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Intersection of Patent Infringement and Antitrust Liability in Abbreviated New Drug Application Litigation, The

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The Intersection of Patent Infringement and Antitrust Liability in Abbreviated New Drug Application Litigation

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I. INTRODUCTION

A battle has been raging, over the past ten years, regarding the competing interests of patent protection and antitrust prohibitions in the specialized area of law concerned with patented drugs regulated by the Food and Drug Administration ("FDA").[1] The contestants are the Federal Trade Commission ("FTC") and parties to Abbreviated New Drug Application (ANDA) litigation, which are a branded drug company and a generic challenger.[2] The ANDA litigation parties, two

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1. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355(b), (j), (l); 35 U.S.C. §§156, 271, 282)("the Hatch-Waxman Act"). *See, e.g.,* In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 190–92 (2d Cir. 2006) (discussing the statutory and regulatory framework of the Hatch-Waxman Act). In brief, Congress passed the Hatch-Waxman Act in 1984 to encourage competition between generic and brand drugs. Under this Act, companies seeking to market a generic version of a patented drug may complete an Abbreviated New Drug Application ("ANDA") and rely on a prior determination by the FDA that the patented version of the drug is safe. *See* 21 U.S.C. § 355(j). When the manufacturer of a generic drug files an ANDA, they must certify that, to the best of its knowledge, the generic drug does not infringe the patent covering the brand or innovator drug. *Id.* § 355(j)(2)(A)(vii). One way for the applicant to satisfy the certification requirement is to certify under paragraph IV of § 355(j)(2)(A)(vii) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." As an incentive for generic drug manufacturers to challenge drug patents, the Hatch-Waxman Act grants the first generic manufacturer who files an ANDA, *i.e.* the "first to file", with a paragraph IV certification a 180-day exclusivity period in which the FDA will not approve any other ANDA applications for the same generic drug. *Id.* § 355(j)(5)(B)(iv).

2. The Hatch-Waxman Act makes it an act of patent infringement to file an Abbreviated New Drug Application (ANDA) containing a paragraph IV certification with the FDA in the face of an innovator, or branded drug company, having regulatory approval to market a drug and a patent or patents on said drug, a formulation of the drug or methods of making or using the drug. 35 U.S.C. § 271(e)(2)(A) (2010). Generally, generic drug makers filing an ANDA trigger this infringement provision by asserting that the patent or patents listed with the FDA for an innovator drug (in a listing known as "the Orange Book") are not infringed, or are invalid or unenforceable. The patentee then has 45 days to file suit, which invokes a 30-month stay in any approval of the generic drug maker's ANDA by the FDA. ANDA litigation is unlike any other patent infringement case. The accused infringer is not on the market and accordingly is not at risk for a damages assessment, and has not put investment at the risk of an injunction. Schering-Plough Corp. v. Fed. Trade Comm'r, 402 F.3d 1056, 1073–74 (11th Cir. 2005) ("It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, [the generic challengers] normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down [the patentee's]'s profits, as it took sales away. As a result, [the patentee] would have sued [the generic challengers], seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then settled under this scenario,

prior adversaries, are generally defendants in complaints brought not only by the FTC, but by consumer groups, drug wholesalers, retailers, and states' attorneys general. These complaints allege that the ANDA litigation parties have violated antitrust laws through settlement agreements used to end ANDA patent litigation. The gravamen of this complaint is that the branded drug-maker has generally settled with the generic challenger on terms where the generic challenger is either paid money, or otherwise granted something of economic value, in exchange for refraining from entering the marketplace as early as it would have if the generic company had prevailed in the litigation. These settlement agreements have been termed "reverse payment" or "pay-for-delay" settlement agreements.[3] On the other hand, the generic drug generally has entered the marketplace sooner than it would have otherwise been able if it had lost the ANDA litigation. However, the FTC argues that these settlements are acknowledgements by the branded drug-maker that the patents at issue are "weak," or otherwise subject to invalidation or a finding of unenforceability. Thus, any delay in generic drug entry is anticompetitive and a violation of the antitrust laws.[4]

During the 2013 term, the U.S. Supreme Court resolved the question of the legality of "reverse payment" settlement agreements, in *FTC v. Actavis*.[5] While the Court did not find these agreements presumptively illegal, the Court held that they were susceptible to antitrust scrutiny and should be evaluated under a "rule of reason" analysis.[6] In so holding, the Court overruled the majority of courts of appeal that have deemed the practice free of antitrust implications, for reasons directly related to the nature of the activities giving rise to such litigation and the exclusivity rights conferred by patents. Specifically, in ANDA litigation, it is the patentee who bears all the risk that her patent will be found invalid or unenforceable. As a consequence, over the past decade patentee-drug innovators have increasingly adopted the "reverse payment" method of settling ANDA litigation. This practice has raised antitrust concerns from consumers, but most especially by the FTC, which has initiated and participated in antitrust suits as a plaintiff or *amicus*.

II. THE FTC'S POSITIONS

The FTC's original position regarding "reverse payments" was that these agreements are *per se* violations of Section 5 of the Federal Trade Commission Act as an "unreasonable restraint of trade."[7] Accordingly, the Commission called

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the money most probably would flow from the infringers to [the patentee] because the generics would have put their companies at risk by making infringing sales.").

3. The term "reverse payment" refers to settlement agreements that require the patentee to pay the accused infringer.

4. Including, *inter alia*, Sections 1 and 2 of the Sherman Act (Sherman Act, July 2, 1890, ch. 647, 26 Stat. 209, 15 U.S.C. §§ 1–7) and Section 5 of the Clayton Act (Clayton Antitrust Act of 1914, Pub. L. 63–212, 38 Stat. 730, enacted October 15, 1914, codified as amended at 15 U.S.C. §§ 12–27, 29 U.S.C. §§ 52–53).

5. 133 S. Ct. 2223 (2013).

6. The rule "tests 'whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.'" Board of Trade of City of Chicago v. United States, 246 U.S. 231, 238 (1918).

7. *See* In the Matter of Abbott Labs., A Corp., & Geneva Pharm., Inc., A Corp., C-3946, 2000 WL 681849, at *6 (F.T.C. May 22, 2000); In the Matter of Schering-Plough Corp., A Corp., Upsher-Smith

for an outright ban on such agreements.[8] Having universally lost in courts on this theory, as set forth in more detail below, the FTC has moderated its position, advocating that "reverse payment" agreements are presumptively illegal and should be reviewed for antitrust liability under a "quick look" rule of reason approach.[9] The quick look approach requires that the court find any reverse payment agreement that delays a generic company from entering the market in exchange for payment as *prima facie* evidence of an antitrust violation due to an unreasonable restraint on trade.[10] A party can rebut this finding by showing that the payment: (1) was for a purpose other than to delay market entry of the generic company; or (2) provided a pro-competitive benefit.[11]

There are several reasons for the FTC's crusade against "reverse payment" settlements. First, generic competition decreases the costs of drugs to consumers and, more importantly, to the Federal government, which is the largest drug purchaser in the country if not the world. Second, generic drug companies are motivated under the Hatch-Waxman Act to challenge patents because the first generic company to file an ANDA with a certification that its product does not infringe or that the innovator's patents are invalid or unenforceable, garners a 180-day exclusivity period as the only generic on the market.[12] Third, reverse payment settlements upset the statutory purpose, permitting "bad" patents to remain in force and delaying generic entry.[13] Fourth, generic drug companies prevailed in ANDA litigation against brand-name drug companies 75% of the time between 1992 and 2002.[14] Finally, the FTC contends that branded drug companies enter into reverse payment arrangements because they know that their patents are invalid or unenforceable, and the agreements permit them to undeservedly collect "monopoly" profits.[15]

The factual underpinnings of the FTC's contentions that reverse payment settlement agreements of ANDA litigation require antitrust scrutiny, are set forth in

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Labs., A Corp., & Am. Home Products Corp., A Corp., 9297, 2001 WL 418903, at *1 (F.T.C. Apr. 2, 2001); In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

8. *See* Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 2 (2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf [hereinafter *Pay-for-Delay Report*].

9. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013) ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'").

10. *See* In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).

11. *Id.*

12. 21 U.S.C. § 355(j)(5)(B)(iv) (2013).

13. *Pay for Delay Report*, *supra* note 8, at 8.

14. *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at viii (2002), *available at* http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (providing incentives for brand-name companies to pursue these types of agreements).

15. This conclusion has been almost universally rejected by the Courts of Appeal until very recently. *See* Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 105 (2d Cir. 2010); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1337 (Fed. Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206 (2d Cir. 2006); Schering-Plough Corp., 402 F.3d at 1075–76; and Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1311 (11th Cir. 2003). As a result (in part) of FTC advocacy against these agreements, Congress enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2000. 342 U.S.C. § 1395w-101 (2009) (§110 of the Act), 21 U.S.C. § 355 (2009) (§§ 1111-1118 of the Act), 21 U.S.C. § 355(j)(5) (2009) (§ 1102 of the Act) (provisions requiring all such agreements to be filed with the FTC).

more detail in a series of reports issued between 2010-2013 on the subject. In 2010, the FTC's report characterized these agreements as harming consumers while enriching both innovator and generic drug makers, due in large part to a delay up to 90% in the reduction in the cost of a branded drug that occurs upon generic competitor entry in the market.[16] The report notes that the FTC "deterred" the use of such agreements, between April 1999 and 2004, buttressed by a single court of appeals decision, which held that these agreements are *per se* illegal.[17] However, later appellate decisions have upheld "reverse payment" agreements,[18] which the Commission contends is "misapply[ing] the antitrust law[s]".[19] As a consequence, the FTC's report contends that generic drug entry has been delayed for an average of seventeen months, and that in 2009, pay-for-delay agreements "protect at least $20 billion in sales of brand-name pharmaceuticals from generic competition."[20] The report estimated that the "cost to American consumers was $3.5 billion per year."[21]

The 2010 report noted that there were 66 agreements that "involved some form of compensation" for delayed entry, between fiscal years 2004-2009. During the same period, ANDA litigation was settled without pay-for-delay agreements in 152 instances.[22] Of the 66 agreements involving delayed generic entry, 51 (77%) were between the brand-name pharmaceutical company and the first generic company to file an ANDA.[23] These data were significant, because "[s]ettlements with first-filer generics can prevent *all* generic entry," since the generic company to first file an ANDA has a 180–day exclusivity period to market the generic version of the drug, which it is entitled under the Hatch-Waxman Act.[24] Thus, delaying market entry for the first ANDA filer prevented any subsequent ANDA filer from entering the market until the first filer has utilized the 180-day exclusivity period.

Not all settlement agreements between generic and brand-name drug manufacturers involve direct cash payments to the generics companies, The FTC's report describes other arrangements, including an agreement from the brand-name pharmaceutical company not to introduce an "authorized generic," ("AG")[25], which are not excluded by the 180-day exclusivity period awarded to the first to file an ANDA.[26] This type of agreement was included in about 25% of the "pay-for-delay" agreements discussed in the report.[27] The situation was no better a year later, and the FTC's 2011 report contained a tabulation of reverse payment settlement agreements by year, up to the date of publication.[28] Finally, by the time its

16. *Pay-for-Delay Report, supra* note 8, at 1.

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

18. Schering-Plough Corp. v. Fed. Trade Comm'n., 402 F.3d 1056, 1076 (11th Cir. 2005); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 216 (2d Cir. 2006); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1341 (Fed. Cir. 2008).

19. *Pay-for-Delay Report*, *supra* note 8, at 1.

20. *Id.* at 2.

21. *Id.*

22. *Id.* at 4.

23. *Id.* at 5.

24. *Id.* (emphasis in original).

25. *Id.* at 5 (*i.e.*, a generic version of the drug made by the brand-name company).

26. *Id.*

27. *Id.*

28. Paradoxically, the Report actually showed the percentage of reverse payment settlement agreements in overall decline during the period from 2004-2011; Federal Trade Comm'n, Overview of Agreements Filed in FY 2011, A Report by the Bureau of Competition, at 2 (2011), *available at*

2013 report was published, the Commission's data indicated that the "vast majority of patent settlements (greater than 70%) continued to be resolved without compensation to the generic manufacturer."[29] This trend reflects the impact of the FTC's campaign against pay for delay agreements. Currently, instead of a cash payment provision, the majority of agreements contain an agreement from the innovator not to bring an "authorized generic" version of the drug to market, in competition with the generic drug maker.

Not surprisingly, the FTC has taken the position that agreements involving a promise by the innovator not to market an authorized generic should also be presumptively illegal, applying the following reasoning.[30] First, authorized generics "destroy…a significant amount of the value that a generic company otherwise would obtain from [the] 180-day…exclusivity period."[31] Second, a branded company's agreement not to market an AG "enables the generic company to maximize its revenues during the first-filer exclusivity period."[32] Finally, these "economic realities" compel the conclusion that "a no-AG commitment is without a doubt a method of paying a generic company for delayed entry."[33]

III. DEVELOPMENT OF A CIRCUIT SPLIT ON THE LEGALITY OF REVERSE PAYMENT AGREEMENTS

Despite the FTC's protestations, U.S. Court of Appeals have developed different positions on the legality of reverse payment agreements. While Circuits including the Sixth and Third Circuits adhered to the position that reverse settlement agreements are *per se* illegal, the Second, Eleventh, and Federal Circuits rejected this position, finding that these agreements are not anticompetitive so long as they do not exceed the scope of the patent. To resolve this circuit split, the U.S. Supreme Court granted the FTC's petition for certiorari in the Eleventh Circuit's landmark decision, *Schering Plough Corp. v. Fed. Trade Commission*, which paved the way for reverse payment agreements between brand and generic drug companies. The Supreme Court rejected both approaches, and held that courts must apply a rule of reason analysis to determine the legality of a reverse payment agreement.

A. The Sixth Circuit Finds Reverse Payments Agreements per se Illegal

The Sixth Circuit Court of Appeals, in *In re Cardizem CD Antitrust Litig.*,[34] issued the first appellate decision on reverse settlement payment agreements. The

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http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/1110mmaagree-2.pdf.

29. Federal Trade Commission, *Overview of Agreements filed in FY 2012, A Report by the Bureau of Competition*, at 2 (2013), *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

30. *See* In re K-Dur Antitrist Litig., 686 F.3d 197, 207 (3rd Cir. 2012).

31. Federal Trade Commission's Motion for Leave to File *Amicus Curiae* Brief, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 5 (D. N.J. Aug. 10, 2012) *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-effexor-xr-antitrust-litigation/120810effexoramicusbrief.pdf.

32. *Id.* at 7.

33. *Id.* at 9.

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

decision supported the FTC's position, but was based on facts not found in later cases that have upheld such agreements. The *Cardizem* case was brought by a variety of patient groups against Hoechst Marion Roussel (HMR) and Andrx, over a settlement agreement containing a reverse payment provision. The settlement agreement at issue ended ANDA litigation over a patent for HMR's drug, Cardizem CD.[35] Andrx filed an ANDA for Cardizem CD, and asserted antitrust counterclaims in the ensuing litigation. On the same day that the 30-month stay expired, the parties settled.[36]

The settlement agreement provided that Andrx would not market a generic version of Cardizem CD until either: Andrx received a final determination in its favor in the patent infringement lawsuit; HMR or Andrx entered into a licensing agreement; or HMR entered into a licensing agreement with a third party.[37] Andrx also agreed to dismiss its counterclaims for unfair competition and antitrust violations[38] and to pursue its ANDA claim. Finally, Andrx agreed not to relinquish or transfer its 180-day exclusivity period or any other right. HMR agreed to pay Andrx $40 million per year, beginning on the date that the FDA approved Andrx's ANDA. HMR also agreed to pay Andrx $100 million per year, less the interim $40 million payments, once there was either: a final judgment that the patent in dispute, U.S. Patent No. 5,470,584 ("the '584 patent"), was not infringed; HMR dismissed the patent infringement lawsuit; or the parties reached another resolution to their lawsuit.[39] In addition HMR agreed not to seek preliminary injunctive relief during the ANDA suit.[40] Two weeks later, Andrx began to market its generic product, starting the 180-day exclusivity period.[41] This date of market entry was almost 12 years before the expiration date of the '584 patent.

The agreement contained a number of provisions not found in other legal agreements. For example, Andrx was the first generic company to file an ANDA, and the agreement did not require the generic company to change its paragraph IV certification.[42] Since the parties settled the ANDA litigation, the 180-day exclusivity period could not begin to run until Andrx entered the marketplace – a date delayed by the agreement.[43] Moreover, the agreement contained a provision wherein Andrx agreed neither to relinquish, nor transfer, its right to the exclusivity period.[44] In addition, the agreement purportedly covered generic Cardizem CD products that did not satisfy the dissolution limitations in the patent claims, and thus did not infringe the '584 patent.[45]

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35. *Id.* at 902, 904. The active ingredient in Cardizem is diltiazem hydrochloride, used for treating angina and hypertension and as a preventative for heart attack and stroke. U.S. Patent No. 5,470,584 (filed Feb. 27, 1995).

36. *Id.* at 903. ("On June 9, 1999, the FDA approved Andrx's reformulated product. That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement. On June 23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run.").

37. *Id.* at 902.

38. *Id.*

39. *Id.* at 903. Which did not resolve the issues of invalidity, unenforceability, or infringement, and HMR did not refile or pursue the lawsuit

40. *Id.* at 903.

41. *Id.*

42. *See supra* note 2 for an explanation of paragraph IV certification in an ANDA application.

43. *In re Cardizem CD Antitrust Litig.,* 332 F.3d at 903.

44. *Id.* at 902.

45. *Id.* at 915.

The antitrust lawsuit against HMR and Andrx was consolidated from several complaints from individuals, states, and other groups.[46] These complaints were brought under Section 1 of the Sherman Act and § 4 of the Clayton Act. The plaintiffs advanced a "but for" argument, that a generic Cardizem would have been on the market absent the agreement, and that the exercise of its 180-day exclusivity period barred other generics from coming to market.[47] The district court held the agreement was *per se* illegal, because the reverse payment provisions and actual payments from HMR to Andrx delayed generic entry and constituted a naked, horizontal restraint of trade.[48] The court certified an interlocutory appeal to the Sixth Circuit on the question of whether the reverse payment settlement was an antitrust violation.[49]

In its opinion, the appellate court noted that while the literal meaning of Section 1 of the Sherman Act would render *per se* illegal every agreement in restraint of trade, the Supreme Court has "long recognized" that the statute is meant only to prohibit unreasonable restraints, and that courts assess whether a restraint is unreasonable using a rule of reason.[50] To determine what constitutes an unreasonable restraint of trade, the fact finder must consider several factors including "'specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'"[51]

However, there are some agreements that "have such predictable and pernicious anti-competitive effect[s], and such limited potential for pro-competitive benefit," that they are considered incapable of satisfying the rule of reason under any circumstances,[52] and are deemed *per se* illegal.[53] Courts have recognized that certain kinds of agreements cannot satisfy the rule of reason under any circumstances, and such agreements have a "conclusive presumption" of illegality.[54] For such agreements, "no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on

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46. *Id.* at 903.

47. *Id.* at 904. Plaintiffs fell into three groups: (1) the "State Law Class Plaintiffs," indirect purchasers, and class representatives, from various states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin and the District of Columbia) whose complaints, initially filed in state court and then removed to federal district court by defendants, alleged violations of state antitrust and consumer protection statutes; (2) the "Sherman Act Class Plaintiffs," direct purchasers, and class representatives, whose complaint, filed in federal district court, alleged a violation of federal antitrust law; and (3) the "Individual Sherman Act Plaintiffs," two groups of purchasers (filed by The Kroger Co., Albertson's, Inc., The Stop and Shop Supermarket Co., and Eckerd Corp. and by CVS Meridian, Inc. and Rite Aid Corp.), not representatives of any class, whose complaints, also filed in federal district court, alleged violations of federal antitrust law; the plaintiffs from seven states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin) and the District of Columbia claim violations of state antitrust law. *Id.* at n.8.

48. In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 705 (E.D. Mich. 2000).

49. *In re Cardizem CD Antitrust Litig.,* 332 F.3d at 900 (The court certified the following question for interlocutory appeal to the 6th Circuit: "In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.").

50. *Id.* at 906 (citing State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).

51. *Id.* (quoting *State Oil*, 522 U.S. at 10).

52. *Id. (*citing Northern Pacific Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).

53. *Id.*

54. *Id.* at 906.

competition."[55] The Supreme Court is cited as being almost dismissive of such instances: "a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them."[56] Citing the *Nat'l Coll. Athletic Ass'n v. Bd. of Regents of the Univ. of Oklahoma*[57], the Sixth Circuit identified naked, horizontal price restraints as *per se* illegal, pursuant to this line of Supreme Court precedent.[58]

With this analytical framework in mind, the Sixth Circuit listed facts it termed "undisputed and dispositive."[59] First, under the agreement, HMR was assured that Andrx, its only potential competitor at the time, would remain out of the market at a cost of $10 million per quarter, even after Andrx had obtained FDA approval for its generic version of the drug.[60] Second, as a consequence of this agreement, Andrx and all other generic competitors were kept out of the market in view of Andrx's 180-day exclusivity period, and Andrx's agreement not to relinquish or transfer this right.[61] Keeping the generic companies out of the market was enough for the court to characterize the settlement agreement as a naked horizontal restraint that was *per se* illegal.[62]

The Sixth Circuit was not persuaded by the defendants' arguments to the contrary. Specifically, the court rejected defendants' argument that the agreement was a proper exercise of the patent right.[63] The court also determined that the plaintiffs

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55. *Id.* (citing Nat'l Coll. Athletic Ass'n v. Bd. of Regents of the Univ. of Oklahoma, 468 U.S. 85, 100 (1984)).

56. *Id.* at 907.

57. 468 U.S. 85, 100 (1984).

58. *In re Cardizem CD Antitrust Litig.,* 332 F.3d at 907. The Supreme Court is cited as being almost dismissive of such instances: "a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them." *Id.* at 907 (quoting Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 n.6 (1977)) (This type of agreement is defined as "an agreement between competitors at the same level of the market structured to allocate territories in order to minimize competition," stating that "[t]his Court has reiterated time and time again that horizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act.").

59. *Id.*

60. *Id.* at 907.

61. *Id.* at 907–08 (which commenced only when Andrx first entered the marketplace; thus there was a direct nexus between the agreement's provisions keeping Andrx off the market and the delay in generic Cardizem coming to the marketplace from any source).

62. *In re Cardizen CD Antitrust Litig*., 332 F.3d at 906 n.11. (In a footnote, the court addressed the consequences of a *per se* determination, instead of applying a rule of reason analysis:

> The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach. *See, e.g.,* Arizona v. Maricopa Cty. Med. Soc., 457 U.S. 332, 344 (1982) ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a full-blown inquiry might have proved to be reasonable."); United States v. Topco Assocs., Inc., 405 U.S. 596, 609 (1972) ("Whether or not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.").

63. *Id.* at 908. ("[T]he Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation….As the plaintiffs point out, 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.") And arguments that there were pro-competitive effects that offset the anticompetitive effects were unavailing because of the court's determination that the agreement was *per se* illegal.

had sufficiently pled an antitrust injury.[64] The consumers suffered the antitrust injury because they "were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint." Preventing such an outcome was "undoubtedly a *raison d'etre*" for passage of the Sherman Act.[65] In addition, the injury "flows from that which makes defendants act unlawful."[66] The court found "incredible" the argument that Andrx would not have entered the market, for fear of patent infringement liability, in the absence of the $89 million paid by HMR under the agreement.[67] All of these considerations mitigated against the parties to the agreement, which the court found to be illegal under the Sherman Act.

B. The Eleventh, Second, and Federal Circuits Apply the "Scope of the patent" Test

The Eleventh Circuit came to a different conclusion than the Sixth Circuit on the legality of reverse payment agreements.[68] In *Schering-Plough Corp. v. Federal Trade Commission*, the FTC issued a "cease and desist" order prohibiting Schering-Plough from settling any patent infringement lawsuit with a generic drug company where Schering-Plough gave the generic company "anything of value" and "agree[d] to suspend research, development, manufacture, marketing, or sales of [the generic] product."[69] The product at issue was an extended-release formulation of a potassium supplement claimed in U.S. Patent No. 4,863,743. Schering-Plough filed suit in response to Upsher-Smith Laboratories ("Upsher") ANDA

64. *Id.* at 909 (specifically (1) "injury of the type the antitrust laws were intended to prevent" and (2) injury "that flows from that which makes defendants' acts unlawful") (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.* 429 U.S. 477, 489 (1977)). Part of the court's decision was based on the standard of review, where all allegations in the complaint are taken as true and all inferences are drawn in plaintiffs' favor. *Id.*

65. *Id.* at 910.

66. *Id.* at 911 (*i.e.*, causing consumers to pay more for the branded drug than they would have paid for Andrxs generic version).

67. *Id.* There are several distinctions that can be used to explain the different outcomes in this case and the other cases that did not find a reverse payment agreement to be *per se* illegal. For example, in the three cases that did not find an antitrust violation in a reverse payment agreement, discussed below, the courts were careful to state that there were circumstances in which the agreement could be illegal. These included an extension of the exclusionary right of the patent in excess of the proper scope of the claims, initiation or continuance of "sham" litigation where the patentee knew that the patent was invalid or unenforceable or that the accused product did not infringe the asserted claims, or *Walker Process*-type violations. The court found that Andrx's reformulated product did not infringe the claims of the '584 patent, and thus that payment from HMR to Andrx was not a legitimate exercise of the patent's exclusionary right. Moreover, unlike other instances where the first ANDA filer changed its certification from paragraph IV to paragraph III, and thus gave up its 180-day exclusivity period, not only did Andrx not change its certification, but the reverse payment agreement contained an affirmative requirement that Andrx neither relinquish nor transfer the right. The effect of this provision was to keep other potential generic entrants from the marketplace. Finally, while in other cases the change in certification permitted other generic drug companies to file their own ANDAs and to thus be able to obtain FDA approval (and in some of those cases that is precisely what occurred, although the patentee sometimes prevailed and other generic companies did not enter the market), here the reverse payment agreement had a preclusive effect on other potential generic entrants.

68. 402 F.3d 1056 (11th Cir. 2005).

69. *Id.* at 1057-58. The basis of the order was the Commission's determination that the settlement agreement between Schering-Plough and Upsher Pharmaceuticals (containing a reverse payment) was an unreasonable restraint of trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1 and Section 5 of the FTC Act, 15 U.S.C. § 45(a).

filing on a generic version of Schering-Plough's formulation product, and the parties settled before trial.[70] The Administrative Law Judge (ALJ) hearing the case in the first instance found both these agreements legal and dismissed the FTC complaint.[71]

The case was then heard by the full Commission, who reversed the ALJ.[72] The Commission backed off its initial position that reverse payment agreements are *per se* illegal, but held that the *quid pro quo* of payment was for delayed generic market entry, which delay "would injure competition and consumers."[73] The Commission based its decision on generic market entry that "might have been" agreed upon between the parties in the absence of payments.[74] Although the Commission could not tie the entry dates to the monetary compensation, it developed the rule that reverse payments were illegal, with an exception for litigation costs to be capped at $2 million and a requirement that the FTC must be notified of the existence and terms of the agreement.[75]

The Eleventh Circuit reversed, following its own precedent in *Valley Drug Co. v. Geneva Pharm., Inc.*[76] In *Valley Drug Co.* the Eleventh Circuit reversed the district court's determination that this agreement was *per se* illegal, based on the exclusionary powers of a patent.[77] Patents, according to the court, intrinsically distort the competitive landscape, and thus defeat a determination that the agreement was *per se* illegal.[78]

The FTC did not use a *per se* standard against Schering-Plough, however, but instead applied a "rule of reason" analysis. The rule "tests 'whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.'"[79] Here, the Commission differed from the ALJ merely by showing "a detrimental market effect," which the court characterized as "a low threshold" for making a finding of antitrust liability.[80] The Eleventh Circuit stated that when patents are involved,

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70. *Id.* The agreement contained a $60 million initial licensing fee, $10 million in milestone royalty payments and 10-15% running royalties on five drugs owned by the generic company, including an anti-cholesterol drug having an estimated net present value of $250 million. In addition, Upsher agreed to a compromise date for market entry of it generic potassium product.

71. *Id.* at 1061-62. The ALJ's reasoning was that, unless the patent was invalid or the generic products did not infringe, the agreements were not violations of the antitrust laws. Significantly, the FTC adduced no evidence before the ALJ that these agreements were anything other than arm's-length transactions between the parties. The ALJ found that the FTC did not prove that, without the payment, either a better settlement agreement or litigation would have resulted in earlier generic market entry.

72. *Id.* at 1062.

73. *Id.*

74. *Id.*

75. *Id.* A requirement adopted in the 2003 Medicare Prescription Drug Improvement and Modernization Act.

76. 344 F.3d 1294, 1303-04 (11th Cir. 2003).

77. *Valley Drug*, 344 F.3d at 1312–13.

78. *Schering-Plough*, 402 F.3d at 1064 ("In the context of patent litigation . . . the anticompetitive effect may be no more broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would 'obviously chill such settlements'") (quoting *Valley Drugs*, 344 F.3d at 1309).

79. *Id.* (citing FTC v. Indiana Federation of Dentists, 476 U.S. 447, 457 (1986)).

80. *Id.* at 1065.

> Thus, under the Commission's standard, once the FTC met the low threshold of demonstrating the anticompetitive nature of the agreements, it found that Schering and Upsher did not sufficiently establish that the challenged activities were justified by procompetitive benefits. Despite the appearance that it openly considered Schering and Upsher's procompetitive affirmative de-

neither *per se* illegality nor a rule of reason analysis is appropriate in assessing antitrust liability, "because they seek to determine whether the challenged conduct had an anticompetitive effect on the market."[81] The court stated that it is the legitimate exclusionary power of the patent that the court said must be considered in making an antitrust determination.[82] Following *Valley Drug*, the court announced that "the proper analysis of antitrust liability requires 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."[83]

Turning to the patent at issue and the agreement between the parties, the court noted that the FTC's characterization of the agreements as linking the payments to the delayed market entry was not supported by substantial evidence.[84] In fact, the court found that the evidence before the ALJ was directly contrary to the FTC's position -- that the reverse payment was "a bona fide fair-value payment" for rights to market these drugs.[85]

Regarding allegations that the agreement violated the FTC Act, and whether the agreements represented an "unfair method of competition," the court said that there must be an actual anticompetitive effect, not one that is "hypothetical or presumed."[86] Interestingly, the Court opined that the certainty resulting from the settlement would lead to "more intense competition."[87] Citing *Valley Drug*, the Court advanced the idea that litigation can be a more costly means to achieve the same exclusion reached by settlement, contrary to the "logic" employed by the Commission that payment was merely a *quid pro quo* for delayed generic market entry.[88]

The court's opinion also notes that under typical infringement situations, Schering would be entitled to lost profits damages for Upsher and ESI entering the marketplace.[89] Hatch-Waxman "essentially redistributes the relative risk assess-

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fense, the Commission immediately condemned the settlements because of their absolute anticompetitive nature, and discounted the merits of the patent litigation. It would seem as though the Commission clearly made its decision before it considered any contrary conclusion.

81. *Id.*

82. *Id.* at 1067 ("Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. *Simpson v. Union Oil Co.*, 337 U.S. 13, 14 (1964) (Patent laws 'are in pari materia' with the antitrust laws and modify them pro tanto (as far as the patent laws go)").

83. *Id.* at 1066.

84. *Id.* at 1071. Indeed, in the proceedings before the ALJ, FTC counsel "acknowledged that it could not prove that Upsher [and ESI, another generic entrant] could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006. This reinforces the validity and strength of the patent." *Id.* at 1068.

85. *Id.* at 1069.

86. *Id.* at 1072 ("By contrast, …the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from" any possible infringement. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation,* 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)). *Id.* at 1074.

87. *Id.* at 1073.

88. *Id.*

89. *Id.* at 1073–74 ("It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then settled under this scenario, the money most

ments."[90] Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation. Their exposure to liability amounted to nothing more than litigation costs, but paled in comparison to the immense volume of generic sales and resulting profits.[91]

Following this line of reasoning, the court posed a "pre-Hatch-Waxman" hypothetical regarding settlement of a similar lawsuit, wherein if the patent-holder settled for less than the damages it was entitled to, the "windfall" garnered by the generic would be like the reverse payment here (since presumably the settlement would effect a delay in generic market entry).[92] And looking long-term, the court posited that a ban on reverse payments would remove the incentive for settlement, and in some percentage of cases, the patentee would prevail, thus delaying generic market entry even longer.[93] Accordingly, the court stated that the anticompetitive cost to consumers of the Hatch-Waxman litigation needs to be considered.[94]

Finally, the court posited that the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product.[95] According to the court, the intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim.[96] Similarly, Hatch-Waxman settlements, like the ones at issue in this case, (which resulted in the patentee's purchase of a license for some of the alleged infringer's other products) may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation.

The Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*, agreed with the Eleventh Circuit's analysis in *Schering-Plough*.[97] In *In re Tamoxifen*, the FTC sued a number of related companies[98] and Barr Pharmaceuticals over a settlement agreement of ANDA litigation regarding the breast cancer drug tamoxifen.[99] The district court in the underlying ANDA litigation found the patent inva-

probably would flow from the infringers to Schering because the generics would have put their companies at risk by making infringing sales.").

90. *Id.*

91. *Id.* ("By entering into the settlement agreements, Schering realized the full potential of its infringement suit -- a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future. Furthermore, although ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. . . . Ultimately, the consideration paid to Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements.").

92. *Schering-Plough*, 402 F.3d at 1074.

93. *Id.*

94. *Id.* at 1075.

95. *Id.*

96. *Id. See* In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 133 (E.D.N.Y. 2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, "cleared the field" for other ANDA filers).

97. *See* In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).

98. *Id.* (Collectively designated "Zeneca").

99. *Id.* The reverse payment amounted to $21 million and an agreement between the companies wherein Barr became the source of an "authorized generic" version of the drug, *i.e.*, that Zeneca would act as a supplier of tamoxifen for Barr to be resold in the U.S. at a price higher than would typically occur when a generic version of a drug enters the marketplace.

lid, and the parties' agreement was contingent on getting a vacatur of this judgment.[100] While this judgment was being appealed to the Federal Circuit, the parties settled.[101]

In the district court case brought by plaintiffs and the FTC, the court dismissed the complaint based on the existence of a patent;[102] the district court held that only by misusing a patent can the patentee be liable for an antitrust violation.[103] The district court suggested that a reverse payment merely to keep a generic drug off the market might have a different character than an agreement, as here, which settles active litigation.[104] Additionally, Barr's petition to extend its 180-day exclusivity period was also not illegal, being exempt from antitrust liability under the *Noerr-Pennington* doctrine.[105]

Although the Second Circuit recognized that there are competing legal principles between consumer protection under the antitrust law and the exclusivity conferred to patentees under patent law,[106] the court did not believe that a ban on reverse payments was the answer.[107] Instead, the court reviewed the antitrust allegations before it on the merits. The first allegation discussed in the opinion was that the district court should have considered the patent presumptively invalid based on the earlier determination of invalidity.[108] The court rejected this view, saying that the established principle is that courts should encourage settlement in the public interest.[109] The court was unwilling to presume that the Federal Circuit would have affirmed the district court's invalidity determination if that determination had been reviewed in an appeal of the underlying ANDA litigation.[110]

Secondly, the court found that the timing of the settlement agreement -- after an invalidity decision in the ANDA litigation -- was irrelevant, saying that both

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100. *Id.* at 190-94. The basis for the District Court's invalidity decision was non-disclosure of material prior art. Imperial Chem. Indus., PLC v. Barr Laboratories, 795 F. Supp. 619, 626 (S.D.N.Y. 1992), *vacated* pursuant to settlement sub nom. Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co., 991 F.2d 811 (Fed. Cir. 1993).

101. *Id.* at 190.

102. In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 124 (E.D.N.Y. 2003) *aff'd*, 466 F.3d 187 (2d Cir. 2006). *See* U.S. Patent No. 4,536,516.

103. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d at 124. An additional fact relevant to the District Court's later-vacated decision was that Barr, the first ANDA filer, re-asserted its 180-day data exclusivity period that prevented other generics that were preparing to enter the market. Prior to Barr's action, several other generic companies filed ANDAs and Zeneca prevailed in all of these lawsuits. The FDA permitted Barr to recoup its 180-day exclusivity period, which was subsequently challenged and overturned by the District Court. The FTC's position was that the settlement agreement amounted to "reviving" an invalid patent, continuing Zeneca's "monopoly" over tamoxifen, prevented other generics from entering the marketplace, maintained a high price on tamoxifen, and amounted to the companies "sharing…unlawful monopoly profits." *In re Tamoxifen Citrate Antitrust Litig.*,.466 F.3d at 196–97.

104. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d at 133.

105. Specifically, the court held that regulatory agency action, taken or petitioned in good faith, does not raise antitrust injury if it is "the result of the legal monopoly that a patent holder possesses." *Id.* at 138. Moreover, "forcing" other ANDA filers to "prove" that the patent was invalid was not an antitrust injury, particularly since Zeneca prevailed in these actions (implying that the patents were not invalid). *Id.* at 137.

106. *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 202.

107. *Id.* at 202–05.

108. *Id.*

109. *Id.* at 202.

110. *Id.* at 203.

parties had reason to settle before having the decision reviewed by the Federal Circuit.[111]

Third, plaintiffs and the FTC contended that the amount of the reverse payment greatly exceeded the value of the settlement even under a "best case scenario."[112] The court expressly refused to hold that a reverse payment is a *per se* antitrust violation.[113] Indeed, the court said that the Hatch-Waxman regime encourages settlements having reverse payments, because the statute reverses the usual positions of the parties.[114] Indeed the court went further, viewing reverse payments as expected consequences of the incentives created under the Hatch-Waxman system.[115]

The Second Circuit also said that "excessive" reverse payments could be a violation if merely "a device for circumventing antitrust law."[116] The court recognized that "at first blush," a reverse payment may look *per se* anticompetitive, but said that "upon reflection" suspicion abates "so long as the patent litigation is neither a sham nor otherwise baseless."[117] Under the circumstances in this case, settlements are a way to protect what the patentee is lawfully entitled to -- exclusivity.[118] The court went on to say that a rule that would penalize a patentee for settling a lawsuit neglects to consider that there is always a risk that a court will invalidate a patent, and that a patentee might legitimately decide to insure against that risk by settling.[119]

The court termed "unrealistic … the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent" because "[e]very settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. [I]t is unlikely that the holder of a weak patent could stave off *all* possible challengers with exclusion payments because the economics simply would not justify it."[120]

The court considered the alternative advocated by the FTC, holding these agreements to be presumptively unlawful, and rejected it:

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111. *Id.* at 204 (noting that "it takes no citation to authority to conclude that appellants prevail with some frequency in federal courts of appeals even when a high degree of deference is accorded the district courts from which the appeals are taken.").

112. *Id.* at 205.

113. *Id.* at 206.

114. *Id.* Typically in patent litigation, according to the court, the risk is with the accused infringer (the generic drug maker), who must develop the competing generic drug, obtain approval, and then enter the marketplace "at risk" of patent infringement litigation. The provisions of Hatch-Waxman changed this calculus, the court opined, because the generic drug maker does not need to expend very much of its resources in developing its ANDA. As a consequence, in the court's view, the generic drug maker has relatively "little to lose" in ANDA litigation. *Id.* at 207. The situation of the generic drug maker is in contrast to the patentee, who has lost the possibility of damages from the generic drug maker and can, at best, effectively obtain an injunction (either from the court or by the refusal of the FDA to provide regulatory approval until its Orange Book-listed patent(s) expire). The patentee's incentive is to prevent infringement, and a patentee may be willing to reach this result even if it needs to incur certain costs in the short term (*i.e.*, reverse payments).

115. *Id.*

116. *Id.* at 208.

117. *Id.*

118. *Id.* at 211.

119. *Id.*

120. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 212.

> But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course.[121]

Finally, while the court was "not so sure" that Barr's later attempts to recover its 180-day exclusivity period as the first ANDA filer were immune from antitrust considerations under the *Noerr-Pennington* doctrine, the scope of the anticompetitive aspects of the agreement was not illegally excessive, and the court could discern no antitrust injury.[122]

Once again, a circuit court rejected the FTC's call for a substantially *per se* determination that reverse payments are illegal and should be banned in all circumstances after carefully considering the agreement as a whole.

In 2010, the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, followed its own[123] and the Eleventh Circuit's[124] precedent[125] by ruling that the reverse payment settlement agreement, between defendants Bayer AG and several generic drug makers,[126] was not illegal under U.S. antitrust law and prevailing precedent.[127]

Arkansas Carpenters Health involved the antibiotic Cipro, to which Bayer AG held the patent.[128] The case arose when antitrust plaintiffs appealed the district court's grant of summary judgment for the ANDA settlement party defendants. The district court concluded that defendants did not violate Section 1 of the Sherman Act in settling its patent infringement litigation with a "reverse exclusionary payment" settlement.[129] The terms of the reverse settlement agreement

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121. *Id.* The court also considered the terms of the agreement, specifically whether the exclusionary terms of the agreement exceeded the scope of the patent protection -- *i.e.*, to enlarge the patent right. The answer here is that it did not, in part because the patent at issue was to a composition rather than a formulation. Under these circumstances, the patent scope was broader and the exclusionary right accordingly more expansive. In addition, the court noted that, unlike other instances of reverse payments, there was no generic bottleneck, since several other generic companies filed ANDAs on Zeneca's drug. And Barr entered the market under license, so there was competition in the marketplace (albeit as an "authorized generic" that sold for about 5% less than the branded).

122. *Id.* at 217-18.

123. *See supra* text accompanying notes 97-122.

124. *See supra* text accompanying notes 68-96.

125. *See* Arkansas Carpenters Health & Welfare Fund v. Bayer AG., 604 F.3d 98, 104–06 (2d Cir. 2010).

126. Including The Rugby Group, Watson Pharmaceuticals Inc., and Barr Laboratories Inc. *Arkansas Carpenters*, 604 F.3d at 100.

127. *Id.* at 106-110.

128. *Id.* at 100.

129. *Id.* at 104-10. As the consolidated case name indicates, the drug at issue was ciprofloxacin (or "Cipro"), a patented U.S. Patent No. 4,670,444 antibiotic owned by Bayer. *Id.* at 100. The other defendants were generic drug makers capable of making generic versions of Cipro who had filed ANDAs with the FDA to obtain regulatory approval for selling generic Cipro. *Id.* at 100-01. Under the provisions of the Hatch-Waxman Act, Bayer sued each of these generic drug makers to block FDA approval until the conclusion of the patent litigation. *Id.* at 101. The court recognized that "the Hatch-Waxman Act redistributes the relative risks between the patent holder and the generic manufacturer, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement." *Id.* The panel's opinion cited the earlier determination that such "reverse payments" were not illegal in *In re Tamoxifen Citrate Antitrust Litig.*,

between Bayer and Barr, the first ANDA filer, required Bayer to pay Barr $398.1 million,[130] and guarantee that the generic manufacturers could sell "brand name" Cipro, for six months prior to the expiration date of the patent.[131] Bayer received Barr's promise, and the promise of the other generic manufacturers, not to enter the marketplace with a generic version of Cipro, and concessions regarding the validity and enforceability of the patent, ending the ANDA lawsuit.[132] Barr "reserved its right to reinstate its ANDA-IV [lawsuit] if Bayer's patent were later held to be invalid."[133] Bayer's patent was later challenged by four different generic manufacturers,[134] none were successful.[135]

Plaintiffs responded to the reverse payment agreement by filing more than thirty antitrust lawsuits, which were consolidated for trial before the district court granted defendants' summary judgment motion.[136] The court expressly rejected a "*post hoc* determination of the potential validity" *vel non* of U.S. Patent No. 4,670,444 ("the '444 patent'), which would be contrary to the statutory presumption of validity and "would work a revolution in patent law."[137] Further, the district court stated that "in the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent."[138] The district court reasoned that there is no requirement that ANDA litigants are required to consider the public's interest in low-cost generic drugs, and such a rule would undermine "well-settled principles of patent law."[139] Finally, the district court noted that attempting to quantify the value of the public's interest in low cost drugs in these settlement agreements would contravene patents' presumption of validity and impact patent licensing in other transactions.[140]

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466 F.3d 187 (2d Cir. 2006) abrogated by *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (U.S. 2013). *Arkansas Carpenters*, 604 F.3d at 105.

130. *Arkansas Carpenters*, 604 F.3d at 110 n.8. A $49.1 million lump sum, and quarterly payments between $12.5 million and $17.125 million until six months prior to patent expiry. *Id.* at 102.

131. *Id.*

132. *Id.*

133. *Id.* at 102 n.9.

134. *Id.* "Four generic manufacturers—Ranbaxy, Schein, Mylan, and Carlsbad—subsequently challenged the Cipro patent." *Id.*

135. *Id.*

136. *Id.* at 102-03. The panel quoted from the district court opinion:

> The ultimate question – and this is the crux of the matter – is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. However, any adverse effects within the scope of a patent cannot be redressed by antitrust law.

Id.

137. *Id.* at 103 (quoting In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008) abrogated by F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (U.S. 2013) and *aff'd in part sub nom. Arkansas Carpenters*, 604 F.3d 98 (2d Cir. 2010)).

138. *Id.* (quoting In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 540 (E.D.N.Y. 2005) *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008) abrogated by F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (U.S. 2013) and *aff'd in part sub nom. Arkansas Carpenters*, 604 F.3d 98 (2d Cir. 2010)).

139. *Id.*

140. 604 F.3d 98, 102. In an interesting footnote, the Second Circuit explained that the "indirect purchaser plaintiffs" had included "*Walker Process*" antitrust claims, based on the willful assertion of an unenforceable patent, pursuant to *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.* 382

The Second Circuit analyzed defendants' behavior in the context of the Sherman Act prohibitions, informed by the opinions of other Circuit Courts of Appeal[141] as well as the Federal Trade Commission's arguments that reverse payment arrangements are *per se* illegal restraints of trade.[142] The court noted that "[a]uthorities are divided on this question."[143] Notably, while academic commentators and FTC economists take the *per se* illegal view, most courts have applied the "rule of reason" and held that such agreements are not sufficiently anticompetitive to establish antitrust liability.[144]

The Second Circuit noted that it is bound by its Circuit's precedent[145] and applied the "rule of reason" test to the facts. The court noted that there were no allegations that Bayer's '444 patent was a sham or that Bayer procured it by fraud.[146] The court said that "the only reasonable basis for distinguishing *Tamoxifen* would be if plaintiffs demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the Cipro patent,"[147] which plaintiffs could not do. Since a generic version of Cipro would "necessarily infringe" the '444 patent, the exercise of the patent to exclude generic Cipro was precisely within the scope of the patent's exclusionary right.[148] And while plaintiffs argued, on appeal, that the settlement agreement involved or permitted "manipulation" of the 180-day exclusivity period and precluded subsequent ANDA paragraph IV challenges, no evidence supported these allegations.[149] The court noted that Barr forfeited its

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U.S. 172, 177 (1965). *Arkansas Carpenters*, 604 F.3d at 110 n.10. Transfer was necessary because *Walker Process* claims "arise under" U.S. patent law and are thus within the exclusive province of the Federal Circuit. *Id.* That Court affirmed the District Court's grant of summary judgment for defendants. *Id.* (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008) abrogated by F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (U.S. 2013)).

141. *See supra* text accompanying notes 97-141.

142. *See* Kevin E. Noonan, *FTC Disapproves of 'Pay-for-Delay' Drug Deals*, PATENTDOCS (Feb. 15, 2010), http://www.patentdocs.org/2010/02/ftc-disapproves-of-payfordelay-drug-deals.html.

143. *Arkansas Carpenters*, 604 F.3d at 105

144. S*ee* Kevin E. Noonan, *Reverse Payments in Generic Drug Settlements* - Part I, Part II, Part III, PATENTDOCS (Feb. 22-23, 25, 2010)), http://www.patentdocs.org/2010/02/reverse-payments-in-generic-drug-settlements.html. The most relevant of these judicial determinations finding no antitrust liability is *Joblove v. Barr Labs. Inc.* (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 216 (2d Cir. 2006), being binding precedent on the court. In that case, the Second Circuit panel determined as a matter of law that the reverse-payment agreement was not anticompetitive to a degree that raised antitrust liability. *Id.* Here, the panel noted the similarities between the *Tamoxifen* court's reasoning and the analysis supplied by the district court; in *Tamoxifen* the court said:

> Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.

Arkansas Carpenters, 604 F.3d at 106 (quoting *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d at 213). Under the *Tamoxifen* precedent, there is a three-prong test for determining that a reverse payment agreement is legal: "where (1) there was no restriction on marketing noninfringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3) the agreement did not bar other generic manufacturers from challenging the patent." *Id.*

145. 604 F.3d at 106.

146. *Id.*

147. *Id.*

148. *Id.* In this regard the court distinguished so-called "formulation patents," which are limited to certain formulations of an active pharmaceutical ingredient, with "compound patents" (such as the '444 patent), which encompass all formulations of a drug.

149. *Id.*

180-day exclusivity period under the law, which required the ANDA filer to prevail in litigation invalidating an Orange Book-listed patent.[150]

However, the court also noted that the "practice of entering into reverse exclusionary payment settlements has increased" since the *Tamoxifen* decision.[151] Also significant for the panel were remarks from Senator Orrin Hatch to the effect that he found reverse payment provisions "appalling."[152] Finally, and perhaps most significantly, the court considered the *Tamoxifen* decision to have been based on "an erroneous characterization" of the law, specifically that the 180-day exclusivity period would be ceded by the first ANDA filer upon entering into a reverse payment-containing settlement of ANDA litigation.[153] While calling for a reconsideration of the *Tamoxifen* precedent by the court *en banc*, the panel followed precedent and affirmed the district court's decision that the agreement did not violate the antitrust laws.[154]

The Federal Circuit followed this trend of rejecting the FTC's view on reverse payment agreements in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.[155] In this case, several unions and other patient groups, as well as individual patients, sued defendants, including Bayer AG & Bayer Corp., Hoechst Marion Roussel, Watson Pharmaceuticals, and Barr Labs. Plaintiffs' claims involved ciprofloxacin hydrochloride ("Cipro"), Bayer's product, for which Barr was the first ANDA filer.[156] Litigation pursuant to 35 U.S.C. § 271(e)(2) of the Hatch-Waxman Act ensued and the parties settled.[157]

Plaintiffs alleged antitrust violations under Sections 1 and 2 of the Sherman Act, illegal contracts in restraint of trade, and claims under state antitrust and consumer protection laws. Later, plaintiffs added a *Walker Process* claim.[158] However, the district court granted summary judgment against the plaintiffs, holding that any anticompetitive effects "were within the exclusionary zone of [the patent]."[159] The court's decision was based on a rule of reason analysis that did not get past

150. *Id.* at 107.

151. 604 F.3d at 109. Fourteen settlements prior to the *Tamoxifen* decision, none of which contained reverse payment provisions, compared with 27 settlements after the decision, in which 20 contained reverse payment provisions. It should be noted that these data were gleaned from *amicus* briefs arguing against the legality of reverse-payment provisions in settlement agreements. *Id.*

152. *Id.*

153. *Id.* The panel's sentiments, noted above, were obvious in its conclusion:

> In sum, as long as *Tamoxifen* is controlling law, plaintiffs' claims cannot survive. Accordingly, we AFFIRM the judgment of the district court. However, we believe there are compelling reasons to revisit *Tamoxifen* with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc.

Id. at 110.

154. *Id.*

155. 544 F.3d 1323 (Fed. Cir. 2008)

156. U.S. Patent No. 4,670,444 (filed May 29, 1984).

157. In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008). Under the terms of the settlement agreement, defendants agreed not to challenge the validity or enforceability of the patent, and Barr would convert its paragraph IV certification to a Paragraph III (agreeing not to enter the market until the patent expired). The reverse payment from Bayer to Barr totaled $398.1 million. Bayer also agreed to make quarterly "reverse payments" or supply Barr with Cipro for resale until after the patent expired. *Id.* at 1328-29 & n.5.

158. *Id.* at 1329 (despite the fact that the patent had been through a re-exam with a claim specific to ciprofloxacin hydrochloride exiting unamended).

159. *Id.* at 1330 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d at 523–40).

the first step: any anti-competitive effects fell within the ambit of the patent exclusionary right and hence were not illegal.

On appeal, the Federal Circuit affirmed.[160] The panel reviewed the judgment *de novo* on all issues.[161] The plaintiffs asserted five points of error: (1) the agreement was *per se* illegal, or illegal under a proper application of the rule of reason; (2) the agreement improperly extended the exclusionary zone of patent; (3) the district court should have considered the law of regional circuits and government agencies (FTC); (4) that the District Court should have considered the effects of these kinds of agreements on other generic entrants; and, (5) the effects on competition of Barr's 180-day exclusivity period.[162]

As to the first asserted point of error, the court reminded the plaintiffs that the Supreme Court has not interpreted the Sherman Act as prohibiting all agreements in restraint of trade, just those that constitute unreasonable restraints.[163] The Federal Circuit found no basis for finding the agreement *per se* illegal and instead applied the Second Circuit's analysis.[164] Judge Prost opined that "there was no evidence that the Agreements created a bottleneck on challenges to the patent or otherwise restrained competition outside the 'exclusionary zone' of the patent."[165]

The second allegation of error was that the settlement agreement improperly extended the exclusionary scope of the patent. The Federal Circuit considered plaintiffs' argument,[166] but noted that the district court had cited many Supreme Court and Courts of Appeals holdings that "any adverse anti-competitive effects within the scope of the patent could not be redressed by antitrust law."[167] The Federal Circuit concluded that the purpose of Bayer's ANDA agreement was to "exclude the defendants from profiting from the patented invention," as was Bayer's right, as the patentee of the drug.[168] The court explained that "[s]ettlement of patent claims by agreement between the parties – including exchange of consideration – rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition."[169] Of special importance to this decision is the court's discounting the allegation that the settlements hinder challenges to the patent, in view of the fact that four other generic manufacturers had challenged the patent after the settlement at issue.[170]

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160. 544 F.3d 1323. The opinion was written by Judge Prost, joined by Judge Schall and Judge Ward, District Judge for the Eastern District of Texas, sitting by designation. *Id.*

161. *Id.* at 1330-31.

162. *Id.* at 1331. The two final arguments raised on appeal were that the district court should have considered the effects of these kinds of agreements on other generic entrants, and the court should have considered the effect of Barr's 180-day exclusivity period on competition. *Id.*

163. *Id.* at 1331-32 ("Only agreements that have a 'predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit' are deemed to be per se unlawful under the Sherman Act." (quoting State Oil Co. v. Khan., 522 U.S. 3, 10 (1997))).

164. 544 F.3d 1332.

165. *Id.*

166. *Id.* at 1332-33.

167. *Id.* at 1333 ("This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of 'the right to exclude others from making, using, offering for sale, or selling the invention,'" (quoting U.S. Patent Act 35 U.S.C. § 154(a)(1) (2014))) and concluding "[t]hus, 'a patent is an exception to the general rule against monopolies and to the right of access to a free and open market.'" (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945))).

168. *Id.*

169. *Id.* (quoting Standard Oil Co. v. United States, 283 U.S. 163, 171 & n.5 (1931)).

170. *Id.* at 1338.

The court declined plaintiffs' invitation to apply the legal opinions of other regional circuits, administrative agencies or legal commentators such as the Sixth Circuit decision in *In re Cardizem CD Antitrust Litigation,*[171] and the FTC's position that reverse payments should be *per se* illegal.[172] The court also distinguished the Sixth Circuit's decision that reverse payment agreements were *per se* illegal, "because the court failed to consider the exclusionary power of the patent in its antitrust analysis."[173]

The Federal Circuit turned instead to decisions from the Eleventh[174] and Second Circuits.[175] These circuits share the Federal Circuit's approach that antitrust violations occur in ANDA reverse payment agreements when the patent is invalid or unenforceable due to inequitable conduct, or when the litigation is a sham.[176] The Federal Circuit also opined that, absent fraud on the U.S. Patent & Trademark Office during patent prosecution or sham litigation, patent validity does not need to be considered in a rule of reason analysis,[177] due to the rule's presumption of validity.[178]

The last of the series of negative judicial responses to the FTC's position came in the Eleventh Circuit's 2012 decision in *Federal Trade Commission v. Watson Pharmaceuticals,* which reaffirmed the holding of *Schering-Plough, Inc.*

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171. 332 F.3d 896 (6th Cir. 2003).

172. In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335 (Fed. Cir. 2008) abrogated by F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 186 L. Ed. 2d 343 (U.S. 2013):

> In [the District Court's rule of reason] analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent. The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch-Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a *per se* violation of the antitrust laws in *In re Cardizem*, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. *In re Cardizem*. Furthermore, th[at] agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. *Id.* at 908 n.13. Thus, th[at] agreement clearly had anti-competitive effects outside the exclusion zone of the patent…To the extent that the Sixth Circuit may have found a *per se* antitrust violation based solely on the reverse payments, we respectfully disagree (citations omitted).

173. *Id.* at 1335.

174. *Id.* at 1335-36.

175. *Id.*

176. *Id.* at 1336. *See* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175-77 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies).

177. *Id.* at 1336-37 (quoting *In re Schering-Plough Corp.,* No. 9297, 2003 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003)). Ironically, citing an FTC position to this effect: "it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." It seems, however, that the FTC has changed its position on this point, because it argued that the "expected value" of the lawsuit at the time of settlement be considered in the rule of reason antitrust analysis. *Id.* at 1337.

178. *Id.* "[T]he district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements." Even Circuit Court Judge Richard Posner, a leader in the "law and economics" movement, seems to agree: "As Judge Posner [has] remarked, if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003).

et al.[179] The case involved a reverse payment settlement between New Drug Application (NDA) holder Solvay Pharmaceuticals and ANDA filers Watson Pharmaceuticals and Paddock Pharmaceuticals over AndroGel, a prescription testosterone formulation prescribed for treating hypogonadism.[180] Watson and Paddock filed separate ANDAs having paragraph IV certifications that Solvay's patent was invalid or unenforceable, and Solvay timely filed suit.[181] The parties settled before the court ruled on defendants' summary judgment motions, after a *Markman* hearing.

The appeal arose pursuant to an investigation by the FTC of the parties' settlement agreements,[182] wherein the FTC alleged violations of Section 5a of the Federal Trade Commission Act.[183] The district court granted defendants' motion to dismiss explaining that, in the Eleventh Circuit, reverse payments did not constitute anticompetitive behavior if "the terms of the settlement remain[ed] within the scope of the exclusionary potential of the patent."[184]

The Eleventh Circuit Court of Appeals affirmed the district court's holding. From the outset the court's opinion showed little patience with the FTC's theories, explaining that new drugs are produced in the U.S. under the maxims "no risk, no reward" and "more risk, more reward," and that "[n]o rational actor … would take [the] risk" of investing more than "$1.3 billion" on a potential drug, in an industry where "[o]nly one of every 5,000 medicines tested . . . is eventually approved for patient use . . . without the prospect of a big reward."[185] Under this system, the court recognized that the successful drug maker who patents its drug will "usually…recoup its investment and gain a profit, sometimes a super-sized one."[186] The court also noted that "more money, more problems" result, and that profits "frequently attract competitors in the form of generic drug manufacturers that challenge or try to circumvent the pioneer's monopoly in the market."[187]

The court returned to its previously stated analysis of the FTC's position, stating that "[t]he lynchpin of the FTC's complaint is its allegation that Solvay probably would have lost the underlying patent infringement action" and that "Solvay

179. F.T.C. v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012) *cert. granted,* 133 S. Ct. 787 (U.S. 2012) and *rev'd and remanded sub nom.* F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (U.S. 2013) (The "et al." included the ANDA filer, Paddock Pharmaceuticals, and its licensee, Par Pharmaceuticals).

180. *Id.* at 1304–05. Unimed (acquired by Solvay and later acquired by Abbott) and Besins Healthcare S.A. held the NDA, as well as Orange Book-listed U.S. Patent No. 6,503,894 directed to the formulation; this patent will expire in August 2020. *Id.* at 1304.

181. *Id.* at 1303-04 (pursuant to 35 U.S.C. § 271(e)(2) in the U.S. District Court for the Northern District of Georgia).

182. *Id.* at 1305 (pursuant to 21 U.S.C. § 355 (2003)).

183. *Id.* (pursuant to 15 U.S.C. § 45(a)(1)).

184. *Id.* at 1306 (pursuant to FED. R. CIV. PRO. 12(b)(6) (failure to state a claim)). In doing so, the District Court rejected the FTC's contentions in its complaint (1) that the settlement agreement between Solvay and Watson is an unfair method of competition; (2) that the settlement agreement among Solvay, Paddock, and Par is an unfair method of competition; and (3) that Solvay engaged in unfair methods of competition by eliminating the threat of generic competition to AndroGel and thereby monopolizing the market. *See* Complaint at ¶¶ 106–113, Fed. Trade Comm'n v. Watson Pharms. Co., Inc., No. CV. 09-00598 (C.D. Cal. Jan. 29, 2009). *i.e.*, d[id] not provide for exclusion going beyond the patent's term or operate to exclude clearly noninfringing products, regardless of whether consideration flowed to the alleged infringer.

185. *Watson Pharms., Inc.*, 677 F.3d at 1300.

186. *Id.*

187. *Id.*

was *not likely to prevail*" in the patent litigation because Watson and Par produced substantial evidence that Solvay's patent was invalid and/or unenforceable and that their generic drug did not infringe.[188] "The difficulty," according to the court, "is [in] deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law," a difficulty that "is made less difficult by the law's pro-precedent tenets" and "[o]ur earlier decisions" which "carry us much of the way to a resolution [of the] case."[189]

In reviewing the Eleventh Circuit precedent, all of which reject the FTC's position, the court discussed the bases for these earlier decisions. While noting that agreements between competitors that keep one competitor from the market to the benefit of the other, and that increase costs to the public, would normally be barred by antitrust laws, the panel held that reverse payment cases were "atypical cases because 'one of the parties [owns] a patent'."[190] This "[made] all the difference" in the panel's view, because the patent holder "[has] a 'lawful right to exclude others'" from the marketplace.[191] Further, the court explained that even subsequent invalidation of the patent would not render the agreement unlawful, as its lawfulness must be considered at the time of settlement, at which time the patentee had the right to exclude competitors.[192] What counts is the "*potential* exclusionary power" of the patent at the time of the reverse payment settlement, not its "*actual* exclusionary power" unless a court had rendered a negative judgment of invalidity or unenforceability prior to the settlement.[193] But the court noted that the mere existence of a patent did not give the parties to a reverse payment settlement *carte blanche*; the settlement cannot "exclude more competition than the patent has the potential to exclude."[194] Such agreements remain "vulnerable to antitrust attack," and are subject to a three-prong analysis" that requires an evaluation 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."[195]

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188. *Id.* at 1305–06.

189. *Id.* at 1306.

190. *Id.* at 1307 (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003)).

191. *Watson Pharms., Inc.*, 677 F.3d at 1307 (quoting *Valley Drug*, 344 F.3d at 1304).

192. *Id.* at 1308 (quoting *Valley Drug*, 344 F.3d at 1305).

193. *Id.* at 1308 (emphasis original).

194. *Id.*

195. *Id.* at 1308, 1310 (citing *Schering–Plough*, 402 F.3d at 1066). In another footnote, the court also clarified the meaning of the term "strength of the patent" as used in the *Schering Plough* case:

> The FTC's brief in this case places great weight on our statement in *Schering-Plough* that a proper antitrust analysis of reverse payment agreements needs to "evaluate the *strength of the patent*." 402 F.3d at 1076 (emphasis added). The FTC argues that evaluating the "strength of the patent" means evaluating "the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement." We disagree. When read in the context of the facts and the reasoning of *Schering-Plough*, the phrase "strength of the patent" refers to the potential exclusionary scope of the patent – that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim. Nowhere in the *Schering-Plough* opinion did we actually evaluate the merits of the infringement claim when defining how much competition the patent could potentially exclude from the market. *Id.* at 1311 n.8.

The court also provided useful contrast between these earlier cases denying antitrust liability with one, *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), in which the court reversed dismissal of an antitrust case brought by a private party. *Id.* at 1312. In that case, the generic drug maker "had agreed 'to refrain from *ever* marketing a generic' version of the patented drug," and the generic drug maker was permitted to "retain its 180 day exclusivity period" despite having "no

The court then synthesized the rule from these cases, ruling that "[a]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[196] The court assessed the FTC's allegations under this standard.[197] The court declined to adopt the FTC's rule that "an exclusion payment is unlawful if…it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date."[198] The court reasoned that "[r]ational parties settle to cap the cost of litigation and to avoid the chance of losing," noting that "[o]ne side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty."[199] Patent litigation is analogous, according to the opinion, and "[w]hen both sides of a dispute have a substantial chance of winning and losing . . . it is reasonable for them to settle" without incurring antitrust liability for doing so[200]

The court also emphasized the burden that the FTC's approach would place on parties and courts, noting that the FTC's approach would discourage settlements and contravene the general consensus that settlements of litigation should be encouraged.[201]

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intention of marketing the drug" in this country. *Id.* at 1311–12 (quoting *Andrx Pharms.*, 421 F.3d at 1231, 1235). This resulted in the generic drug maker's 180-day exclusivity period to "act…like a cork in a bottle" preventing another generic drug maker from entering the market. *Id.* at 1311. (This tactic was eliminated by later amendments to the statute wherein the first ANDA filer can forfeit its exclusivity rights if it fails to market a generic version of a patented drug "within certain time periods." 21 U.S.C. § 355(j)(5)(D)).

196. *Watson Pharms., Inc.*, 677 F.3d at 1312.

197. *Id.* (noting those allegations to be: (1) that Solvay was "not likely to prevail" in the underlying patent infringement litigation; (2) that accordingly the patent has "*no* exclusionary potential" (emphasis in original); and (3) if a patent has no exclusionary potential, the reverse payment arrangement "necessarily" exceeds its "potential exclusionary scope" and thus is tantamount to "'buying off' a serious threat to competition.").

198. *Id.*

199. *Id.* at 1313. The rationality, rather than possible perfidity, of this behavior is illustrated colorfully as follows:

> A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.

Watson Pharm., Inc., 677 F.3d at 1312.

200. *Id.* The court continued its theme of the rationality of this behavior, citing the opinion in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*:

> No matter how valid a patent is -- no matter how often it has been upheld in other litigation or successfully reexamined -- it is still a gamble to place a technology case in the hands of a lay judge or jury. Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects.

Id. (citing 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003)). In addition, the court noted practical difficulties with the FTC's approach, including "an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled," calling it a "retrospective predict-the-likely-outcome-that-never-came approach" (and noting that "[p]redicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages."). *Id.* at 1313-14.

201. The court also noted that the FTC itself had voiced concerns over the approach now espoused in appeal:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are in-

Finally, the court suggested that the FTC's concerns are likely to be overstated, because of "the reality that there usually are many potential challengers to a patent, at least to drug patents" and other generic competitors will arise to challenge the patent.[202] If the FTC is correct that reverse payment arrangements indicate a "weak" or vulnerable patent, the "[b]lood in the water" will likely provoke a "feeding frenzy" of patent challenges in the Court's view.[203] "Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent."[204]

C. The Third Circuit Rejects the Second, Eleventh and Federal Circuits by Ruling that Reverse Payment Agreements are Presumptively Illegal Under a "Quick Look" Truncated Rule of Reason Approach

Together, the aforementioned cases from the Second, Eleventh, and Federal Circuits defined what became known as "the scope of the patent" test for reverse settlement payment agreements. Under this test, an agreement that did not exceed the legitimate scope of the patent, presumed valid by the Patent Act, did not raise antitrust concerns or liability. This position was soundly rejected by the Third Circuit in *In re K-Dur*, where a three-judge panel agreed with the FTC that such agreements should be presumptively illegal.[205] The court established that the proper approach is to evaluate any agreement alleged to be one that restrains trade by the "rule of reason," following its appreciation of applicable Supreme Court

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formed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

Id. at 1314.

202. *Id.* at 1315.

203. *Id.*

204. *Id.* (comparing Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004)("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent [is] invalid others will try the same thing.")

205. *See* In re K-Dur Antitrust Litig., 686 F.3d 197 (3rd Cir. 2012). The facts of the case are these. The drug K-Dur 20 is a specific formulation of potassium chloride sold by Schering-Plough Co. (now owned by Merck) and protected by a formulation patent (U.S. Patent No. 4,863,743). Characterized as "separate from the FTCs challenge" (but no doubt motivated by it), the plaintiffs here filed various lawsuits that were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation, fortuitously for plaintiffs and the FTC, in an appellate circuit that had not ruled on the reverse payment practice. The case named as plaintiffs drug wholesalers (Louisiana Wholesale Drug Co.) and retailers (CVS Pharmacy, Rite Aid, Walgreens, Eckerd, Safeway, Kroger, Albertson's, Hy-Vee and Maxi Drug) against Merck & Co. (the successor-in-interest to Schering-Plough) and Upsher-Smith Laboratories. *Id.* at 207. A Special Master appointed by the Court filed a Report and Recommendation that the lawsuits be dismissed, based on Schering's right under the patents to "exclude infringing products until the end of [the patent's] term," and that reverse payment agreements warrant antitrust scrutiny only if they either exceeded the scope of the underlying patents or if the patent infringement lawsuits brought under the authority of the patents were objectively baseless (grounds that other appellate circuits had also considered in assessing the legality of reverse payment agreements). *Id.* at 208.

precedent.[206] In doing so, the court stated that "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect."[207] This inquiry has three parts, according to the Third Circuit: there must be a showing of an anticompetitive effect on the market, which shifts the burden "to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive effect."[208] The antitrust plaintiff can rebut this showing if it can establish that the restraint on trade is not "reasonably necessary to achieve the [purportedly] pro-competitive objective" asserted by the antitrust defendant.[209]

The court rejected what it termed "precedent from other Circuits," namely cases that have almost unanimously found reverse payment agreements to be lawful.[210] The opinion noted that in each case, the appellate court found the reverse payments to be lawfully based on the patent's presumption of validity and the patentee's right to exclude, and that the agreements did not involve an improper extension of that exclusionary right. The panel opinion termed these considerations the "scope of the patent" test. However, the court declined to follow these cases, noting that the cases are not binding authority.[211]

The panel then explained that it did not believe that the "scope of the patent" test was the appropriate test and should not entitle reverse payments to avoid antitrust scrutiny.[212] The court formed this conclusion because "that test [in the panel's view] improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition."[213] The court provided three grounds for this conclusion. First, the court stated that it creates "an almost unrebuttable presumption of patent validity," due to the fact that the settlement "forces a presumption that the patent holder would have prevailed" in the underlying (and settled) ANDA litigation.[214] This presumption has no substantive vitality, according to the panel, because it is merely "a procedural device and is not a substantive right of the patent holder."[215] The court also believed that using the presumption of validity to uphold reverse payment agreements was "particularly misguided" when the basis for the underlying patent infringement defense is non-infringement, because the burden is properly on the patentee, not the challenger,

206. *Id.* at 218.
207. *Id.* at 209 (*citing* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).
208. *Id.*
209. *Id.*
210. *Id.* at 211-12 (citing Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. Federal Trade Comm'n, 402 F.3d 1056 (11th Cir. 2005); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 105 (2d Cir. 2010); and In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008)).
211. *In re K-Dur Antitrust Litig.*, 686 F.3d at 211, n.8.
212. *Id.* at 218.
213. *Id.* at 214.
214. *Id.* at 214-15.
215. *Id.* at 214 (citing Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983)).

to prove infringement.[216] The panel opinion further "question[ed] the assumption" that subsequent ANDA filers will come forward to challenge "weak" patents.[217]

The Third Circuit panel considered the pernicious effects of reverse settlements as being directed to first ANDA filers, which it asserts are the "most motivated" due to the promise of 180 days of market exclusivity.[218] The panel also cited several Supreme Court cases for the proposition that patent rights are "a limited exception to a general rule of the free exploitation of ideas," and that "the public interest supports judicial testing and elimination of weak patents."[219] The panel explicitly limited the scope of its decision to "reverse payments between patent holders and would be (*sic*) generic competitors in the pharmaceutical industry."[220] It is clear that the panel was motivated at least in part by its perception, as argued by the FTC, that reverse payment settlement agreements were contrary to and in contravention of Congressional goals of "increase[ing] the availability of low cost generic drugs," (despite findings in other circuits that in some circumstances reverse payment settlements do just that).[221] Nevertheless, the panel found that "[t]he line that Congress drew between these competing objectives [of stimulating innovation and furthering the public interest] strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry."[222] And the panel limited the scope of its decision only to settlements that involve payments from the patentee to the putative generic competitor, stating: "[n]othing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger."[223]

The proper procedure under Third Circuit law is thus to use a "quick look" rule of reason analysis "based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties" and that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade."[224] In doing so, the court also "agreed[d] with the FTC that there is no need to consider the merits of the underlying patent suit because '[a]bsent proof of other offsetting considerations, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that

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216. *In re K-Dur Antitrust Litig.*, 686 F.3d at 214.
217. *Id.* at 215.
218. *Id.*
219. *Id.* This in contrast to the 11th Circuit's recognition that:
> No matter how valid a patent is -- no matter how often it has been upheld in other litigation or successfully reexamined -- it is still a gamble to place a technology case in the hands of a lay judge or jury. Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects.

In re Coprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003).
220. *In re K-Dur Antitrust Litig.*, 686 F.3d at 216.
221. *Id.* at 217.
222. *Id.*
223. *Id.* at 217-18. According to the court, "the vast majority of pharmaceutical patent settlement [will be] unaffected" by its ruling. *Id.* at 218.
224. *Id.*

represents an otherwise reasonable litigation compromise,'" citing the Commission's Final Order in this matter (that was overturned by the Eleventh Circuit).

Although this case involved the same manufacturer, pharmaceutical product and similar issues as *Schering-Plough Corp. v. Fed. Trade Comm'n* in the Eleventh Circuit, the Third Circuit reached an opposite result, further dividing the Circuits on the issue of the legality of reverse payment agreements.

D. The Supreme Court Settles the Split

Following the Eleventh Circuit's decision in *Federal Trade Commission v. Watson Pharmaceuticals*, the FTC sought certiorari. Prompted by the disagreement among the Circuits, the Supreme Court granted *certiorari*, heard oral arguments and ruled 5-3 in favor of the Federal Trade Commission, in the case now styled *FTC v. Actavis, Inc.*[225] Writing for the majority,[226] Justice Breyer reversed the lower court's dismissal of the FTC's complaint that a "reverse payment" settlement was anticompetitive and violated the antitrust laws. But the Court refused to accept the FTC's position that such agreements are presumptively unlawful, holding that lower courts should apply an antitrust "rule of reason" analysis when evaluating such agreements.

Announcing the Court's opinion, Justice Breyer wrote that reverse payment settlement agreements can "sometimes violate the antitrust laws," and thus that the district court should not have dismissed the FTC's case.[227] The opinion focused on the risk to the consuming public posed by settlement of cases where the patent is invalid or not infringed. Although the Court was willing to accept that the agreement's "anticompetitive effects fall within the scope of the exclusionary potential of the patent," this fact did not sufficiently "immunize the agreement from antitrust [scrutiny]."[228] The majority's concern was that, while the holder of a valid patent may be exempt from antitrust liability when enforcing the exclusionary right, ANDA litigation involves an allegation that either the patent is invalid, in which case the immunization is lost, or the generic product does not infringe, in which case the patent cannot be enforced against the non-infringing generic drug.[229] Accordingly, such reverse payment settlement agreements "tend to have significant adverse effects on competition."[230] For this reason, the majority believed that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."[231] Consequently,

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225. 133 S. Ct. 2223 (2013).
226. The majority included Justices Breyer, Kennedy, Ginsburg, Sotomayor and Kagan. *Id.*
227. *Id.* at 2227.
228. *Id.* at 2230.
229. *Id.* at 2231.
230. *Id.*
231. *Id.* Support for this proposition (vigorously disputed by the dissenting Justices; *see below*) can be found in Justice Breyer's opinion in several of the Court's earlier cases, including *United States v. Line Material Co.*, 333 U. S. 287, 308 (1948) (retail price-setting between patentees); *United States v. United States Gypsum Co.*, 333 U. S. 364, 390–391 (1948) (both cases from those days where the only patents that were valid were those the Court had not yet ruled upon); and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U. S. 172, 174 (1965) (incongruously, a case that

> "[R]ather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anti-competitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."[232]

The opinion also cites several earlier cases where settlement agreements were held to violate antitrust laws.[233] The majority seemed to be seeking some sort of "balance" with regard to accommodating patent *and* antitrust policies. Finally the Court found that the "procompetitive" purposes of the Hatch-Waxman Act are consistent with having courts apply antitrust principles to reverse payment settlement agreements in ANDA litigation.[234]

The majority recognized the Eleventh Circuit's concern that "antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement," an outcome that "will prove time consuming, complex, and expensive."[235] However, the Court found the "general legal policy favoring the settlement of disputes," insufficient to override the majority's concerns regarding anticompetitive effects of reverse payment settlement agreements. In response to the Eleventh Circuit's concern, the majority offered five "considerations" on which it based its holding that the FTC should be permitted to establish an antitrust violation:

> *First*, the specific restraint at issue has the potential for genuine adverse effects on competition.... The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.[236]

The opinion also stated this concern as "[t]he patentee and the challenger gain; the consumer loses."[237] The majority disregarded the idea that entering into such an agreement would merely entice additional generic challengers to get in line to be bought off by the patentee, due to the loss of the 180-day exclusivity for

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established one of the grounds for finding reverse payment settlement agreements unlawful, *i.e.*, asserting a patent obtained by "fraud on the Patent Office").

232. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. at 2231.

233. These cases were not in the Hatch-Waxman context, but included *United States v. Singer Mfg. Co.*, 374 U. S. 174 (1963) (where the issue was collusion between three patentees to enforce the strongest patent against their competitors); *United States v. New Wrinkle, Inc.*, 342 U. S. 371, 378 (1952) (more price fixing) and *Standard Oil Co. (Indiana) v. United States,* 283 U. S. 163 (1931) (patentees setting royalty rates). The question of whether any of these situations are at all relevant to reverse payment settlement agreements was not addressed in the opinion, which merely seemed content to find cases where the Court has in the past found that settlement "agreements are not outside the scope of antitrust attack" (and does not consider whether the circumstances surrounding this prior approbation is in any way related to the question before the Court).

234. *F.T.C. v. Actavis, Inc* 133 S. Ct. at 2242.

235. *Id.* at 2234.

236. *Id.* at 2234 (emphasis in original) (internal quotation marks omitted).

237. *Id.* at 2235.

later ANDA filers, and the 30-month delay in FDA approval raised by ANDA litigation against subsequent filers.[238] These considerations convinced the majority that, rather than producing an untenable situation where the owner of a weak patent cannot possibly "buy off" all potential competitors, the Hatch-Waxman regime in fact produces a critical generic challenger, the first filer, who if successfully bought off by a reverse payment settlement agreement will effectively chill future challenges by other generic drug makers.[239]

> *Second*, these anticompetitive consequences will at least sometimes prove unjustified. [Here, the majority's concern is that a court cannot tell without inquiry whether a particular reverse payment settlement agreement is or is not "justified" under antitrust principles.] Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about… anticompetitive consequences….[240]

This uncertainty led the majority to conclude that the district court erred in dismissing the FTC's complaint, because by doing so it denied the Commission the chance to establish whether or not there were such justifications for the agreement.

> *Third*, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.

Once again the majority is concerned with the size of the payment, which a court can use to be a strong indicator of market power.[241]

> *Fourth*, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed.

The majority finds the Eleventh Circuit throws the baby out with the bathwater by refusing to apply antitrust principles due to the difficulties of litigating patent infringement and validity (when, of course, the appellate court was merely recognizing that the impetus for these settlements would disappear should the parties be required to litigate in an antitrust context what they avoid litigating in an ANDA context).[242]

According to the majority, "it is normally not necessary to litigate patent validity to answer the antitrust question," because "[a]n unexplained large reverse

238. *Id.*
239. *Id.*
240. *Id.* at 2235–36 (emphasis in original) (citations omitted).
241. *Id.* at 2236.
242. *Id.*

payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[243]

> *Fifth*, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.[244]

Here, the majority posits that the parties can settle an ANDA dispute in other ways by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.[245]

The majority summarized these considerations as follows:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration – the desirability of settlements – that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.[246]

However, the FTC did not entirely win the day, nor did the Court fully agree with the decisions (or rationales) from the Third and Sixth Circuits. The Court rejected the FTC's suggestion that these agreements are presumptively unlawful and that the rule of reason should be applied using a "quick look" or other shortcut. The majority explained that the "quick look" approach was permissible only in instances where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."[247] Instead, the Court held that the FTC must establish antitrust liability using a "rule of reason" analysis. In conducting this analysis, district courts can structure the inquiry to avoid litigating patent validity, the Court explained. However, the Court left it to these "lower" courts to determine how exactly to accomplish this.[248]

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243. *Id.*

244. *Id.* at 2237.

245. *Id.* Once again the majority return to the existence of a payment, saying that "the basic antitrust question" comes down to the reasons for the payment (and, of course, a court's determination of whether those reasons are valid).

246. *Id.*

247. *Id.* (quoting California Dental Assn. v. FTC, 526 U. S., 756, 770 (1999) (Breyer, J., concurring in part and dissenting in part)). This treatment is not justified for reverse payment settlement agreements according to the majority, because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.*

248. *Id.* at 2238.

The Chief Justice wrote the dissent, applying much of the same precedent but reaching the opposite conclusion.[249] The dissent contended that the existence of a patent, cabined within its proper scope, should be enough to justify a reverse payment settlement of ANDA litigation.[250] Instead of following "well-established" principles of patent law, the dissent asserted that the majority would "use antitrust law's amorphous rule of reason to inquire into the anticompetitive effects of such settlements."[251] Besides finding no support in the patent law or other statutes for the majority's holding, the dissent objected to the ruling because it "will discourage the settlement of patent litigation."[252] Patent law "provides an exception to antitrust law, and the scope of the patent… forms the zone within which the patent holder may operate without facing antitrust liability."[253] The dissent also noted that the only time a settlement was found to violate antitrust law in past Supreme Court precedent was when the settlement went beyond the boundaries of the patent grant.[254] The dissenting opinion dissected the authority cited by the majority and provided context that contradicted the majority opinion.[255]

The dissenting Justices contended that the majority's fancy that the antitrust question can be answered without considering the validity of the patent is unrealistic, and "depriving [the patentee] of such a defense – if that's what the majority means to do – defeats the point of the patent, which is to confer a *lawful* monopoly on its holder."[256] And the dissent evinced little faith in the many presumptions underlying the majority opinion, regarding the mechanics and purpose of the Hatch-Waxman Act or how district courts will apply the Court's decision.[257]

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249. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. at 2238 (Roberts, C. J., dissenting) (joined by Scalia & Thomas, JJ.) (Justice Alito recused himself from this case).

250. *Id.*

251. *Id.*

252. *Id.*

253. *Id.* According to the Chief Justice, "[t]his should go without saying, in part because we've said it so many times."

254. *Id.* at 2239 (citing United States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963)). Actions within the scope of the patent are not subject to antitrust scrutiny unless patents are obtained by fraud (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965)) or the patentee engaged in sham litigation (citing Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U. S. 49, 60–61 (1993)).

255. *Id.* at 2240-42. And the history of the application of antitrust law in the patent context is telling:

> The majority is therefore right to suggest that these 'precedents make clear that patent-related settlement agreements can *sometimes* violate the antitrust laws.' Ante, at 10 (emphasis added). The key word is sometimes. And those sometimes are spelled out in our precedents. Those cases have made very clear that patent settlements – and for that matter, any agreements relating to patents -- are subject to antitrust scrutiny if they confer benefits beyond the scope of the patent. This makes sense. A patent exempts its holder from the antitrust laws only insofar as the holder operates within the scope of the patent. When the holder steps outside the scope of the patent, he can no longer use the patent as his defense. The majority points to no case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon.

According to the Chief, "settling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful." *Id.* at 2244 (emphasis in original).

256. *Id.* at 2244 (emphasis in original).

257. *Id.* at 2245 ("Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting

IV. CONCLUSION

The Supreme Court's decision in *Actavis* will likely make reverse payment settlement agreements less likely, which can be expected to harm rather than facilitate generic competition. Unable to settle, innovator patentees will be motivated to litigate every case to conclusion, to avoid antitrust scrutiny involving the same or similar infringement and validity questions more effectively settled in ANDA litigation. Coupled with the FTC's position that transfer of "anything of value" from the branded drug maker to a generic competitor should also merit antitrust scrutiny, there is now much less advantage for either party in an ANDA lawsuit to settle. As a result, the Court's ruling will impose on generic manufacturers seeking to challenge a patent the costs and risks of ANDA litigation; it is hard to see how this will motivate the types of generic challenges envisioned in the Hatch-Waxman Act. It is unlikely that the majority envisioned this consequence, but it is the outcome that will almost certainly ensue.

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legal considerations present in the circumstances.'"). The policy implications are bleak regarding benefits to the consumer:

> The irony of all this is that the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place. Patent litigation is costly, time consuming, and uncertain. . . . Generics "enter this risky terrain only after careful analysis of the potential gains if they prevail and the potential exposure if they lose." . . . Taking the prospect of settlements off the table -- or limiting settlements to an earlier entry date for the generic, which may still be many years in the future -- puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in the first place. The majority assures us, with no support, that everything will be okay because the parties can settle by simply negotiating an earlier entry date for the generic drug manufacturer, rather than settling with money. . . . But it's a matter of common sense, confirmed by experience, that parties are more likely to settle when they have a broader set of valuable things to trade.

Id. at 2247 (citations omitted).