining FDA approval for its generic.¹⁰⁵

The FTC filed an administrative complaint against the three parties in 2001, charging them with violations of section 1 and 2 of the Sherman Act, and section 5 of the Federal Tort Claims Act (“FTCA”).¹⁰⁶ An ALJ heard the case and dismissed the complaint, finding the agreements not illegal *per se*.¹⁰⁷ The ALJ found that the FTC failed to prove its case regarding monopolization, that their argument required invalidity or non-infringement of the patent to be proven, and that there was no evidence that the payments resulted in later entry dates and less competition.¹⁰⁸ The FTC then appealed to the full commission, which reversed the ALJ.¹⁰⁹ The FTC found that “the *quid pro quo* for the payment was an agreement to defer the entry dates, and that such delay would injure competition and

101. *Id.* at 1058-59, 1060.

102. *Schering-Plough Corp.*, 402 F.3d at 1059.

103. *Id.*

104. *Id.* at 1060.

105. *Id.* at 1060-61. Notably, Schering at the time did not expect ESI to obtain FDA approval by the required date. *Id.*

106. *Id.* at 1061.

107. *Id.*

108. *Id.* at 1061-1062.

109. *Id.* at 1062. *See* No. FTC 9297, 2003 WL 22989651.

consumers.”¹¹⁰ In addition, the FTC found the payments not to be legitimate consideration for the licenses obtained, and created a rule banning settlements involving a reverse payment in excess of \$2 million for litigation costs.¹¹¹ Schering appealed the decision to the Eleventh Circuit.

Reviewing for substantial evidence, the Eleventh Circuit relied on its decision in *Valley Drug*, finding neither the rule of reason nor the *per se* analysis to be appropriate in the instant case.¹¹² Rather, they applied *Valley Drug*, finding the proper analysis to be “an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”¹¹³ After cautioning against restraints on settlements, the court found both agreements to be within the scope of the patent.¹¹⁴ Finally, addressing anticompetitive effects, the court found the agreements to be a legitimate compromise and an expected byproduct of the Hatch-Waxman redistribution of risk, and noted that the ban proposed by the FTC would be unwise.¹¹⁵

5. Tamoxifen (*Second Circuit 2005*)

The Tamoxifen decision, despite ruling with the majority of courts that the key question was whether the scope of the patent exceeded the scope of the agreement, accentuated a number of the problems with the current regulatory regime, and found reverse payment settlement agreements to be “suspicious.”¹¹⁶ And while the decision was well reasoned at points and levied an excellent criticism of reverse payment settlements in general (albeit unintentionally), the majority failed to address the true scope of the patent, assuming generally that settlement agreements are within that scope so long as they are not based on “sham” litigation. Notably, the court even stated that paying to “protect” one’s patent from litigation is legal.¹¹⁷

110. *Schering-Plough Corp.*, 402 F.3d at 1062.

111. *Id.*

112. *Id.* at 1065.

113. *Id.* at 1066 (citing *Valley Drug*, 344 F.3d at 1312).

114. *Schering-Plough Corp.*, 402 F.3d at 1068-72. Notably the court found that the Schering-Upsher agreement covered the “identical reach of the ‘743 patent.” *Id.* at 1073.

115. *Id.* at 1072-1076.

116. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 392 (2d Cir. 2005).

117. *Id.* at 389 (“[w]e do not think that the fact that the patent holder is *paying to protect* its patent monopoly, without more, establishes a Sherman Act violation.”); *Id.* at

Tamoxifen was the most widely prescribed drug for the treatment of breast cancer.¹¹⁸ After Imperial Chemical Companies (the predecessor to AstraZeneca, hereinafter collectively “Zeneca”) obtained the patent for tamoxifen in 1985, along with FDA approval, Barr Laboratories (“Barr”) filed an ANDA requesting approval to market a generic version of tamoxifen.¹¹⁹ Barr amended its application in 1987 to include a paragraph IV certification.¹²⁰ Zeneca then brought an infringement suit within forty-five days, against Barr and its supplier.¹²¹ The district court ruled in favor of Barr, finding the tamoxifen patent invalid because Zeneca deliberately withheld crucial information from the Patent and Trademarks Office (“PTO”).¹²²

Zeneca appealed the decision to the Federal Circuit, but while the appeal was pending the parties entered into a confidential settlement agreement (the “Tamoxifen Agreement”).¹²³ In the Tamoxifen Agreement, Zeneca agreed to give Barr \$21 million and grant them a non-exclusive license to sell Zeneca manufactured tamoxifen under Barr’s label, and paid Barr’s supplier \$9.5 million, plus \$35.9 million over the next ten years.¹²⁴ In exchange, Barr amended its ANDA to a paragraph III certification, agreeing not to market its own generic version of Tamoxifen until the Zeneca patent expired.¹²⁵ Additionally, the Tamoxifen Agreement allowed Barr to revert to a paragraph IV certification upon a final and unappealable ruling that the tamoxifen patent was invalid or unenforceable.¹²⁶ The Tamoxifen Agreement was contingent on the Federal Circuit granting *vacatur* of the district court judgment, which it did upon a joint

392 n.22 (“we think that Zeneca was then entitled to *protect its tamoxifen patent monopoly through settlement.*”) (emphasis added).

118. *Id.* at 377.

119. *Id.*

120. *Id.*

121. *Id.*; *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 126 F.R.D. 467, 469 (S.D.N.Y. 1989).

122. *In re Tamoxifen*, 429 F.3d at 377 (citing *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F.Supp. 619, 626-627 (S.D.N.Y. 1992)).

123. *In re Tamoxifen*, 429 F.3d at 377.

124. *Id.*

125. *Id.*

126. *Id.* at 378.

motion by Barr and Zeneca.¹²⁷ After entering the agreement and obtaining *vacatur*, Barr began selling tamoxifen under its label, selling to wholesalers at a 15-percent discount, and quickly obtained an 80-percent market share.¹²⁸

Subsequently, three more paragraph IV ANDAs were filed by would-be generic DMs, and Zeneca succeeded in three corresponding infringement suits.¹²⁹ Meanwhile, Barr asserted its right to a 180-day marketing exclusivity period in order to prevent Mylan and Pharmachemie (two of the three companies that subsequently filed ANDAs) from marketing generic versions of Tamoxifen until after Barr had triggered and exhausted the exclusivity period.¹³⁰ The FDA affirmed Barr's right to its exclusivity period, and after Mylan and Pharmachemie challenged the FDA decision successfully in district court, the District of Columbia Circuit upheld the FDA decision, vacating the district court decision as moot, because Mylan and Pharmachemie had subsequently lost their patent suits against Zeneca, and were therefore precluded from marketing tamoxifen until the Zeneca patent expired.¹³¹ The tamoxifen patent expired on August 20, 2002, and generic DMs soon began marketing their own versions of tamoxifen.¹³²

Consumers and consumer groups soon filed a consolidated class action challenging the legality of the Tamoxifen Agreement.¹³³ The complaint alleged, *inter alia*, that the Tamoxifen Agreement facilitated Zeneca's continued monopolization of the tamoxifen market and prevented competition from other generic DMs of tamoxifen.¹³⁴ Defendants moved to dismiss under FRCP 12(b)(6),

127. *Id.*; See *Imperial Chem. Indus., PLC v. Heumann Pharma GMBH & Co.*, 991 F.2d 811, 1993 WL 118931, at *1, U.S. App. LEXIS 14872, at *1-*2 (Fed. Cir. Mar. 19, 1993) (unpublished opinion).

128. *In re Tamoxifen*, 429 F.3d at 378 n.9.

129. See *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. Apr. 10, 1997)(unpublished opinion); *Zeneca Ltd. v. Pharmachemie B.V.*, 2000 WL 34335805, at *15, 2000 U.S. Dist LEXIS 22631, at *51-*53 (D. Mass. Sept.11, 2000); *AstraZenecaUK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239, slip op. at 2-3 (W.D.Pa. Nov. 30, 2000).

130. *In re Tamoxifen*, 429 F.3d at 379-380.

131. *Id.* at 380.

132. *Id.*

133. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F.Supp.2d 1371 (2001) (order of the judicial panel on multi-district litigation transferring the consolidated cases to the Eastern District of New York).

134. See *In re Tamoxifen Citrate Antitrust Litig.*, 277 F.Supp.2d 121, 127-128 (E.D.N.Y. 2003).

and the district court granted that motion.¹³⁵ The district court stated that market-division agreements between a monopolist and a potential competitor would normally violate the Sherman Act, but there is an exception for a patent-holding monopolist.¹³⁶ The court drew the line between lawful and unlawful conduct by noting that a patent holder is prohibited from acting in bad faith “beyond the limits of the patent monopoly” to restrain or monopolize trade.¹³⁷ The court also distinguished the case from other cases, finding unlawful conduct by stating that this case ended litigation definitively, and thus removed any bar that would prevent others from bringing their own ANDAs.¹³⁸ The court also found that Barr’s assertion of its 180-day exclusivity right was protected under the *Noerr-Pennington* doctrine,¹³⁹ and that plaintiffs had suffered no antitrust injury, as the only harm was due to the legal monopoly that a patent holder possesses.¹⁴⁰

Plaintiffs appealed, and the Second Circuit Court of Appeals affirmed, with a dissent by Judge Pooler.¹⁴¹ Yet again, the majority here found that the issue turned on the scope of the patent, noting that “[i]f the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation.”¹⁴² The court did not, however, define the “scope of the . . . patent.”¹⁴³

135. *Id.* at 140.

136. *Id.* at 128-129.

137. *Id.* at 129.

138. See *In re Tamoxifen Citrate Litig.*, 429 F.3d 370, 381 (2d Cir. 2005).

139. The *Noerr-Pennington* doctrine refers to a trio of Supreme Court cases in which the court held that, absent an objectively baseless and bad faith “sham,” petitioning the government cannot be the basis for an antitrust violation. This includes lobbying, bringing lawsuits, and petitions to all departments of the government. See *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

140. *In re Tamoxifen*, 429 F.3d at 382.

141. *Id.*

142. *Id.* at 384.

143. Rather, they only noted that a patentee is “entitled to defend the patent’s validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.” *Id.* at 394 (quoting *Asahi Glass, Co., Ltd. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 992-993 (N.D. Ill. 2003)). Further, they found

After discussing the tension between the patent and antitrust laws and stressing the importance of encouraging settlement in all litigation, the court cautioned that rules restricting patent settlements might run against the grain of both the patent and antitrust laws by delaying innovation.¹⁴⁴ Next, the court engaged in an excellent review of the redistribution of risk in litigation created by the Hatch-Waxman Act, noting that “Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude.”¹⁴⁵ This discussion appears to have been the basis for the court’s decision to avoid “categorically condemning reverse payments” in settlement.¹⁴⁶ Nonetheless, the court then examined whether the payments here were excessive, and whether excessive reverse payments should be banned in general, but rejected both notions, again resting on the importance of allowing settlement in patent litigation, in whatever form it may take.¹⁴⁷ Then, addressing the Tamoxifen Agreement, the court found that “(1) the agreements did not bar the introduction of any non-infringing products;¹⁴⁸ (2) they ended all litigation between Zeneca and Barr, thus opening the field to other generic challengers; and (3) they did not foreclose competition because they allowed Barr to market Zeneca’s version of Tamoxifen.”¹⁴⁹ Finally, the court found that any actual harm to consumers was a result of the lawful monopoly power that inheres in a patent, and not from antitrust violations. In reaching this conclusion, the majority stressed the inability of courts to assess the likely outcome on appeal of the patent litigation, as well as the presumption of validity afforded to patents, finding the fact that the settlement was reached after a district court finding of invalidity to be “of little moment.”¹⁵⁰

that “the Settlement Agreement did not unlawfully extend the reach of Zeneca’s tamoxifen patent.” *In re Tamoxifen*, 429 F.3d at 397. Setting at least one certain boundary, however, the court did find that “an agreement to time the deployment of the exclusivity period to extend the patent’s monopoly power might well constitute anticompetitive action outside the scope of a valid patent.” *Id.* at 401.

144. *In re Tamoxifen*, 429 F.3d at 383-388.

145. *Id.* at 390-391 (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005)) (citation omitted).

146. *In re Tamoxifen*, 429 F.3d at 391.

147. *Id.*

148. Thus distinguishing the case from *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

149. *In re Tamoxifen*, 429 F.3d at 407 (Pooler, J., dissenting).

150. *Id.* at 388.

Judge Pooler, in a concise dissent, disagreed with the majority's standard—that, to violate the Sherman Act, an agreement must exceed the scope of the patent or arise from an objectively baseless “sham” lawsuit—and found a number of other errors in the majority's opinion.¹⁵¹ He criticized the majority's reliance on the presumption of validity of the patent and reluctance to assess the strength of the patent, especially after an initial invalidity determination, and opined that such an early ruling precluded needed discovery, finding the majority's pleading standard too stringent.¹⁵²

It is important to note that the majority addressed a number of the shortcomings of the Hatch-Waxman Act. First, they noted the excessive redistribution of risk, in which an ANDA filer risks only the costs of litigation, while the pioneer drug inventor risks losing its entire monopoly on a valuable drug. Second, they agreed that the reverse payment settlements were a likely outcome of that redistribution of risk. Third, they even agreed that the incentives created by Hatch-Waxman encourage the maintenance of a monopoly on a pioneer drug, as the benefit of maintaining that monopoly and sharing the profits often exceed the best possible outcome of litigation for a generic challenger.¹⁵³

Despite extensive analysis, the majority in *In re Tamoxifen* relied on the importance of settlement and the presumption that paying to protect a patent monopoly is conduct within the scope of the patent, in issuing their decision. The majority seemed simply to have acquiesced to the fact that Hatch-Waxman encourages these type of agreements, almost taking it as a signal of their immunity to antitrust challenges. Moreover, the majority points to the fact that settlement of the initial litigation opens the door for subsequent challenges by other ANDA filers, thus essentially ignoring the FDA approval-delaying, and thus monopoly-extending effects of the thirty-month stay provision and the 180-day exclusionary marketing grant to the first filer. And, once again, the court entirely failed to *analyze* whether the scope of the patent exceeds the scope of the agreement, but instead simply presumed that any non-sham settlement is covered by the exclusionary zone of the patent.

151. *Id.* at 408.

152. *Id.*

153. See the court's hypothetical, which, although “vastly oversimplified,” clearly illustrates the propensity for pioneers and generics to share monopoly profits instead of allowing generic entry. *Id.* at 393 n.24.

6. Ciprofloxacin (*Federal Circuit 2008*)

Lastly, in the most recent decision in the reverse-payment line, the Federal Circuit ruled with the majority of courts that the key inquiry is whether the scope of the agreement exceeds the scope of the patent. In this case, the court noted that any anticompetitive effects were within the exclusionary zone of the patent, thus essentially finding no “antitrust injury,” as the only injury asserted was simply due to the lawful exclusionary right that inheres in the patent. Once again, however, the court failed to address the extent of the scope of the patent.

Ciprofloxacin, or Cipro, is a widely prescribed anti-bacterial drug. Bayer received a patent on the drug, and FDA approval to market Cipro in 1987.¹⁵⁴ In 1991, Barr filed an ANDA for a generic version of Cipro, including a paragraph IV certification claiming that the Cipro patent was invalid or unenforceable.¹⁵⁵ Bayer then sued Barr for patent infringement in 1992, Barr counterclaiming for declaratory judgment that the patent was invalid.¹⁵⁶ Four years later, the parties entered into settlement discussions which resulted in a series of settlement agreements (the “Cipro Agreements”).¹⁵⁷ These agreements provided that Barr (and its co-defendants) would not challenge the validity or enforceability of the Cipro patent, Barr would convert its ANDA to a paragraph III certification, and Bayer would pay Barr \$49.1 million. In addition, Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments to Barr until December 31, 2003 (22 days after expiration of the patent, but five months before the FDA’s additional six months of marketing exclusivity would run).¹⁵⁸ Barr also agreed not to make or market *any* generic version of Cipro in the United States.¹⁵⁹ Bayer then filed for a reexamination of its patent, cancelled and amended certain claims, and reaffirmed its rights to the Cipro patent.¹⁶⁰ Four other generic

154. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1328 (Fed. Cir. 2008).

155. *Id.*

156. *Id.*

157. *Id.*

158. *In re Ciprofloxacin*, 544 F.3d at 1329. In total, Bayer paid Barr \$398.1 million. *Id.* at 1329 n.5.

159. *Id.* Notice that this could be read to include non-infringing alternatives, though the existence of such alternatives is unlikely given that the Cipro patent is directed to the actual compound, not to a formulation or a dissolution profile as in some other cases.

160. *Id.*

companies then filed paragraph IV ANDAs and Bayer prevailed in the subsequent patent litigation.¹⁶¹

The antitrust plaintiffs then filed a consolidated complaint in the Eastern District of New York, alleging that the Cipro Agreements were an illegal market allocation in violation of sections 1 and 2 of the Sherman Act.¹⁶² The court denied the plaintiffs' motion for partial summary judgment claiming that the agreements were illegal *per se*. The court then denied plaintiffs' subsequent motion for summary judgment regarding whether the agreements had anticompetitive effects.¹⁶³ However, the court granted the defendants' motion for summary judgment, employing a rule of reason approach, finding that the relevant market was Ciprofloxacin and that Bayer had market power, but any adverse effects on competition were within the exclusionary zone of the Cipro patent.¹⁶⁴ The absence of evidence that the Cipro Agreements created a bottleneck on challenges to the patent or otherwise restrained competition beyond the scope of the patent was fatal to the plaintiffs' case.¹⁶⁵ Notably, the court rejected the notion that the exclusionary power of the patent should be tempered by the patent's potential invalidity.¹⁶⁶

On appeal to the Federal Circuit ("FC"), the FC affirmed the district court's decision on all counts.¹⁶⁷ The FC first determined that the district court appropriately applied a rule of reason analysis, finding that, under Second Circuit precedent, the district court determined the relevant market, addressed the question of market power, and then found that the agreements did not restrain competition outside the exclusionary zone of the patent.¹⁶⁸ Next, addressing appellants assertion that Bayer simply sought to "insulate itself from competition and avoid the risk that the patent is held invalid,"¹⁶⁹ the court found that the district court did not err in

161. *Id.*

162. *Id.*

163. *Id.* at 1329-1330.

164. *Id.* at 1330.

165. *Id.* at 1330.

166. *In re Ciprofloxacin*, 544 F.3d at 1330. (once again rejecting *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F.Supp.2d 1279 (S.D.Fla. 2005)).

167. *In re Ciprofloxacin*, 544 F.3d at 1340-1341. Interestingly, jurisdiction was invoked because of a *Walker Process*-type state antitrust claim added to the amended complaint that was dismissed as preempted by federal patent law.

168. *Id.* at 1332.

169. *Id.* at 1333.

rejecting that argument.¹⁷⁰ Rather, the court found, the Cipro Agreements were within Bayer's rights as a patentee, as the "essence of the Agreements were to exclude the defendants from profiting from the patented invention."¹⁷¹ The court found that the "mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation."¹⁷² Next, the court reaffirmed that the appropriate question in this context is to determine "whether the agreements restricted competition beyond the exclusionary effects of the patent,"¹⁷³ and rejected the holding of *In re Cardizem* to the extent it held otherwise. Moreover, the court found that, in the absence of fraud on the PTO or sham litigation, the court need not consider the validity of the patent in an antitrust analysis of a settlement agreement involving a reverse payment.¹⁷⁴ Finally, the FC addressed the *Walker Process*-type state antitrust claim, affirmed the preemption ruling, and dismissed any notion that the agreement extended the patent by retaining Barr's 180-day exclusivity period.¹⁷⁵

7. *Current Majority Rules*

The majority of courts, including the Federal, Second, and Eleventh Circuits in *Cipro*, *Tamoxifen*, *Valley Drug* and *Schering-Plough*, have held that the proper inquiry in reverse payment settlements is to compare the scope of the patent to the scope of the settlement agreement. In the absence of fraud on the PTO or "sham" litigation, these courts have held that reverse payment settlements are not *per se* illegal if the scope and exclusionary effects of the settlement fall within the scope of the patent. The majority has rejected the argument that "paying for delay" is *per se* illegal, or that paying to protect a patent from challenges is outside the scope of the patent's protection. In short, these holdings have given great weight to the general policy encouraging settlement of patent litigation,

170. *Id.*

171. *Id.*

172. *Id.* at 1334.

173. *Id.* at 1335. (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005)).

174. *Id.* at 1335. (confirming rejection of the approach taken in *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F.Supp.2d 1279 (S.D.Fla. 2005)).

175. *In re Ciprofloxacin*, 544 F.3d at 1339

warning that restricting the right to settle will disincentivize patent litigation and may even undermine the incentive to patent.¹⁷⁶

In perhaps their greatest shortcoming, the majority has shied away from in-depth analysis of the true scope of the patent, rejecting any notion that the patent's scope depends on its actual validity. Instead, the majority has relied almost exclusively on the presumption of patent validity to justify upholding any settlement of patent litigation. In distinguishing the contrary holding in *In re Cardizem*, the courts almost universally point to the fact that the settlement in that case explicitly prevented Andrx from marketing non-infringing generic drugs, while failing to note that the reverse payments in their cases certainly discouraged development of non-infringing alternatives, and perhaps even included an unwritten understanding that the generic DMs would not market alternatives. Oddly enough, Andrx, the generic DM in *In Re Cardizem*, actually ended the agreement by reformulating its generic drug into a non-infringing form and obtaining FDA approval to market it. It seems hard to distinguish the case on the basis that the agreement foreclosed non-infringing generic entry, when in fact non-infringing generic entry was what brought the agreement to a close.

Thus, the current "majority" rule amongst the circuits essentially allows any reverse payment settlement, so long as it is expressly limited to the patented drug and does not involve fraud on the PTO or "sham" litigation.

8. *Current Minority Rule*

The minority rule is, unfortunately, not much better than the majority rule. While the *Cardizem* court rightly found a *per se* violation of the antitrust laws, the case does deserve to be distinguished from the others. *Cardizem* failed to focus on the correct inquiry, comparing patent scope to the exclusionary effect of the settlement.

In stark contrast is the *In re Terazosin* case, the *Valley Drug* case on remand to the district court. The district court there was the only court brave enough to undertake an extensive analysis of the true scope of the patent. The court then compared the scope of the patent to the scope of the settlement, and determined the correct outcome. As suggested by Hovenkamp, Janis, and Lemley, reverse payment settlements would be *per se* illegal absent the existence of a

176. See, e.g., *In re Tamoxifen Citrate Litig.*, 429 F.3d 370, 383-388 (2d Cir. 2005).

patent, a fact also expressly recognized by almost every court. Thus, a true rule of reason analysis is not proper.¹⁷⁷ Rather, these otherwise *per se* agreements should be analyzed first to determine whether they exceed the exclusionary power of the patent, and then under a more succinct *per se* analysis if any part of the settlement exceeds the exclusionary power of the patent.¹⁷⁸

Thus, while even the district court in *Cardizem* used the wrong approach (though it probably reached the right outcome), the combination of the majority's inquiry, with the minority's emphasis on the legality of the agreement outside the patent litigation context, should result in the correct analysis. This analysis was undertaken by the district court in *Terazosin*, and though it may not have been perfect, as the majority may be correct in discouraging a full inquiry into the likely outcome of the patent litigation, it was on the right track.¹⁷⁹ The true problem, however, lies not only in the judicial analysis of the problem, but in the nature of the Hatch-Waxman Act itself. A comprehensive solution is needed.

III. The Root of the Problem

As stated above, the problem at the root of these reverse payment settlements is multi-faceted, and requires understanding of the effects of the Hatch-Waxman Act, a proper analysis of the antitrust and patent questions in court, and ardent enforcement by the FTC/DOJ and private litigants. This section will first explore how the regulations in place create a re-allocation of risks and incentives in making both pioneer and generic drugs. By using hypothetical examples, this section will also show how the new risks and incentives created by the Hatch-Waxman Act have created the current problem of reverse-payment settlements. Next, this section will address the pressing question of the true scope of the patent. If indeed the majority of courts are correct in their interpretation that reverse-payment settlements in the pharmaceutical context violate antitrust law only if the agreements exceed the scope of the patent, then we must understand the true scope of the patent. The key inquiry here, in this author's opinion, is whether paying a challenger to drop a patent lawsuit, at least in the Hatch-Waxman context, is within the

177. See Hovenkamp et al., *supra* note 11, at 1730.

178. *Id.*

179. It should be noted that Judge Pooler's dissent in the *Tamoxifen* case called for the same analysis. See *In re Tamoxifen*, 429 F.3d at 407 (Pooler, Judge, Dissenting).

normal scope of the patent itself, or is a means of protecting a weak patent from challenge. If such a payment is in fact outside the scope of the patent, then reverse-payment settlements of the type illustrated in the above case law are not protected by patent law, and are subject to antitrust liability.

A. A Perverse Inversion of Incentive

The regulatory root of the problem lies in the perverse redistribution of incentives created by the Hatch-Waxman Act. The statute encourages the division of markets by settling patent litigation, and maintenance of a patent monopoly creates a pot bigger than the expected combined profits of market entrants if the patent is invalidated.¹⁸⁰ It thus incentivizes the parties to settle, and gives generic DMs the upper hand in negotiating a settlement.¹⁸¹ As illustrated by the hypothetical below (reflected in a similar hypothetical in *Tamoxifen*),¹⁸² Hatch-Waxman redistributes litigation risk and allows nearly cost-less generic market entrance upon patent invalidation, thereby creating a perverse system that encourages the continuance of monopoly pricing on patented drugs through the end of the patent's life. This benefit creates a windfall for generics, protects bad patents, and in the end, harms only one party: the consumer. The result is that the system in place, which was created to lower drug prices by encouraging generic entrance,¹⁸³ is deeply flawed.¹⁸⁴

1. *Reallocating Risk*

As stated by the Second Circuit in *Tamoxifen*, Hatch-Waxman reallocates the risk inherent in patent litigation.¹⁸⁵ Hatch-Waxman immunizes the preparation of an ANDA from infringement liability and makes the filing of an ANDA an act of infringement.¹⁸⁶ Hatch-Waxman thus allows an ANDA filer to incite patent infringement litigation without putting itself at risk of incurring damages. The

180. See *In re Tamoxifen*, 429 F.3d at 393 n.24.

181. *Id.*

182. *Id.*

183. See *supra* note 26 and accompanying text.

184. See, e.g., Avery, *supra* note 15.

185. See generally *In re Tamoxifen*, 429 F.3d at 390-391.

186. See generally Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e) (2000), 35 U.S.C. § 156 (2000), and 21 U.S.C. § 355(j) (2000)).

pioneer DM, by contrast, risks losing its monopoly on the drug market by filing an infringement action because, in doing so, it will expose its patent to potential invalidation. Thus, while both parties will incur substantial litigation costs, the ANDA filer has little else to lose,¹⁸⁷ but the pioneer DM could lose billions of dollars in revenue upon an unfavorable outcome.¹⁸⁸ This is a complete inversion of the incentives in a normal infringement action, where the infringer has a substantial risk of loss (in the form of damages for infringement and an injunction on the infringing activity), and the patentee stands to gain more and lose less (by eliminating a competitor and earning infringement damages). Therefore, Hatch-Waxman reverses the normal risk calculus involved in pharmaceutical patent litigation because it allows the generic DM to force patent litigation without incurring the risk of loss.

To add to the inversion of risk, the pioneer DM stands to lose much more by invalidation of a patent than a generic DM stands to gain. The development of pioneer drugs is a high-risk, high-reward undertaking. Pioneer DMs routinely spend hundreds of millions or even billions of dollars developing a new drug, isolating it, developing into an administerable form, ushering it through multiple rounds of FDA trials, and finally bringing it to market. In return, these pioneer DMs are usually rewarded with the exclusive right to market the drug by a combination of patent protection and exclusive FDA approval. Because of the high-risk and the massive sunk costs, as well as the surprising failure rate of such drugs at some point between invention and FDA approval, the pioneer DMs need to recoup their investment and earn a substantial profit from the drugs that do reach the market in order to adequately incentivize the development of new drugs. Without the promise of a monopoly and the accompanying profits, pioneer DMs and their stockholders would be loathe to invest the time and money required to bring these drugs to market.

Generic DMs, on the other hand are in a comparatively low-risk, low-reward industry. In essence, the generic DMs are able to piggyback on the work of the pioneer DMs, thus avoiding the massive sunk costs and years of development required of a pioneer. In order

187. See Requirements for Submission of In Vivo Bioequivalence Data, 68 Fed. Reg. 61640, 61645 (Proposed Oct. 29, 2003) (estimating that preparing and filing an ANDA can cost between \$300,000 and \$1 million).

188. For example, note that in the *Tamoxifen* case, Barr captured 80-percent of the market for tamoxifen in a short period of time, with only a 15-percent wholesale discount. See *supra* note 128 and accompanying text; *In re Tamoxifen*, 429 F.3d at 378 n.9.

to bring a drug to market, a generic need only file an ANDA, set up manufacturing facilities, and begin marketing and selling the drug. The average cost differential between the generic road to market and that of the pioneer is probably in the area of two orders of magnitude.¹⁸⁹ However, if generic entry is allowed, it is not limited to a single producer, but rather to any generic capable and interested. Thus, generic DMs generally enter a competitive market and must sell their product at a much lower cost, reflecting the much lower cost they incur to bring a drug to market.

The competitive level of the market is greatly reduced by the fact that Hatch-Waxman allows six months of market exclusivity to the first generic to file a paragraph IV ANDA.¹⁹⁰ The six-month head start actually allows the first generic producer to capture a substantial portion of the market without lowering prices all the way to a competitive level.¹⁹¹ This may be the result of the structure of the pharmaceutical distribution industry, because the first discount producer of a drug is able to develop distribution channels and can lock in long-term contracts with many purchasers, thus preventing subsequent generics from gaining an appreciable market share.

The result is that, in litigation, the pioneer DM stands to lose a massive source of income, as its monopoly market share and monopoly pricing will give way to a competitive market in which it is unlikely to maintain much market share, even if it drops prices. The generic DM, on the other hand, has little to lose, but could potentially gain a large market share, while not entirely dropping prices to competitive levels. Pioneers often stand to lose billions, while generic producers usually stand to make tens or hundreds of millions. It is no surprise then that, while normal infringement settlements commonly result in payments from the accused infringer to the patentee, often paired with a license, Hatch-Waxman settlements more commonly involve a reverse payment. As one commentator noted, even a patentee with a 75-percent chance of winning at trial might wish to curtail that risk by sharing 25-percent of its monopoly profits with an

189. Assuming a cost of around \$5 million to \$10 million for a generic and \$500 million to \$1 billion for a pioneer.

190. See *supra* note 186. See *supra* note 126 and accompanying text; *In re Tamoxifen*, 429 F.3d at 378 n.9.

191. See *supra* note 186.

ANDA filer, rather than risk the devastating loss of a patent monopoly.¹⁹²

2. *A New Best Outcome*

As illustrated by the hypothetical in *In re Tamoxifen*, a generic first challenger can often make more money from a reverse-payment settlement than it can from invalidating a patent and gaining generic entry, even with the 180-day market exclusivity included.¹⁹³ Thus, by preserving monopoly profits, both the challenging generic and the patentee can exceed the profit they would make in a competitive market.¹⁹⁴ For clarity, I offer a hypothetical below:

Suppose Pioneer Drugs, Inc. (“Pioneer”) creates a new drug to relieve headaches which it plans to market as “Relief.” Pioneer obtains a patent and FDA approval to market Relief, and quickly begins to make a handsome profit.

Immediately thereafter, Generic Pharmaceuticals (“Generic”) applies to make and sell a generic version of Relief, filing an ANDA with a paragraph IV certification claiming that the Relief patent is invalid as an obvious improvement on aspirin. As the first filer, Generic will be entitled to a 180-day marketing exclusivity period beginning from the first date of marketing or a district court ruling in its favor. Pioneer sues for patent infringement within forty-five days, thus triggering the thirty-month stay of FDA approval for Generic’s drug.

After motions for summary judgment and extensive discovery over a period of two-and-one-half years, Generic and Pioneer prepare themselves for trial. On the eve of trial, however, Generic and Pioneer meet to discuss a potential settlement. After reviewing the merits of the case, it is apparent to both parties that Generic will probably win at trial, as the Relief patent is clearly obvious. They then review the current market conditions.

192. See Hovenkamp et al., *supra* note 11, at 1758-1759. See also Cotter, *supra* note 11, at 1812 (suggesting that this type of reverse payment settlement should be allowed); cf. Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, 17 ANTITRUST 68, 72 (2003) (suggesting that although one may want to alleviate a 10-percent uncertainty by settlement, “[i]n our legal system, a 10 percent chance of rain is not rain.”).

193. *In re Tamoxifen*, 429 F.3d at 393 n.24.

194. For an amusing analogy, see McDonald, *supra* note 192, at 68 (describing the economic analysis by Butch Cassidy, played by Paul Newman, of E.H. Harriman paying a large amount of money to hunt him down, he said: “That’s bad business If he’d just pay me what he’s spending to make me stop robbing him, I’d stop robbing him.”).

At this time, after being on the market for more than two years, Relief is one of the most widely prescribed medications for people with chronic and migraine headaches. In its first year, Pioneer sold 50 million pills for a total profit of \$500 million. In the second year, Pioneer sold 100 million pills for a total profit of \$1 billion. Pioneer expects to maintain those profits for the next ten years for a total of \$10 billion over that span.

Generic, meanwhile, has estimated that it can afford to sell the pills at 75-percent of Pioneer's price for the 180 days in which it can market exclusively, thus obtaining an 80-percent market share. After that, when other DMs enter the market, Generic will have to sell pills at between 20-percent and 50-percent of the current Relief price, with an expected market share of 60-percent at most. Thus, Generic expects to profit up to 75-percent (profit per pill) of 80-percent (market share) of \$500 million (Pioneer's would-be profit) for the first half-year, totaling \$300 million. For the rest of the year, at best, Generic hopes to make 50-percent of 60-percent of \$500 million, for a total of \$150 million. After that, it will make \$300 million per year at most, and possibly significantly less. Meanwhile, with a best-case scenario of maintaining a 10-percent to 20-percent market share at the current Relief price, Pioneer expects to make significantly less than \$200 million per year, at most, if Generic wins its suit.

After reviewing their potential profits under a competitive market, Pioneer makes a suggestion: why not split the current \$1 billion per year profit instead of settling for \$300 million and \$200 million in a best case scenario. If Pioneer pays Generic \$500 million per year to stay out of the market for Relief, Pioneer, and Generic will both end up with significantly more than their expected profit under a competitive market. And to ensure that neither party is disadvantaged in a competitive market, the agreement can include a dissolution provision in the case of subsequent invalidation of the Relief patent. However, because the Hatch-Waxman regime discourages subsequent ANDA filers from filing until the first litigation has been resolved (because they don't get the 180-day exclusivity period, and why pay for litigation when someone else is already doing the dirty work?), no other company has yet filed an ANDA. If one does, litigation will trigger the thirty-month stay, thus ensuring extension of the Relief monopoly for nearly three years. Additionally, Generic will have the ability to assert its 180-day exclusivity, thus further extending the monopoly another six months.

Under this system, the incentive to protect one's monopoly by "paying for delay" is matched by the generic's incentive to maximize its profits by avoiding invalidation of the pioneer patent, and splitting the monopoly profits instead.

Further, to add to the already diminished incentive to file an ANDA, subsequent filers will be disadvantaged because (a) Pioneer will have already litigated its patent and will probably know its best defenses and biggest weaknesses; (b) the litigation is likely to be dragged out for more than thirty months, and even an invalidity determination at the district court level (which triggers the beginning of the 180-day period and allows for FDA approval of the generic) will retain the threat of infringement damages if the case is overturned on appeal; and (c) even if the subsequent ANDA filer wins, two companies will already be ahead of it as far as production and distribution channels, and could simply lower their prices, preventing the subsequent ANDA filer from garnering a substantial market share.¹⁹⁵

The question is how an agreement in this context is different from a naked horizontal restraint. Even if the agreement allows for subsequent litigation, as emphasized in *In re Tamoxifen*, it nonetheless forestalls generic entry for at least thirty months. And even if the agreement is a valid settlement of patent litigation, perhaps necessitated by a regulatory regime that encourages such settlements, is that "substantial pro-competitive justification" not rebutted by the existence of an "alternative means that is less restrictive of competition," such as allowing earlier generic entry?¹⁹⁶

It is clear that such a market division agreement would not be allowed absent an immunity from the antitrust laws, such as that granted by the "legal monopoly" that inheres in a patent.¹⁹⁷ But is "paying to protect" a patent within the scope of that patent? As the *Cardizem* court found, the answer should be no.¹⁹⁸ The exclusionary power of a patent is a power vindicated through the courts, and

195. See generally Avery, *supra* note 15 (discussing the additional problem of authorized generics and their discouraging effect on subsequent ANDA filers). But cf. Hemphill, *supra* note 11 (noting that authorized generics can be a pro-competitive form of settlement in lieu of reverse payments, much like delayed entry).

196. See Hovenkamp et al., *supra* note 11, at 1762-1763.

197. See, e.g., *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (11th Cir. 2003).

198. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

paying to protect a patent is an extra-legal remedy outside the scope of that patent.

B. Extra-Legal Protection and the True Scope of the Patent

The question squarely addressed by the *Cardizem* and *Terazosin* courts, yet largely ignored by the majority of appellate courts is how to define the true scope of the patent. As Carl Shapiro noted, the true grant of power from the patent is not the right to exclude, but the right to try to exclude.¹⁹⁹ And the presumption of validity, although heavily relied on the by majority of courts in this context, is expressly a “rebuttable” presumption.²⁰⁰ The question that then arises is whether the true scope of the patent and its exclusionary effects actually encompass the right to pay others not to infringe one’s patent, or not to challenge it. The *Cardizem* court found the question quite easy to answer, noting that it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competition by paying the only potential competitor \$40 million per year to stay out of the market.²⁰¹ Yet, the *Tamoxifen* court essentially held exactly the opposite, in noting that “[w]e do not think that the fact that the patent holder is *paying to protect* its patent monopoly, without more, establishes a Sherman Act violation,” and “we think that Zeneca was then entitled to *protect its tamoxifen patent monopoly through settlement*.”²⁰² An analogy to real property law sheds some light on the minority argument:

The power to exclude afforded by a patent can be analogized to the power to exclude afforded by fee simple absolute in a piece of real property. As an owner of a patent, one has the absolute right to exclude others from practicing the subject of the patent. Similarly, as the owner of real property, one has the absolute right to exclude others from trespassing on that property. In both cases, one can remedy a violation of that right to exclude by bringing a lawsuit—an action for trespass or an action for infringement. Alternatively, one could forebear the right to sue by contracting not to sue, in exchange

199. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003).

200. See 35 U.S.C. § 282 (2000).

201. *In re Cardizem*, 332 F.3d at 908.

202. *In re Tamoxifen Citrate Litig.*, 429 F.3d 370, 389, 392 n.22 (2d Cir. 2005) (emphasis added).

for some form of compensation. Generally, such a contract is known as a license in the patent context, and an easement in the real property context. Bringing, threatening, and settling lawsuits, as well as contracting for the forbearance of those rights are considered to be valid exercises of the patent and property rights, and are thus naturally within the scope of those rights.

When one pays to protect one's rights in property, either physical or intellectual, however, it is an extra-legal payment. That is, such a payment is beyond the bounds of the legal right. Paying someone not to sue for declaratory judgment of invalidity of a patent (or to drop their invalidity or non-infringement claims in an infringement suit against them) is like paying someone not to trespass on one's property. Rather than an exercise of the right to exclude others from the property, the payment is more like paying for "protection" in the racketeering context. As an example, compare the following two hypotheticals:

1. *The Bar*

John Adams owns a bar. Tony Soprano and twenty friends show up to the bar every day for a week, occupying every seat, ordering only water, and paying no tips. After repeatedly asking them to leave, John finally threatens to sue Tony and his friends for trespassing and to have the police remove them from the property. Tony says that he and his friends will show up the next day anyway. John sues for damages and Tony countersues to quiet title to the property, alleging that his friend Larry has the real deed to the bar. Larry, however, is a devout Christian who has been looking for a new place to build a church, and he is unaware of his claim to the building. After talking it out, and discussing the fact that neither John nor Tony wants another church in town, and both would profit much more if John were able to maintain his ownership of the property, John Adams agrees to pay Tony \$500 a week if Tony will agree to drop the suit and not show up to the bar every day.

2. *The Fork Patent*

John Adams owns a patent on a new type of fork. He makes and sells the forks for \$15 each. Tony Soprano decides that he also wants to make these forks. He begins to make the forks and sells them for \$5 each. John Adams sues for patent infringement and Tony alleges invalidity of the patent. Tony and John discuss the case, and determine that if the patent is declared invalid, a fork-making

conglomerate, Forks & Knives, Inc., will sell the same forks for \$0.50 each on a national scale, though they won't be able to begin selling for 6 months. John and Tony decide to settle their case, with John agreeing to pay Tony \$1,000 a week to stay out of the fork market, and to drop his invalidity claims.

3. *Analysis*

In both hypotheticals, the patentee/property owner is paying to protect his property rights. In each case the patentee/property owner has a legal means of recourse through which he can enforce his property rights. But in both cases, the owner elects to pay to protect his property right, perhaps out of fear that the property right is vulnerable to attack. Moreover, in both cases a final adjudication in favor of the challenger will result in a less favorable outcome than settlement. Yet these settlements are merely contracts to avoid competition or adverse action by other parties. They are extra-legal remedies, in that they are made *instead* of enforcing legal rights, rather than as a part of the enforcement of those rights. The legal remedy is the right to invoke the power of the courts and the legal system to exclude others from one's property. A settlement encompassed within that legal remedy would be recognition that the legal remedy will likely succeed. In order to avoid the absolute nature of the legal remedy, the parties might choose to settle, including a compromise involving a payment from the defendant to the plaintiff. Alternatively, if the defendant is sure to win, he can either pursue his legal remedy to the end or obtain an agreement that the property owner will not enforce his legal rights as against the defendant, i.e., a favorable license agreement or a cheap easement. A situation in which the property owner pays the defendant to agree to drop the lawsuit is almost always indicative of an anticompetitive intent, as the parties will only do so if the legal remedy sought by the plaintiff is unlikely to be obtained and both parties will be better off sharing in the fruits of the pre-litigation environment.

IV. Proposed Solutions

If indeed competitive markets are favored, the Hatch-Waxman Act works in opposition to the favored outcome, at least in its propensity to allow collusive agreements. Some previous proposals to remedy this propensity have merit, but few if any address the entire scope of the problem. This section will first review some proposed solutions to the problem, from the FTC, scholars, and even courts.

After a brief analysis of these proposals, this section will propose a new and comprehensive solution that can be enacted only through a combination of change in regulation and the courts.

A. Previous Proposals

Previous proposals to fix the problem posed by these reverse-payment settlements have been posited by scholars, courts, and administrative agencies alike. The FTC proposed a rule that would limit reverse payments in Hatch-Waxman settlements to reasonable litigation costs, capped at \$2 million.²⁰³ Herbert Hovenkamp, Mark Janis, and Mark Lemley proposed a presumption of illegality in such settlements, to be rebutted by the defendant.²⁰⁴ Though these proposals have some merit, the problem is that these would-be solutions only address one facet of the problem. Additionally, these solutions would probably have the effect of pushing the parties towards secrecy and concealment of the true scope of their agreement. Rather than clear and open reverse payment settlements (though most are “confidential”), we would have settlements with sham licensing, secret side agreements, or agreements that otherwise evade detection and make enforcing the antitrust laws even more difficult. That likely outcome is, of course, inflated by the fact that all such agreements must now be submitted to the FTC, and parties would be loathe to include such a provision in a written agreement, if such stringent restrictions were imposed. Nor would such restrictions be entirely effective, as they ignore the underlying perverse incentives created by the Hatch-Waxman Act.²⁰⁵ Such rules might, in fact, force excessive patent litigation costs upon pioneer drug inventors, and could even disincentivize generic DMs from entering the market at all. A similar proposition—that reverse payment settlements be limited to the amount a generic DM could earn in a competitive market—would work no benefit to consumers, would still allow for collusive settlements, and would only have the effect of maintaining profits in the hands of the pioneer inventor, rather than a would-be generic DM.²⁰⁶

203. See *supra*, notes 110 and 111 and accompanying text.

204. See Hovenkamp et al., *supra* note 11, at 1759-1760.

205. See *supra* Section III.A. (discussing the reallocation of risk in ANDA paragraph 4 filings and the litigation that arises therefrom).

206. See *In re Tamoxifen*, 429 F.3d at 395.

De facto proposals by courts have come closer to the right answer, but there is still no consensus. The district court in *In re Terazosin* (the *Valley Drug* case on remand) suggested that the court review the strength of the patent's exclusionary power by reviewing the likely outcome in the underlying patent litigation at the time of the settlement, and then comparing that to the scope of the agreement.²⁰⁷ The majority of appellate courts have held that the proper analysis involves comparing the scope of the patent's exclusionary right to the effects of the settlement, in order to determine whether the latter falls within the former.²⁰⁸ The minority case, *In re Cardizem*, suggested that such agreements are *per se* illegal, as they are not within the scope of the patent, but are being used to protect the patent from attack.²⁰⁹

Clearly, most of the courts have focused on, and have probably deduced the proper question, seeking to balance the countervailing interests of patent and antitrust law—does the scope of the agreement exceed the scope of the patent's exclusionary power? Yet, in answering that question, the courts have taken approaches ranging from a scrutinizing appraisal of the likely outcome of the underlying patent litigation,²¹⁰ to a broad assumption that anything involving a settlement and only affecting a patented product (i.e., not restricting sales of non-patented products) falls under that scope, unless sham or fraud is involved.²¹¹ Yet even when the courts have addressed the perverse incentives created by the Hatch-Waxman Act, they have generally reached only so far as acknowledging that the incentive exists, and in turn use it as a justification for upholding the legality of reverse payment settlements.²¹²

To solve the problem, a two-step approach must be taken. First, the Hatch-Waxman regime should be amended to dilute the parties' ability to pay to maintain a patent monopoly, and to eliminate the incentive to do so. Second, courts in the future must squarely address what the true scope of the patent is, and whether that reaches to payments to protect the patent from attack. The section below addresses the implications of these potential solutions.

207. See *supra* notes 97 and 98 and accompanying text.

208. See generally, *supra* Section II.B.

209. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

210. See *supra* notes 97 and 98 and accompanying text.

211. See generally, *supra* Section II.B.1(7).

212. *Id.*

B. A New Proposal

1. *Amending the Hatch-Waxman Act*

The perverse regime created by the Hatch-Waxman amendments was probably unintentional. Indeed, the amendments were created with the purpose of encouraging early generic entry, thus lowering drug costs for consumers.²¹³ Yet, at least in the context of reverse payment settlements, the statutory regime has had the opposite effect. Hatch-Waxman in fact creates a system whereby the monopolist can settle litigation and, because of the thirty-month stay provision and the 180-day market exclusivity afforded to the first ANDA paragraph IV filer, can effectively forestall actual generic entry without prevailing on any patent claims. To do this, the pioneer drug company need only settle with the first ANDA paragraph IV filer, and agree to pay that party to refrain from marketing a generic drug. Not only does such an agreement prevent that competitor from entering the market, but it prevents others from entering the market subsequently. Even if another ANDA filer is successful in invalidating or infringing a patent, the 180-day exclusivity can afford the scheming monopolist and the first-filer an additional half-year of monopoly profits. And, largely ignored by the courts, the *additional* thirty-month stays in litigation against subsequent ANDA filers grant even the most undeserving monopolist an *additional* thirty months of exclusivity on top of the first thirty-month stay. The fact that subsequent ANDA paragraph IV filers could file just after the first filer is irrelevant, as few parties are willing to risk and pay for litigation when the first filer already has the 180-day exclusivity right, and will already be embroiled in heated litigation. Undertaking an expensive patent lawsuit when someone else is already footing the costs and presumably able to exclude you for 180 days after the final resolution of that suit, would seem a fool's errand.

a. Divorcing the FDA Approval Process from Patent Law

To rectify the myriad problems that inhere in the Hatch-Waxman regulatory scheme, an important step to be taken is to divorce FDA approval from patent law. As is evident in the reverse settlement cases and the accompanying public outcry,²¹⁴ the complex intertwining

213. See *supra* note 26 and accompanying text.

214. See *supra* notes 9, 36, 63-65

of patent law and FDA approval is not only unnecessary, but harmful to competition and to the consumer.

A regime in which patent law and FDA approval were divorced would incentivize generic entrance, as they could file and gain approval for an ANDA immediately after an NDA was approved. However, the ANDA approval would be meaningless where patent litigation could act as the Sword of Damocles hanging over the heads of the would-be generic market entrants. Importantly, though, *only* the threat of patent litigation and the cost of infringement would prevent market entrance, and the patent monopoly could not be maintained through collusive price-fixing agreements and market divisions, protected under the guise of the necessary regulatory approval. Pioneers would, of course, object, as discussed in Section (c) below.

b. Non-Patent Based Exclusivity

Alternatively, recognition by the FDA of the difficulty of obtaining approval, could be just as effective, without raising the specter of anti-competitive settlements that protect bad patents. This recognition could take the form of exclusive approval to market the drug for ten years, or a period of time determined by economists on a congressional fact-finding committee, perhaps accompanied by a similar 180 day exclusivity period for the first ANDA filer, and maybe even secondary semi-exclusivity periods granted to subsequent filers. The cost of obtaining FDA approval for a new drug, often in the hundreds of millions of dollars when taking all expenses into consideration, deserves patent-like protection even if the drug is not protected under intellectual property laws.

c. Eliminating the Thirty-Month Stay

A further means of divorcing patent law from FDA approval would be to eliminate the thirty-month stay triggered at the outset of patent litigation. Pioneer DMs might argue that the thirty-month stay is the only way to keep generic DMs out of the market, and that without it, cheap competition would lower drug prices and prevent pioneers from reaping their monopoly profit. This would greatly reduce the incentive of pioneers to develop their drugs in the first place, because without a guarantee that one will be free from competition, the expected value of a drug will not warrant great expense at the research and development stage. This is a legitimate concern, but the power of the patent and the potential for non-

patent FDA exclusivity should alleviate such concerns in legitimate patent disputes.

A valid patent would allow the pioneer to reap his monopoly profits either by sufficiently deterring competition or by leading to massive damages or extremely beneficial settlements in patent litigation. And if the FDA recognized the value inherent in bringing a drug to market, regardless of patent rights, FDA exclusivity could provide valuable protection even for products with weak or no patent protection. On the other hand, where patents are so weak that they are almost assured of being defeated in litigation, generics will take a calculated risk and will likely settle the litigation favorably with a cheap license, or win quickly, thereby opening the market to cheap generic drugs and thus benefiting both competition and consumers.

3. *Redefining the Scope of the Patent in the Courts*

In addition to changing the Hatch-Waxman regime, courts must address the question of patent scope head-on. This is one reason why it may be proper to grant the Federal Circuit exclusive jurisdiction over reverse-payment patent settlements, because the scope of the patent must be determined, an area of law arguably within the exclusive jurisdiction of the Federal Circuit. However, to ignore the difference between “paying for delay” or paying to protect the patent monopoly, and coming to a legitimate settlement ignores the reality of the patent scope. Therefore, whether a full analysis of the likelihood of success in the underlying litigation is warranted or not, the question of patent scope is a necessary predicate to the outcome of this type of litigation. Nor is such a drawn-out analysis of the underlying strength or validity of the patent too difficult for courts to undertake. Indeed, as illustrated by the district court in *In re Terazosin*, such an analysis is not only possible, but can provide a deeper insight into the true facts of the case, and can thus lead to the correct conclusion.²¹⁵

V. Conclusion

Reverse payment settlements in pharmaceutical patent litigation under the Hatch-Waxman Act extend pharmaceutical patent monopolies and maintain monopoly prices on needed drugs. This harms consumers and the general public, while allowing pioneer DMs

215. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F.Supp.2d 1279 (S.D.Fla. 2005).

and generics to split the monopoly profits at the public expense. Yet these settlements are allowed, and even encouraged, by the current regulatory regime and the majority of circuit court rulings.

A solution to these problems is needed, but can only be achieved through a comprehensive approach. By amending the Hatch-Waxman Act, correctly defining the scope of the patent, and encouraging zealous enforcement of the antitrust laws by both the FTC/DOJ and private litigants, the problem can be solved. A satisfactory result would be an increase in litigation seen through to the end, settlements allowing earlier generic entry in lieu of reverse payments, and lower drug prices for consumers.