

2013

The Need for Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements

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Cover Page Footnote

J.D. Candidate, 2014, Fordham University School of Law; B.B.A., 2010, The George Washington University. I would like to thank my advisor, Professor Olivier Sylvain, for his guidance with this Note. For Mom, Dad, and Eamon.

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Tania Khatibifar*

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INTRODUCTION

Reverse payment settlements have ignited a firestorm debate among all affected parties: consumer groups, brand-name pharmaceutical companies, generic manufacturers, pharmaceutical wholesalers and retailers, lawmakers, executive agencies, and the federal courts. The Federal Trade Commission ("FTC") has waged a decade-long battle against such private settlements of pharmaceutical patent litigation as illegal market-sharing

agreements,¹ with skirmishes among the circuits trending in favor of the settling parties² until recently.³ The Third Circuit's recent decision in *In re K-Dur Antitrust Litigation* unsettled this trend,⁴ and the Supreme Court granted the FTC's petition for a writ of certiorari in a separate case on the issue on December 7, 2012.⁵

A reverse payment settlement is an agreement ending a pharmaceutical patent infringement suit under which a putative patent holder agrees to compensate an alleged infringer, typically a generic firm, to settle a patent infringement case.⁶ In exchange, the alleged infringer agrees not to challenge the patent holder's patent or sell a generic version of the drug for a stated term.⁷ Because the payment flows from the plaintiff to the defendant, it has been called a "reverse" payment.

This Note argues that any standard of antitrust review for reverse payment settlements must involve an evaluation of the patent's strength at the time the patent holder and generic firm enter into a settlement. The Court of Appeals for the Federal Circuit is the court of competent jurisdiction to review a district court's evaluation of a patent's strength. Part I reviews reverse payment settlements generally and the statutory schemes that promote their emergence. Part II presents three approaches the circuit courts have adopted to review reverse payment settlements: per se illegality, a rebuttable presumption of illegality, and the scope of the patent test. Part III argues that any standard of antitrust scrutiny must consider the patent's strength at the time of the settlement—an approach no circuit has yet adopted—and that

¹ FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: AN FTC STAFF STUDY, at 1 (2010) [hereinafter 2010 FTC STUDY], available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> ("Pay-for-delay" agreements are 'win-win' for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits.").

² See *infra* Part II.B.

³ See *infra* Part II.C.

⁴ 686 F.3d 197 (3d Cir. 2012).

⁵ F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298, 1303 (11th Cir. 2012), cert. granted *sub nom.* F.T.C. v. Actavis Inc., 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416).

⁶ See *infra* Part I.A.

⁷ See *infra* Part I.A.

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the Federal Circuit is the proper appellate court to review patent strength.

I. BACKGROUND: REVERSE PAYMENT SETTLEMENTS AND THE STATUTORY SETTING

To understand the debate over the propriety of reverse payment settlements in the pharmaceutical industry, one should be familiar with the statutory provisions that regulate FDA approval of new and generic bioequivalent drugs. One should also understand the basic antitrust law principles enshrined by the Sherman Antitrust Act (the “Sherman Act”), and how they interact with basic patent law principles under the pharmaceutical industry’s unique regulatory approval scheme.

A. *Reverse Payment Settlements*

A reverse payment settlement is a resolution between disputing parties in a pharmaceutical patent infringement suit under which a putative patent holder agrees to compensate an alleged infringer to settle a patent infringement case.⁸ In exchange, the alleged infringer agrees not to challenge the patent holder’s patent or sell a generic version of the drug for a stated term.⁹ Because the payment flows from the plaintiff to the defendant, it has been called a “reverse” payment.¹⁰ More “evocatively,”¹¹ the FTC has referred to these settlements as “pay-for-delay” agreements.¹²

The FTC has filed lawsuits and published studies censuring these settlements since 2001,¹³ arguing that they are unreasonable

⁸ JOHN R. THOMAS, CONG. RESEARCH SERV., RL33717, PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS: IMPLICATIONS FOR COMPETITION AND INNOVATION, at 1 (2010), available at <http://scholarship.law.georgetown.edu/facpub/574>.

⁹ See THOMAS, *supra* note 8.

¹⁰ See THOMAS, *supra* note 8.

¹¹ *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 780 (2d Cir. 2010).

¹² See generally 2010 FTC STUDY, *supra* note 1.

¹³ Fed. Trade Comm’n, *Pay-for-Delay: When Drug Companies Agree Not to Compete*, FTC RESOURCES FOR REPORTERS, <http://www.ftc.gov/opa/reporter/competition/payfordelay.html> (last visited Oct. 26, 2012).

restraints of trade in violation of federal antitrust laws.¹⁴ Other commentators have argued that the Drug Price Competition and Patent Term Restoration Act of 1984,¹⁵ commonly referred to as the Hatch-Waxman Act, created an incentive scheme that encourages such settlements.¹⁶ As of this writing, Congress has not articulated a test for determining whether reverse payment settlements implicate antitrust laws, although both chambers have introduced bills attempting to proscribe such agreements.¹⁷ Congress's failure to enact a policy has effectively left the question for the federal courts to decide,¹⁸ and six circuits have addressed whether reverse payment settlements are legal.¹⁹ On December 7, 2012, the Supreme Court granted the FTC's petition for a writ of

¹⁴ See, e.g., Brief of the FTC as Amicus Curiae Supporting Appellants and Urging Reversal at 13, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2077, 10-2078, 10-2079), available at <http://www.ftc.gov/os/2011/05/110518amicusbrief.pdf> ("Because such an agreement closely parallels market allocation arrangements universally recognized as unlawful, a presumption of antitrust illegality is justified."); Complaint for Injunctive Relief at 26, *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010) (Civil Action Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2:08-cv-2141), available at <http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf> ("Through its course of conduct, Cephalon has excluded competition and willfully maintained its monopoly . . . by compensating its potential competitors and abusing competitive and regulatory processes."), abrogated by *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), petition for cert. filed, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), petition for cert. filed, 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265).

¹⁵ Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

¹⁶ See *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1303 (11th Cir. 2012) ("Federal law encourages generic drug manufacturers to file paragraph IV certifications."), cert. granted sub nom. *F.T.C. v. Actavis Inc.*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416). See generally Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617 (2006).

¹⁷ Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009). Both bills died. The House reintroduced the Protecting Consumer Access to Generic Drugs Act in the 112th Congress. H.R. 3995, 112th Cong. (2012). The Senate reintroduced the Preserve Access to Affordable Generics Act in the same Congress. S. 27, 112th Cong. (2012). Both bills died again.

¹⁸ THOMAS, *supra* note 8, at 2.

¹⁹ *In re K-Dur Antitrust Litig.*, 686 F.3d at 209.

certiorari to review the judgment of the Eleventh Circuit in *F.T.C. v. Watson Pharmaceuticals, Inc.*²⁰

B. *The Statutory and Regulatory Landscape*

Before reviewing the three main approaches to evaluating reverse payment settlements, it is necessary to understand the statutory provisions that regulate FDA approval of new and generic bioequivalent drugs and to review the basic antitrust principles enshrined by the Sherman Act. The pharmaceutical industry's unique regulatory scheme has given rise to a unique tension between antitrust law and patent law in that industry.

1. The Hatch-Waxman Act of 1984

Congress enacted the Hatch-Waxman Act (“Hatch-Waxman” or the “Act”) in 1984 to achieve two seemingly disparate objectives—specifically, (1) to increase the availability of low cost generic drugs, and (2) to increase incentives for innovation in the pharmaceutical industry.²¹ Three particular provisions in the Act advance the first objective, while three more advance the second.²² But before reviewing each, a brief overview of the FDA approval process before 1984 is apposite.

Before Hatch-Waxman, a generic firm could not legally develop a generic version of a brand-name drug until the innovator's patent expired.²³ Once the innovator's patent did

²⁰ 677 F.3d 1298 (11th Cir. 2012), *cert. granted sub nom.* *F.T.C. v. Actavis, Inc.*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416).

²¹ H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48; *see also* Presidential Statement on Signing the Drug Price Competition and Patent Term Restoration Act of 1984, 20 WEEKLY COMP. PRES. DOC. 225 (Sept. 24, 1984) (announcing that “[t]he legislation will . . . make the generic versions [of brand-name drugs] more widely available to consumers[] and grant pharmaceutical firms added incentives to develop new drugs”).

²² *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 41–45 (2009) [hereinafter Carrier, *Unsettling Drug Patent Settlements*].

²³ *See* *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified at 35 U.S.C. § 271(e) (2006)), *as recognized in* *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

expire, federal food and drug law required the generic firm to obtain FDA approval to market the drug by filing an extensive “New Drug Application” (“NDA”).²⁴ The FDA’s safety and efficacy requirements often required generic firms to coordinate “needlessly costly, duplicative and time-consuming” clinical trials that largely eviscerated the benefit of manufacturing and marketing cheap generic drugs.²⁵ As a result, “[s]ome observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products.”²⁶ In fact, in 1984, generic drugs made up only 18.6 percent of the prescription drugs sold in the United States.²⁷ Hatch-Waxman significantly eroded these statutory and regulatory obstacles to generic drug market entry.

a) Promoting generic competition

i. The “safe harbor” provision

Title II of the Act amended the Patent Act of 1952 and created a “safe harbor” provision for the use of a patented invention “solely for uses reasonably related to the development and submission of information” to the FDA.²⁸ This provision carefully expanded lawful uses of a patented invention to include testing that would allow a generic manufacturer to establish generic bioequivalency.²⁹ The exemption legislatively overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which had held that a

²⁴ WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 (“THE HATCH-WAXMAN ACT”), at 20 (2005), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at 27 (1998) [hereinafter CBO STUDY].

²⁸ 35 U.S.C. § 271(e)(1) (2006).

²⁹ See H.R. REP. NO. 98-857(II), at 8 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692 (“[T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.”).

generic firm's experimental use of a patented invention for business reasons was "a violation of the rights of the patentee to exclude others from using his patented invention."³⁰ *Roche* had effectively required generic manufacturers to delay generic bioequivalency tests until the patentee's patent expired,³¹ which would result in a de facto patent extension³² of about two years after the expiration of the patent.³³ In overruling *Roche*, Congress noted that the safe harbor provision "was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent."³⁴

Two Supreme Court decisions have since interpreted the safe harbor provision, codified at 35 U.S.C. § 271(e)(1), as broadly as possible.³⁵ In *Eli Lilly & Co. v. Medtronic, Inc.*, the Court held that the safe harbor provision exempts not only drugs, but the range of patented inventions covered by the Food, Drug, and Cosmetic Act ("FDCA"), including medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products.³⁶ *Merck KGaA v. Integra Lifesciences I, Ltd.* further expanded the scope of the safe harbor, holding that preclinical studies of patented compounds that were not ultimately submitted to the FDA were protected so long as they were "reasonably related to the development and submission of any information under the FDCA."³⁷ The Court noted that unprotected

³⁰ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified at 35 U.S.C. § 271(e) (2006)), *as recognized in* *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

³¹ See H.R. REP. NO. 98-857(II), at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692 ("Without [the Section] generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent.").

³² Daniel Wobbekind, *Integra Lifesciences I, Ltd. v. Merck KGaA: Re-Examining the Broad Scope of the § 271(e)(1) Safe Harbor*, 23 BERKELEY TECH. L.J. 107, 107 (2008).

³³ See H.R. REP. NO. 98-857(II), at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692 ("This would result in delays of about two years after the expiration of the patent before a generic could go on the market.").

³⁴ *Id.* at 9.

³⁵ See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

³⁶ 496 U.S. at 673-74; *see also* 35 U.S.C. § 156(f) (2006).

³⁷ 545 U.S. at 202 (emphasis added).

uses would include “[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce.”³⁸ Thus the safe harbor provision extinguished the patent holder’s de facto extension of patent rights beyond the patent term³⁹ and, as interpreted by the Court, carved out room for trial and error in generic drug development.⁴⁰

ii. The Abbreviated New Drug Application

Title I of the Act, which amended the FDCA, introduced a new type of application for generic firms seeking FDA approval of a drug, termed the Abbreviated New Drug Application (“ANDA”).⁴¹ Under an ANDA, generic manufacturers who establish that a proposed drug has the same active ingredient(s), route of administration, dosage form, and strength, among other things, as an innovator’s previously approved NDA, can rely, or “piggyback,”⁴² on the FDA’s finding of safety and efficacy for that drug.⁴³ While an ANDA need not contain “duplicative testing requirements” showing a proposed drug’s safety and efficacy,⁴⁴ it must contain information proving bioequivalence to a previously approved drug.⁴⁵

³⁸ *Id.* at 205–06.

³⁹ B. Scott Eidson, *How Safe Is the Harbor? Considering the Economic Implications of Patent Infringement in Section 271(e)(1) Analysis*, 82 WASH. U. L. Q. 1169, 1172 (2004); see also H.R. REP. NO. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678–79 (“It is the Committee’s view that experimental activity does not have any adverse economic impact on the patent owner’s exclusivity during the life of a patent, but prevention of such activity would extend the patent owner’s commercial exclusivity beyond the patent expiration date.”).

⁴⁰ *Merck*, 545 U.S. at 206.

⁴¹ 21 U.S.C. § 355(j) (2006). A similar abbreviated process existed for prescription drugs approved before 1962. See H.R. REP. NO. 98-857(I), at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48; see also CBO STUDY, *supra* note 27, at 3.

⁴² *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

⁴³ 21 U.S.C. § 355(j)(2)(A).

⁴⁴ CBO STUDY, *supra* note 27, at 43.

⁴⁵ 21 U.S.C. § 355(j)(2)(A)(iv). A drug is considered “bioequivalent” to a previously approved drug if:

- (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the

The applicant must also certify that (1) the NDA holder has not filed patent information with the FDA (Paragraph I); (2) the NDA holder's patent has expired (Paragraph II); (3) the NDA holder's patent will expire on a certain date (Paragraph III); or (4) the NDA holder's patent is invalid or the ANDA applicant's proposed drug will not infringe it (Paragraph IV).⁴⁶ The FDA may immediately approve an ANDA certified under Paragraphs I or II.⁴⁷ The FDA cannot approve an ANDA certified under Paragraph III until the patent expires.⁴⁸

A Paragraph IV certification is an act of patent infringement under the Hatch-Waxman Act.⁴⁹ An ANDA applicant making a Paragraph IV certification must notify the patent and NDA holder(s) within twenty days.⁵⁰ The notice must include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is invalid or will not be infringed.⁵¹ If the patent holder does not file a patent infringement suit within forty-five days, the FDA may approve the ANDA immediately.⁵² If the

therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B).

⁴⁶ See 21 U.S.C. § 355(j)(2)(A)(vii).

⁴⁷ 21 U.S.C. § 355(j)(5)(B)(i); see also *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1303 (11th Cir. 2012), cert. granted sub nom. *F.T.C. v. Actavis, Inc.*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416).

⁴⁸ 21 U.S.C. § 355(j)(5)(B)(ii); see also *Watson*, 677 F.3d at 1303.

⁴⁹ 35 U.S.C. § 271(e)(2)(A) (2006). See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification . . .").

⁵⁰ 21 U.S.C. § 355(j)(2)(B).

⁵¹ 21 U.S.C. § 355(j)(2)(B)(iv).

⁵² 21 U.S.C. § 355(j)(5)(B)(iii).

patent holder files a timely claim, it receives an automatic thirty-month stay of FDA approval.⁵³

If before final judgment or the expiration of the thirty-month stay the FDA approves the proposed generic drug, the approval is tentative.⁵⁴ Such an approval becomes effective the earlier of when (1) the thirty-month stay expires; (2) the court rules the patent is invalid or has not been infringed; or (3) the court enters a settlement order or consent decree stating that the patent is invalid or has not been infringed.⁵⁵ If the court decides the patent is valid and has been infringed, the FDA delays approval of the ANDA until the patent expires.⁵⁶

If the court has not resolved the patent litigation before the end of the thirty-month period, the ANDA filer may begin marketing the drug, but assumes the risk that it may be found liable if the court eventually rules the patent is valid and infringed.⁵⁷ Alternatively, the NDA holder and ANDA applicant may settle the suit before final judgment.⁵⁸ The Hatch-Waxman Act does not prohibit settlements.⁵⁹

iii. The 180-day exclusivity period

The Hatch-Waxman Act encourages generic manufacturers to file Paragraph IV certifications (“ANDA-IVs”) and risk the cost of ensuing litigation by rewarding the first firm to file an ANDA-IV

⁵³ *Id.* Some commentators have likened the stay to an automatic preliminary injunction. *E.g.*, 1 HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3 (2010), available at 2010 WL 3999073.

⁵⁴ See 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. 314.105(d).

⁵⁵ 21 U.S.C. § 355(j)(5)(B)(iii).

⁵⁶ See 21 U.S.C. § 355(j)(5)(B)(iii)(II).

⁵⁷ See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 744 (E.D.N.Y. 2001) (“It seems relatively clear, however, that if there is no resolution of the patent litigation and a stay is not granted, and the patent holder has not obtained preliminary injunctive relief, the ANDA filer may begin to market its product. In such an instance, the ANDA filer assumes the risk it might be found liable for infringing the pioneer manufacturer’s patent.”).

⁵⁸ See THOMAS, *supra* note 8, at 8.

⁵⁹ See 21 U.S.C. § 355(j).

with 180 days of generic marketing exclusivity.⁶⁰ During this period, the FDA cannot approve another ANDA-IV for the drug.⁶¹ The exclusivity period begins to run when the first applicant who submits a “substantially complete” ANDA-IV begins commercially marketing its drug.⁶²

Until 1998, the FDA took the position that the 180-day exclusivity period was available only to first filers who successfully defended patent infringement suits.⁶³ Under this interpretation, first filers who were not sued for patent infringement were ineligible for the exclusivity period.⁶⁴ The D.C. Circuit overturned the FDA’s “successful-defense” requirement as inconsistent with the plain language of Hatch-Waxman in *Mova Pharmaceutical Corp. v. Shalala*.⁶⁵ According to *Mova*, the statute clearly provided that the 180-day exclusivity period began on the earlier of the date of the first filer’s first commercial marketing of the drug, or, as the statute provided at the time, the date of a court decision finding the patent to be invalid or not infringed.⁶⁶ The

⁶⁰ See 21 U.S.C. § 355(j)(5)(B)(iv); William J. Newsom, *Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform*, 1 HASTINGS SCI. & TECH. L.J. 201, 206 (2009).

⁶¹ *Id.*; see also FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at i (2011) [hereinafter 2011 FTC STUDY], available at <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf> (“[W]hen the [first filer] challenges the brand’s patent, the FDA may not approve any additional generic competitors until 180 days after the first-filer launches its product.”).

⁶² 21 U.S.C. § 355(j)(5)(B)(iv)(I). But, “[i]f multiple applicants file substantially complete ANDAs with Paragraph IV certifications on the same day as the first to do so, those applicants can share exclusivity.” Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L.J. 49, 55 (2007).

⁶³ See 21 C.F.R. § 314.107(c)(1) (1994).

⁶⁴ *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998).

⁶⁵ *Id.*

⁶⁶ See *id.* The statute stated in relevant part:

If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or

court reasoned that “Congress may have intended to reward the first ANDA applicant for his enterprise whether or not he is later sued.”⁶⁷ Indeed, when Congress amended Hatch-Waxman as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, it provided that the 180-day exclusivity period begins solely on the date of the first commercial marketing of the drug by any first applicant.⁶⁸

Marketing exclusivity is “a bounty worth hundreds of millions of dollars for a major drug.”⁶⁹ In fact, “generics often make more than half of their total profits on a drug during the period of generic exclusivity.”⁷⁰ And the opportunity for 180 days of marketing exclusivity, in addition to the availability of the ANDA process and safe harbor protection, has helped fundamentally transform the pharmaceutical industry. In 1996, twelve years after Congress enacted the Hatch-Waxman Act, the share of generic units sold domestically more than doubled from 18.6 percent to

(II) the date of a decision of a court in [a patent infringement action] holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 2 (1998) (quoting 21 U.S.C. § 355(j)(5)(B)(iv) (1994) (amended 2003)), available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf>.

⁶⁷ *Mova*, 140 F.3d at 1071 n.11.

⁶⁸ 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2006); see also 21 C.F.R. § 314.107(c)(1) (2012). The statute now reads:

[If an ANDA-IV] is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug . . . by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I) (2006).

⁶⁹ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560 (2006) (internal quotation marks omitted).

⁷⁰ C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 948 n.3 (2011).

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42.6 percent.⁷¹ Today, generics represent approximately 80 percent of all drug units sold.⁷²

b) Promoting innovation in the pharmaceutical industry

i. Patent term extension

Before 1962, innovators needed only to demonstrate a drug's safety to obtain FDA approval.⁷³ Unless the FDA rejected the NDA, the innovator could begin marketing the drug sixty days after submitting its application.⁷⁴ Congress amended the FDCA in 1962 to require an NDA to prove the proposed drug's safety *and* efficacy.⁷⁵

Proving efficacy requires additional years of clinical trials.⁷⁶ A “showing of efficacy requires that the drug be investigated in controlled clinical trials by multiple groups, and that these trials, when subjected to a statistical analysis, prove the drug to be efficacious.”⁷⁷ Because innovators conduct most clinical testing after a patent issues,⁷⁸ the new efficacy requirement shortened the innovator's “effective patent life”—the time between FDA approval and patent expiration.⁷⁹ In response, pharmaceutical research and development declined significantly to make up for

⁷¹ CBO STUDY, *supra* note 27, at 43.

⁷² Pharmaceutical Research and Manufacturers of America (PhRMA), *2012 Industry Profile*, at 2 (2012), available at http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf.

⁷³ Carrier, *Unsettling Drug Patent Settlements*, *supra* note 22, at 43.

⁷⁴ Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 313 (2005) (citing *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984) (explaining § 505 of the FDCA, ch. 675, 52 Stat. 1052 (1938)), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified at 35 U.S.C. § 271(e) (2006)), *as recognized in* *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990)).

⁷⁵ *Id.* (citing *Roche*, 733 F.2d at 864 (explaining the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780)).

⁷⁶ See Carrier, *Unsettling Drug Patent Settlements*, *supra* note 22, at 43.

⁷⁷ Lee S. Wilkinson, *Legal Resolution of Denial of Access to Medical Technology*, 14 GOLDEN GATE U. L. REV. 203, 244 (1984).

⁷⁸ *Roche*, 733 F.2d at 864.

⁷⁹ Carrier, *Unsettling Drug Patent Settlements*, *supra* note 22, at 44.

increased costs and reduced returns.⁸⁰ Many scholars have referred to this post-1962 decline in new chemical entities and other new drugs as the “innovation crisis.”⁸¹

To restore innovation after the 1962 amendments, the Hatch-Waxman Act introduced a procedure to extend patent terms.⁸² Innovators may now request patent term extensions from the Director of the United States Patent and Trademark Office (“PTO”) within sixty days of FDA approval.⁸³ The PTO follows four steps to calculate the total period eligible for extension⁸⁴: (1) identify the innovator’s “regulatory review period,” composed of the innovator’s testing and approval phases after the patent issues;⁸⁵ (2) reduce each phase by the amount of time that the FDA finds the applicant did not exercise due diligence in obtaining

⁸⁰ *Id.* at 43–44 (citing John R. Virts & J. Fred Weston, *Returns to Research and Development in the U.S. Pharmaceutical Industry*, 1 *MANAGERIAL & DECISION ECON.* 103, 110 (1980)). Carrier notes that “[b]efore the 1962 amendments, the effective patent life nearly matched the 17-year patent term. By 1981, it had fallen to less than seven years.” *Id.* at 44 (citing James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 *CATH. U. L. REV.* 433, 451–52 (1986)).

⁸¹ *Id.* at 43.

⁸² See 35 U.S.C. § 156 (2006); see also *PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1374 (Fed. Cir. 2010) (noting that § 156 “was designed to restore a portion of the patent life lost during the period of regulatory review, in order to preserve the economic incentive for development of new therapeutic products” (citing H.R. REP. NO. 98-857(I), at 37 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2670)). Section 156 interprets “products” as any drug product, medical device, food additive, or color additive subject to regulation under the FDCA. 35 U.S.C. § 156(f)(1). In addition to extending patent terms for products, § 156 also extends patent terms for methods of using a product and methods of manufacturing a product. 35 U.S.C. § 156(a).

⁸³ 35 U.S.C. § 156(d)(1).

⁸⁴ See FDA: SMALL BUSINESS ASSISTANCE: FREQUENTLY ASKED QUESTIONS ON THE PATENT TERM RESTORATION PROGRAM, <http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm> (last visited Dec. 3, 2012) [hereinafter FDA FAQs ON PATENT TERM RESTORATION].

⁸⁵ See 35 U.S.C. § 156(g)(1)(B); 35 U.S.C. § 156(c); see also FDA FAQs ON PATENT TERM RESTORATION, *supra* note 84. The testing phase is “the period between the effective date of an investigational product exemption (Investigational New Drug Application) and the initial submission of the marketing application (New Drug Application). The approval phase is the period between the submission and approval of the marketing application.” FDA FAQs ON PATENT TERM RESTORATION, *supra* note 84.

regulatory approval;⁸⁶ (3) take one-half of the adjusted testing phase and add it to the adjusted approval phase to arrive at the total eligible period for extension;⁸⁷ and (4) cap the extension at five years⁸⁸ and the remaining term of the restored patent following FDA marketing approval at fourteen years.⁸⁹

Some commentators have openly doubted whether Hatch-Waxman's patent term restoration provision delivers a real benefit to pharmaceutical innovators. In a prepared statement for a hearing before the Senate Judiciary Committee, Gerald J. Mossinghoff, then President of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), explained that "the net effect of Hatch-Waxman has been a deterioration in intellectual property protection for pharmaceuticals." Mossinghoff cited as primarily responsible "the many restrictions placed on the patent term restoration period," the availability of the streamlined ANDA for FDA approval of generic drugs, and the statutory safe harbor from patent infringement.⁹⁰

⁸⁶ 35 U.S.C. § 156(c)(1). Due diligence means "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." 35 U.S.C. § 156(d)(3). The FDA assists the PTO by filing due diligence petitions and appearing at due diligence hearings. See FDA FAQs ON THE PATENT TERM RESTORATION, *supra* note 84.

⁸⁷ 35 U.S.C. § 156(c)(2).

⁸⁸ 35 U.S.C. § 156(g)(6)(A).

⁸⁹ 35 U.S.C. § 156(c)(3); WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RS21129, PHARMACEUTICAL PATENT TERM EXTENSIONS: A BRIEF EXPLANATION, at 2 (2002), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS21129.pdf>.

⁹⁰ *A Decade Later: The Drug Price Competition and Patent Term Restoration Act: Hearing Before the S. Comm. on the Judiciary*, 104th Cong. 121–22 (1996) [hereinafter *Hearings*] (statement of Gerald J. Mossinghoff, President, Pharmaceutical Research and Manufacturers of America). Mossinghoff cited the results of a Boston Consulting Group study to support his proposition:

Before Hatch-Waxman, the typical innovator drug enjoyed a total of 14–17 years of market exclusivity—nine years of effective patent life plus a five- to eight-year period between patent expiration and the marketing of a generic copy. As a result of Hatch-Waxman, the total period of intellectual property protection has shrunk to 11.7 years—since generic drugs can now enter the market immediately after patent expiration. Thus, the net practical effect of Hatch-Waxman was to reduce the period of intellectual property protection for innovator drugs by periods that range from 2.3 to 5.3 years.

Id. at 121.

Other commentators say the patent term extension “has been successful in increasing the patent term.”⁹¹ But drug patent terms alone do not provide a full picture. Before Hatch-Waxman, brand companies enjoyed effective market exclusivity after their patent terms expired for a five- to eight-year period between patent expiration and the marketing of a generic copy.⁹² Thus, Mossinghoff, and commentators like him, argue that the safe harbor provision and ANDA process shortened the innovator’s “de facto” monopoly in lieu of a shorter, de jure patent term extension. Evidently, the benefits of Hatch-Waxman’s patent term restoration are disputed.

ii. Non-patent marketing exclusivity for new chemical entities

The Hatch-Waxman Act amended the FDCA to provide non-patent marketing exclusivity periods to listed drugs that introduce new active ingredients,⁹³ or “new chemical entities.”⁹⁴ The FDA defines a new chemical entity (“NCE”) as “a drug that contains no active moiety that has been approved by FDA” in a previous NDA application.⁹⁵ An “active moiety,” in turn, is “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . or other noncovalent derivative . . . of the molecule, responsible for the physiological or pharmacological action of the drug substance.”⁹⁶

Under this provision, the FDA may not approve an ANDA-IV for the first four years after NDA approval, and it may not approve an ANDA with Paragraph I, II, or III certifications for the first five years.⁹⁷ The provision benefits innovators who discover new active ingredients by “restrict[ing] a potential generic manufacturer

⁹¹ Carrier, *Unsettling Drug Patent Settlements*, *supra* note 22, at 50.

⁹² See *Hearings*, *supra* note 90, at 121 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Research and Manufacturers of America).

⁹³ See 21 U.S.C. § 355(j)(5)(F)(ii) (2006).

⁹⁴ 21 § C.F.R. 314.108(a).

⁹⁵ *Id.*

⁹⁶ *Id.* (emphasis added).

⁹⁷ See 21 U.S.C. § 355(j)(5)(F)(ii); *see also* 21 C.F.R. § 314.108(b).

from bringing a product to market for five years plus the length of the FDA review of the generic application.”⁹⁸

iii. The thirty-month stay of FDA approval

An ANDA-IV applicant must provide a notice statement within twenty days to each patent holder that is the subject of the Paragraph IV certification and NDA holder on whose NDA the applicant relies.⁹⁹ The notice must “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”¹⁰⁰ To trigger a stay of FDA approval of the generic firm’s ANDA, the patent holder must initiate a patent infringement suit within forty-five days of receiving the ANDA filer’s notice.¹⁰¹ During this period, the generic cannot enter the market.¹⁰²

FDA approval of the ANDA becomes effective after thirty months unless the patent expires before then or a district court earlier decides that the patent is invalid or not infringed, in which case approval is effective on the date a court enters judgment in favor of the generic.¹⁰³ The thirty-month stay approximates the length of a patent case to reach final judgment,¹⁰⁴ and has been compared to an automatic preliminary injunction because it provides the patent holder “an absolute, although time-limited,

⁹⁸ CONG. RESEARCH SERV., RL32917, BIOTERRORISM COUNTERMEASURE DEVELOPMENT: ISSUES IN PATENTS AND HOMELAND SECURITY, at 11–12 (2006), available at <http://www.fas.org/sgp/crs/terror/RL32917.pdf> (“The purpose of NCE exclusivity is to encourage the development of innovative drug products that include an entirely new active ingredient (commonly termed the ‘active moiety’), in contrast to ‘me-too’ drugs that consist of chemical variants of previously known compounds.”).

⁹⁹ 21 U.S.C. § 355(j)(2)(B)(i)–(ii).

¹⁰⁰ 21 U.S.C. § 355(j)(2)(B)(iv).

¹⁰¹ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁰² See *id.*

¹⁰³ *Id.*; see also FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY at ii (2002) [hereinafter 2002 FTC STUDY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (“Filing of the lawsuit stays FDA’s approval of the ANDA until the earliest of: (1) the date the patents expire; (2) a determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the Paragraph IV certification.”).

¹⁰⁴ See *id.* at 47. Patent cases take several months longer on average to reach final judgment on appeal. *Id.*

right to exclude a competitor from the market” without any showing that the patent holder will likely prevail on the merits.¹⁰⁵

2. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (the “Medicare Act”), amending the Hatch-Waxman Act.¹⁰⁶ The Medicare Act remedied several of Hatch-Waxman’s “statutory design bugs,”¹⁰⁷ which had permitted litigants’ abuse of the thirty-month stay and 180-day marketing exclusivity period.¹⁰⁸

a) Eliminating abuse of the thirty-month stay of FDA approval

Before the passage of the Medicare Act, several NDA holders used an apparent loophole in the Hatch-Waxman Act to obtain successive thirty-month stays of FDA approval.¹⁰⁹ After a generic firm filed an ANDA-IV, the NDA holder could list with the FDA additional patents in connection with the NDA.¹¹⁰ The late-listed patents required the ANDA applicant to file additional certifications.¹¹¹ Because each certification triggered a statutory

¹⁰⁵ Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 514–15 (2007). Traditionally, a patentee seeking a preliminary injunction must show: “(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

¹⁰⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 and 42 U.S.C.), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of U.S.C.).

¹⁰⁷ See Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1390–91 (2011).

¹⁰⁸ See *Greene*, *supra* note 74, at 349.

¹⁰⁹ *Id.* at 331. Prior to the 2003 amendments, Hatch-Waxman had not expressly proscribed such stacking. *Id.* at 317.

¹¹⁰ See *id.*

¹¹¹ See *id.*

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act of infringement, the brand firm could stack multiple thirty-month stays.¹¹²

Infamously, GlaxoSmithKline (“GSK”) exploited this loophole after a generic manufacturer, Apotex, challenged GSK’s listed patent for the active ingredient in Paxil in 1998.¹¹³ After Apotex’s initial Paragraph IV certification, GSK listed nine additional patents for the drug with the FDA.¹¹⁴ Apotex filed additional Paragraph IV certifications for each.¹¹⁵ GSK brought four additional patent infringement suits against Apotex, resulting in an effective five-year stay on FDA approval for a generic version of the antidepressant.¹¹⁶ The Medicare Act closed this loophole by allowing only one thirty-month stay for patents listed with the FDA at the time the generic firm files an ANDA-IV.¹¹⁷

b) Eliminating abuse of the 180-day exclusivity period

Before the Medicare Act, various Hatch-Waxman litigants entered reverse payment settlements “parking” the 180-day marketing exclusivity period.¹¹⁸ The Hatch-Waxman Act originally provided that the 180-day exclusivity period would be triggered on the earlier of the date of first commercial marketing of the generic drug (the “first commercial marketing” trigger) or the date of a court decision holding the brand firm’s drug patent

¹¹² *See id.*

¹¹³ *See id.* at 332 (citing 2002 FTC STUDY, *supra* note 103, at 51).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ 2002 FTC STUDY, *supra* note 103, at 51–52.

¹¹⁷ 21 U.S.C. § 355(j)(5)(B)(iii) (2006). The statute states in relevant part:

If the applicant made a certification described in subclause (IV) . . . the approval shall be made effective immediately unless, before the expiration of 45 days after . . . the notice . . . is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary . . . before the date on which the application . . . was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period

Id.

¹¹⁸ *Apotex, Inc. v. Pfizer, Inc.*, 385 F. Supp. 2d 187, 190 (S.D.N.Y. 2005), *aff’d*, *Apotex, Inc. v. Pfizer, Inc.*, 159 F. App’x 1013 (Fed. Cir. 2005).

invalid or not infringed (the “court decision” trigger).¹¹⁹ The FDA could not approve a subsequent ANDA until the end of the 180-day period.¹²⁰ To delay triggering the 180-day exclusivity period, NDA holders compensated ANDA filers through settlements.¹²¹ This practice created a bottleneck preventing FDA approval of subsequently filed ANDAs.¹²²

The Medicare Act established “forfeiture events” restricting a first applicant’s entitlement to exclusivity, including if the first applicant (1) fails to market within seventy-five days of final FDA approval or thirty months after submitting its ANDA, whichever is earlier; (2) fails to market within seventy-five days of a court decision finding the patent invalid or not infringed, a court signing a settlement order or consent decree finding the patent invalid or not infringed, or the NDA holder withdrawing its patent information from its NDA; (3) withdraws its application or the FDA considers it withdrawn because it does not meet its requirements for approval; (4) amends or withdraws the certifications that qualified it for exclusivity; (5) fails to obtain tentative FDA approval within the first thirty months of filing, unless the failure is caused by a change in or a review of the requirements for approval after filing; (6) enters into an agreement with another ANDA applicant, the NDA holder, or a patent holder, and the FTC or DOJ files a complaint that results in the FTC or a court’s final, unappealable decision (except for a petition to the Supreme Court for a writ of certiorari) that the agreement violates antitrust laws; or (7) no longer qualifies for the 180-day exclusivity period because all of the patents for which it submitted a certification have expired.¹²³ The Medicare Act thus curbed perceived abuses to the 180-day exclusivity period that some litigants effected through reverse payment settlements.¹²⁴

¹¹⁹ 21 U.S.C. § 355(j)(5)(B)(iv) (1984) (amended 2003). For the statutory text before revision by the Medicare Act, see *supra* note 66.

¹²⁰ *Id.*

¹²¹ *Apotex*, 385 F. Supp. 2d at 190.

¹²² *Id.*

¹²³ *Id.*; see also Lietzan & Korn, *supra* note 62, at 50–51.

¹²⁴ *Apotex*, 385 F. Supp. 2d at 190.

c) Requiring notice to antitrust enforcement agencies

Additionally, the Medicare Act requires any agreement between a brand-name drug company and generic firm regarding the manufacturing, marketing, or sale of the drug listed in the generic's ANDA to be filed with the FTC and United States Department of Justice ("DOJ") for antitrust review.¹²⁵ In effect, this requires parties to give notice of reverse payment settlements to antitrust enforcement agencies.¹²⁶

3. The Patent Act

The United States Constitution empowers Congress to grant inventors exclusive monopoly rights to their inventions: "Congress shall have the power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹²⁷ Less than two years after the States ratified the Constitution in 1788,¹²⁸ the First Congress during its Second Session enacted the Patent Act of 1790, setting the conditions for obtaining a patent.¹²⁹ Subsequent statutory enactments, collectively known as the Patent Acts, modified and added to these conditions.¹³⁰ The Patent Act of 1952 (the "Patent Act"), as amended, currently governs patent law.¹³¹

The Patent Act provides that "[a] patent shall be presumed to be valid" and that "[t]he burden of establishing invalidity of a patent . . . shall rest on the party asserting such invalidity."¹³² In

¹²⁵ Medicare Act, Pub. L. No. 108-173, §§ 1112, 117 Stat. 2066.

¹²⁶ See Carrier, *Unsettling Drug Patent Settlements*, *supra* note 22, at 47.

¹²⁷ U.S. CONST. art. I, § 8, cl. 8.

¹²⁸ Paul Rodgers, UNITED STATES CONSTITUTIONAL LAW: AN INTRODUCTION 108 (2011).

¹²⁹ Patent Act of 1790, ch. 7, 1 Stat. 109–112.

¹³⁰ See Patent Act of 1793, ch. 11, 1 Stat. 318–323; Patent Act of 1836, ch. 357, 5 Stat. 117; Patent Act of 1839, ch. 88, 5 Stat. 353–355; Patent Act of 1870, ch. 230, 16 Stat. 198–217; Patent Act of 1939, ch. 450, 53 Stat. 1212–1213; Patent Act of 1952, ch. 950, 66 Stat. 792–817.

¹³¹ See 35 U.S.C. § 1 et seq (2006).

¹³² 35 U.S.C. § 282(a) (2006). But "[t]he burden always is on the patentee to show infringement." *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (citing *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984)); see also Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative*

patent infringement litigation, the invalidity defense must “be proved by clear and convincing evidence.”¹³³ Accordingly, in Hatch-Waxman litigation, a patent holder enjoys a presumption of validity, and the ANDA filer must show invalidity by clear and convincing evidence.¹³⁴

4. The Sherman Antitrust Act of 1890

Section 1 of the Sherman Act provides that “[e]very contract . . . in restraint of trade . . . among the several States . . . is declared to be illegal.”¹³⁵ The Supreme Court has held that “Congress could not have intended a literal interpretation of the word ‘every,’” and has instead held that the Sherman Act outlaws only unreasonable restraints of trade.¹³⁶ Most restraints are evaluated under a “rule of reason” standard, under which the fact finder must make an “elaborate inquiry into the reasonableness” of a firm’s behavior in the context of a particular industry.¹³⁷

Rule of reason analysis can entail enormous litigation expenses and strain judicial resources.¹³⁸ Thus the Court has developed an alternative doctrine for agreements that are manifestly anticompetitive: “[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.”¹³⁹ Such agreements are per se illegal under Section 1 of the Sherman Act.¹⁴⁰ Several practices have traditionally fallen within

Approach, 41 RUTGERS L.J. 83, 86 n.11 (2009) [hereinafter *Carrier*, *The Legislative Approach*] (citing *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 678 (Fed. Cir. 2008)).

¹³³ *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).

¹³⁴ *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 21 F. Supp. 2d 366, 370 (S.D.N.Y. 1998) *aff’d*, *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).

¹³⁵ 15 U.S.C. § 1 (2006).

¹³⁶ *Arizona v. Maricopa Cnty. Med. Soc’y*, 457 U.S. 332, 343 (1982) (citing *United States v. Joint-Traffic Ass’n*, 171 U.S. 505 (1898)).

¹³⁷ *Id.*

¹³⁸ *See id.*

¹³⁹ *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

¹⁴⁰ *Id.*

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this category, including “price fixing[,] division of markets[,] group boycotts[,] and tying arrangements.”¹⁴¹

II. THE CONFLICT BETWEEN PATENT AND ANTITRUST LAW IN THE PHARMACEUTICAL INDUSTRY

On March 25, 2013, the Supreme Court heard oral arguments in *F.T.C. v. Actavis, Inc.*¹⁴² The case seeks to resolve under what circumstances reverse payment settlements are unreasonable restraints of trade that violate federal antitrust law. Many courts and commentators have observed that the Hatch-Waxman Act creates a climate that encourages reverse payment settlements.¹⁴³ The Second Circuit subscribed to this view in *In re Tamoxifen Citrate Antitrust Litigation*, explaining that under the Hatch-Waxman regulatory scheme, generic firms file ANDA-IVs “before . . . spen[ding] substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug.”¹⁴⁴ Consequently, the first ANDA filer in a patent infringement action stands to lose little “beyond litigation costs and the opportunity for future profits from selling the generic drug,”¹⁴⁵ but stands to gain a lucrative 180-day marketing exclusivity period during which it participates in an effective

¹⁴¹ *Id.* (citations omitted). A tying arrangement is “an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier.” *Id.* at 5–6.

¹⁴² Transcript of Oral Argument, *F.T.C. v. Actavis, Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416), *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-416.pdf.

¹⁴³ *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (noting that “because of the generic manufacturer’s entitlement under the Hatch-Waxman Amendments to institute patent litigation merely by filing an ANDA IV, the statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits”). *See generally* Anjan Chatterji & Xiang Yu, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of Asymmetric Risks in Litigation*, 10 NW. J. TECH. & INTELL. PROP. 19 (2011) (arguing that, in light of the asymmetric litigation risks in Hatch-Waxman litigation, reverse payment settlements need not be collusive to be rational).

¹⁴⁴ *Tamoxifen*, 466 F.3d at 206 (emphasis in original).

¹⁴⁵ *Id.* at 206–07.

duopoly with the original NDA filer.¹⁴⁶ Even though the first filer's litigation expenses may amount to several millions of dollars,¹⁴⁷ its revenues from the exclusivity period could reach hundreds of millions of dollars for "blockbuster" drugs.¹⁴⁸ Thus, a generic firm evaluating the potential risks and benefits of filing an ANDA-IV may rationally decide to roll the dice and trigger a statutory act of patent infringement.¹⁴⁹

The branded patent holder, on the other hand, is in no better position than before if it prevails in the patent infringement action. Money damages are not available since the generic firm usually has not yet entered the market. The patent holder's benefit is virtually limited to continued patent protection against that ANDA challenger.¹⁵⁰ On the other hand, if the brand loses the suit, it relinquishes its patent monopoly.¹⁵¹ Some commentators have pointed to these "exceedingly" asymmetric litigation risks to explain the unconventional reverse flow of consideration from the plaintiff-patent holder to the defendant-generic challenger.¹⁵²

Other courts and commentators have been more skeptical.¹⁵³ Many believe reverse payments resemble collusion and reject any notion that economically rational behavior exonerates antitrust liability.¹⁵⁴ The FTC has stated that "the competition laws exist

¹⁴⁶ *Id.* at 207.

¹⁴⁷ Chatterji & Yu, *supra* note 143, at 19.

¹⁴⁸ *Id.* at 4. A "blockbuster" drug is a drug that generates more than \$1 billion of revenue per year. See GARY GUENTHER, CONG. RESEARCH SERV., RL31511, FEDERAL TAXATION OF THE DRUG INDUSTRY AND ITS EFFECTS ON NEW DRUG DEVELOPMENT, at 3 n.8 (2009), available at <http://policyarchive.org/handle/10207/bitstreams/18823.pdf>. Examples include "Cipro, Claritin, Paxil, Pravachol, Prilosec, Prozac, and Zoloft." Carrier, *The Legislative Approach*, *supra* note 132, at 87 (citing 2002 FTC STUDY, *supra* note 103, at 14).

¹⁴⁹ Chatterji & Yu, *supra* note 143, at 21.

¹⁵⁰ See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007).

¹⁵¹ *Id.*

¹⁵² Chatterji & Yu, *supra* note 143, at 6.

¹⁵³ See, e.g., *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d Cir. 2012), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245), *petition for cert. filed*, 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265); Carrier, *The Legislative Approach*, *supra* note 132, at 88.

¹⁵⁴ See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003) ("We do not think it follows that because

precisely to counteract commercial environments that encourage collusive and anticompetitive behavior.”¹⁵⁵ The Third Circuit recently endorsed this view, criticizing reverse payment settlements because they “permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid.”¹⁵⁶

Since 2001, several circuit courts have developed legal standards under which to analyze reverse payment settlements. Roughly three approaches to evaluating reverse payment settlements have emerged¹⁵⁷: (1) per se illegal treatment (Sixth Circuit);¹⁵⁸ (2) the “scope of the patent” test (Eleventh, Second, and Federal Circuits);¹⁵⁹ and (3) the “quick look” rule of reason test, which applies a rebuttable presumption of illegality (Third Circuit).¹⁶⁰

A. *Per Se Illegal Treatment*

In 2003, before the enactment of the Medicare Act, the Sixth Circuit declared reverse payment settlements per se illegal in *In re Cardizem CD Antitrust Litigation*.¹⁶¹ This case centered on Cardizem CD, a brand-name prescription drug used to treat angina and hypertension and prevent heart attack and stroke.¹⁶² In 1995, Andrx Pharmaceuticals, Inc. (“Andrx”), a generic manufacturer, filed an ANDA-IV seeking FDA approval to manufacture, market, and sell a generic version of Cardizem CD, which at the time was manufactured and marketed by Hoechst Marion Roussel, Inc. (“HMR”).¹⁶³ Andrx was the first generic firm to file an ANDA-IV, entitling it to the coveted 180 days of marketing exclusivity.¹⁶⁴

it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive.”).

¹⁵⁵ Petition for a Writ of Certiorari at 28, *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), (No. 12-416) (internal quotation marks omitted).

¹⁵⁶ *K-Dur*, 686 F.3d at 216.

¹⁵⁷ See Chatterji & Yu, *supra* note 143, at 23.

¹⁵⁸ See *infra* Part II.A.

¹⁵⁹ See *infra* Part II.B.

¹⁶⁰ See *infra* Part II.C.

¹⁶¹ 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

¹⁶² *Id.* at 901.

¹⁶³ *Id.* at 901–02.

¹⁶⁴ *Id.* at 902.

In 1996, HMR brought a patent infringement claim against Andrx.¹⁶⁵ As the suit pended in federal court, the FDA issued tentative approval of Andrx's ANDA.¹⁶⁶ Nine days later, the parties entered into an agreement, wherein Andrx promised it would not market a generic version of Cardizem CD upon receiving final FDA approval or transfer or relinquish its 180-day exclusivity period to another company.¹⁶⁷ In exchange, HMR agreed to compensate Andrx with \$40 million per year, payable quarterly after the FDA issued final approval, and further agreed to compensate Andrx \$100 million per year to abstain from the market after a final, unappealable judgment that Andrx did not infringe HMR's patent.¹⁶⁸ When the thirty-month stay period ended in 1998 and the FDA issued final approval of Andrx's ANDA, HMR began making \$10 million quarterly payments, Andrx did not enter the market, and the 180-day marketing exclusivity period was not triggered.¹⁶⁹ The parties eventually settled the patent infringement suit in 1999 for a final additional sum of \$50.7 million.¹⁷⁰

State law plaintiffs, indirect purchasers, and class representatives filed complaints against HMR and Andrx alleging antitrust injuries.¹⁷¹ Specifically, the plaintiffs alleged "that but for the Agreement, specifically the payment of \$40 million per year, Andrx would have brought its generic product to market once it received FDA approval and at a lower price than the patented Cardizem CD sold by HMR."¹⁷² In addition, the plaintiffs alleged that Andrx's delayed market entry "parked" the start of its 180-day marketing exclusivity period and blocked "other potential generic competitors."¹⁷³

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 902–03.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 903 n.7. A judicial panel on multidistrict litigation consolidated the claims.

Id.

¹⁷² *Id.* at 904.

¹⁷³ *See id.*

The Sixth Circuit held that the HMR-Andrx Agreement “was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade.”¹⁷⁴ In addition to the quarterly payments to refrain from marketing its generic version of Cardizem CD, the court found dispositive the fact that “by delaying Andrx’s entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx’s 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.”¹⁷⁵ At least to the extent that reverse payment settlements involved “parking” the 180-day exclusivity period, the Sixth Circuit’s approach was a clear categorical condemnation of such agreements.

Cases in other circuits, such as *In re Tamoxifen Citrate Antitrust Litigation* in the Second Circuit, have openly questioned the continued vitality of *Cardizem* after the Medicare Act because it involved parking the 180-day exclusivity period and blocking subsequent ANDA filers.¹⁷⁶ The Medicare Act of 2003 subsequently established forfeiture events intended to prevent parking the 180-day exclusivity period, a practice the following cases did not so nakedly involve.¹⁷⁷

B. *The Scope of the Patent Test*

1. The Second Circuit

The Second Circuit articulated the most deferential standard for evaluating reverse payment settlements in *In re Tamoxifen Citrate Antitrust Litigation*.¹⁷⁸ This case involved the patent for tamoxifen, a prescription drug for the treatment of breast cancer.¹⁷⁹ In 1987, Imperial Chemical Industries (“ICI”) brought suit against Barr, a generic manufacturer and the first ANDA-IV filer for

¹⁷⁴ *Id.* at 908.

¹⁷⁵ *Id.* at 908–09 (citing *Arizona v. Maricopa Cmty. Med. Soc’y*, 457 U.S. 332, 351 (1982)).

¹⁷⁶ *See, e.g.*, 466 F.3d 187 (2d. Cir. 2005).

¹⁷⁷ *See supra* Part I.B.2.b.

¹⁷⁸ 466 F.3d 187 (2d Cir. 2005).

¹⁷⁹ *Id.* at 193.

tamoxifen.¹⁸⁰ The district court declared ICI's tamoxifen patent invalid after finding ICI had intentionally withheld critical testing information from the PTO.¹⁸¹ While ICI's appeal was pending in the Federal Circuit, the parties entered into a settlement agreement.¹⁸² Zeneca, ICI's successor-in-interest to the tamoxifen patent, agreed to compensate Barr with \$21 million and a non-exclusive license to sell tamoxifen under Barr's label if Barr would change its ANDA to a Paragraph III certification, thereby agreeing not to sell its generic version of tamoxifen until Zeneca's patent expired.¹⁸³ The parties also agreed that if a subsequent ANDA-IV challenger prevailed against Zeneca in a patent infringement suit, Barr could "revert to a paragraph IV ANDA certification."¹⁸⁴ Finally, the parties moved to vacate the district court's opinion that Zeneca's patent was invalid.¹⁸⁵ The district court granted the motion.¹⁸⁶

Consumer groups filed lawsuits alleging the Zeneca-Barr settlement violated antitrust laws.¹⁸⁷ The plaintiffs also alleged that Zeneca and Barr "'understood' that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first 'paragraph IV' filer."¹⁸⁸ The district court upheld the agreement, and the Second Circuit affirmed.¹⁸⁹

The Second Circuit based its analysis on the principle that courts are "bound to encourage" settlements because settlements are in the interest of the parties and of the public.¹⁹⁰ The court pointed out that, where there are conflicting patent claims, the

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.* at 193–94.

¹⁸⁴ *Id.* at 194.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 196. A judicial panel on multidistrict litigation consolidated and transferred the claims to the Eastern District of New York. The complainants then filed a class action. *Id.*

¹⁸⁸ *Id.* at 194.

¹⁸⁹ *Id.* at 198–99.

¹⁹⁰ *Id.* at 202 (citing *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 143 (2d Cir. 2004)).

Sherman Act does not preclude settlements, even though settlements could harm competition.¹⁹¹ It also recognized that restricting patent settlements might undermine the purpose of patent law because it would generate uncertainty and hamper innovation.¹⁹²

Turning to reverse payment settlements specifically, the Second Circuit explicitly rejected applying the *per se* rule and explained that reverse payments are a natural byproduct of the Hatch-Waxman regulatory regime.¹⁹³ “Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[] considerable leverage in patent litigation”¹⁹⁴ The Second Circuit refused to “categorically condemn[]” reverse payments in what it perceived to be a regulatory regime that redistributed litigation risks and undercut patentee certainty.¹⁹⁵

While the Second Circuit conceded that economically rational behavior is not necessarily lawful,¹⁹⁶ it reasoned that a patent settlement raises antitrust concerns only if the settlement is a vehicle for avoiding antitrust law.¹⁹⁷ Under this reasoning, a large

¹⁹¹ *Id.* at 202–03 (citing *Standard Oil Co. v. United States*, 283 U.S. 163 (1931); *Nestle Co. v. Chester’s Mkt., Inc.*, 756 F.2d 280, 284 (2d Cir. 1985); *U.S. Bancorp Mortg. Co. v. Bonner Mall P’ship*, 513 U.S. 18, 27–29 (1994); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir. 1976); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 1993) (Posner, J., sitting by designation)).

¹⁹² *Id.* at 203.

¹⁹³ *Id.* at 205–06 (“[W]e decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.”).

¹⁹⁴ *Id.* at 207 (quoting *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1074 (11th Cir. 2005)).

¹⁹⁵ *See id.*

¹⁹⁶ *See id.* at 208 (“We agree that even if ‘reverse payments are a natural by-product of the Hatch-Waxman process,’ it does not follow that they are necessarily lawful.”) (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)).

¹⁹⁷ *Id.* (citing *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 1993) (Posner, J., sitting by designation)). Extending the life of an almost certainly invalid patent, for example, would raise antitrust concerns. *Id.* The owner of a weak

reverse payment settlement would not raise antitrust concerns if the patentee is only seeking to *insure* its preexisting property interests.¹⁹⁸ The court conceded again that this rule could have the effect of permitting settlements that protect “undeserved” patent monopolies, but determined that succeeding ANDA challengers would erode a weak patent holder’s monopoly profits and reinstate competition.¹⁹⁹

Finally, the court presented a test for evaluating reverse payment settlements: An agreement is an antitrust violation only if it excludes competition beyond the scope of the patent’s protection.²⁰⁰ As long as competition is restrained within the scope of the patent monopoly, the agreement is lawful unless the plaintiffs can show that (1) the patent was procured by fraud on the PTO or (2) the patent infringement suit is “objectively baseless.”²⁰¹ Applying this test to the facts of the Zeneca-Barr settlement, the court held the agreement did not extend the scope of Zeneca’s tamoxifen patent because it precluded only generic marketing of tamoxifen, not any other non-infringing product.²⁰² Moreover, the court distinguished this agreement from that in *Cardizem*, which involved Andrx “parking” the 180-day exclusivity period and blocking subsequent generic competition.²⁰³ Here, by changing its ANDA to a Paragraph III certification, Barr “appeared to” revoke its eligibility for the exclusivity period.²⁰⁴ Thus the court concluded that any harm to the plaintiffs was the result of the

patent might “sue its competitors” and “settle[] the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license . . . [a mask for] fixing prices, in violation of antitrust law.” *Id.*

¹⁹⁸ *See id.* at 210 (“Whatever the degree of the patent holder’s certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.”).

¹⁹⁹ *Id.* at 212 (“Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers.”).

²⁰⁰ *Id.* at 213.

²⁰¹ *Id.* (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005), *aff’d in part*, 544 F.3d 1323 (Fed. Cir. 2008), *aff’d in part sub nom.* Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010)).

²⁰² *Id.* at 213–14.

²⁰³ *Id.* at 214–15.

²⁰⁴ *Id.*

exclusionary power that reposes in a patent monopoly, not antitrust abuse.²⁰⁵

2. Judge Pooler's Dissent

Judge Pooler, in a widely cited dissent in *Tamoxifen*, criticized the majority's standard as "insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws."²⁰⁶ She proposed a more searching scrutiny:

I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context. In assessing reasonableness, the fact finder must consider all the circumstances affecting a restrictive agreement. *Of course, the strength of the patent must be central to any antitrust analysis involving a patent.* Thus, in assessing the reasonability of a Hatch-Waxman settlement, *I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled* and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period.²⁰⁷

Judge Pooler's standard embeds in the antitrust analysis an evaluation of the strength of the patent.²⁰⁸ Such an evaluation is not a feature of the majority's "scope of the patent" test, an absence that Judge Pooler believed rendered the scope of the patent test imbalanced in favor of antitrust defendants.²⁰⁹ Applying her

²⁰⁵ *Id.* at 219–20.

²⁰⁶ *Id.* at 224 (Pooler, J., dissenting).

²⁰⁷ *Id.* at 228 (emphasis added) (citing *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 56 (2d Cir.1997)).

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 221.

standard to the facts of this case, Judge Pooler reasoned that, in light of the district court finding that Zeneca's tamoxifen patent was invalid, the court should have denied the defendants' 12(b)(6) motion to dismiss and permitted discovery.²¹⁰

3. Declining to Revisit *Tamoxifen*

The Second Circuit recently heard an antitrust challenge to a reverse payment settlement between Bayer, the patentee for the active ingredient in ciprofloxacin hydrochloride (Cipro), and Barr, the generic firm that filed the first ANDA-IV to market a generic version of the drug.²¹¹ The circuit panel, which included Judge Pooler, explained that it was "bound" to apply the standard adopted in *Tamoxifen*²¹² and ruled that the agreement was lawful.²¹³ But the panel also expressed its concern that *Tamoxifen* may have been wrongly decided.²¹⁴ It offered for support four reasons—namely, that (1) the United States has urged the Second Circuit to repudiate *Tamoxifen* for "inappropriately permitt[ing] patent holders to contract their way out of a statutorily imposed risk . . . while claiming antitrust immunity";²¹⁵ (2) the incidence of reverse payment settlements has increased since the *Tamoxifen* decision;²¹⁶ (3) Senator Hatch, one of the bill's drafters, has expressed strong disapproval of the agreements;²¹⁷ and (4) the *Tamoxifen* panel may have misinterpreted the Hatch-Waxman Act.²¹⁸ At the end of its opinion, the court invited the plaintiffs to petition for a rehearing en banc.²¹⁹

²¹⁰ *Id.*

²¹¹ Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (per curiam), *cert. denied*, 131 S. Ct. 1606 (2011).

²¹² *Id.* at 106.

²¹³ *Id.* at 110.

²¹⁴ *Id.* at 108.

²¹⁵ *Id.* at 108–09 (quoting Brief for the United States in Response to the Court's Invitation at 14–15, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (per curiam) No. 05-2851-cv(L), 2009 WL 8385027, at *14–15).

²¹⁶ *Id.* at 109 (citing Brief of Amicus Curiae the American Antitrust Institute in Support of Petitioners at 3 (citing 2002 FTC STUDY, *supra* note 103), Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (per curiam) No. 10-762, 2011 WL 63543, at *3).

²¹⁷ *Id.* at 109 (citing 148 Cong. Rec. S7565 (July 30, 2002) (remarks of Sen. Hatch)).

²¹⁸ *Id.* at 109.

²¹⁹ *Id.* at 110.

In September 2010, over Judge Pooler's strong dissent, the Second Circuit denied rehearing the case en banc.²²⁰ "I think that our *Tamoxifen* decision unambiguously deserves reexamination," she dissented.²²¹ "It will be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals."²²²

4. Before the Supreme Court: *F.T.C. v. Actavis, Inc.*

On December 7, 2012, the Supreme Court granted the government's petition for a writ of certiorari to review the Eleventh Circuit's decision in *F.T.C. v. Watson Pharmaceuticals, Inc.*²²³ The case was renamed to *F.T.C. v. Actavis, Inc.* following Watson's acquisition of the Swiss drugmaker Actavis Group in October 2012.²²⁴ The Court's decision may finally reconcile the pharmaceutical industry's unique tension between patent law and antitrust law, a matter that has concerned the FTC for over a decade.²²⁵

Actavis involves a reverse payment settlement between the NDA holder for AndroGel, Solvay Pharmaceuticals, and two generic manufacturers, then Watson Pharmaceuticals and Paddock Laboratories.²²⁶ AndroGel is a prescription topical gel used to treat low testosterone in adult males.²²⁷ Although the patent for the synthetic testosterone used in AndroGel expired years ago, Watson

²²⁰ Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir. 2010).

²²¹ *Id.* at 781.

²²² *Id.* at 782.

²²³ 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416).

²²⁴ Press Release, Actavis, Watson Announces New Name—Actavis—for Global Operations (Oct. 31, 2012), *available at* <http://ir.actavis.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1752588&highlight=>. Oral arguments for *Actavis* took place on March 25, 2013. Transcript of Oral Argument, *F.T.C. v. Actavis, Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416), *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-416.pdf.

²²⁵ J. Thomas Rosch, Commissioner, Fed. Trade Comm'n, Pharmaceutical Patent Settlements and the Supreme Court, Address Before the CBI's 2nd Annual Life Sciences Compliance, Legal, and Regulatory Congress (Sep. 21, 2012), *available at* <http://www.ftc.gov/speeches/rosch/120921cbipharmaspeech.pdf>.

²²⁶ *Watson*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3216 (U.S. Dec. 7, 2012) (No. 12-416).

²²⁷ *Id.* at 1303.

obtained patent protection for a gel formulation of the drug in 2003.²²⁸ Four months after the PTO granted Solvay's patent application in 2003, Watson and Paddock filed separate ANDA-IVs for the drug with the FDA.²²⁹ Watson, the first filer, became eligible for the 180-day marketing exclusivity period.²³⁰ Solvay brought a patent infringement suit against both companies within forty-five days, triggering the thirty-month stay provision.²³¹ When the thirty-month stay on the FDA's approval of Watson's ANDA expired in 2006, the suit was still pending in federal district court.²³²

Watson estimated "that its generic version of AndroGel would sell for about twenty-five percent of the price of branded AndroGel, which could decrease the sales of branded AndroGel by ninety percent and cut Solvay's profits by \$125 million per year."²³³ Before the district court could rule on Watson and Paddock's motions for summary judgment, which were fully briefed, the parties agreed to settle the suit.²³⁴ The generic manufacturers agreed not to market generic versions of AndroGel until 2015—five years before Solvay's patent would expire—in exchange for multimillion-dollar yearly payments.²³⁵

After the settlements were reported to the FTC pursuant to the Medicare Act, the agency brought an antitrust action under 15 U.S.C. § 45(a)(1) against the parties.²³⁶ The FTC "urged [the court] to adopt a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date."²³⁷ Under

²²⁸ *Id.* at 1304.

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

²³³ *Id.* at 1305.

²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *Id.* 15 U.S.C. § 45(a)(1) states that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45(a)(1) (2006).

²³⁷ *Watson*, 677 F.3d at 1312 (internal quotation marks omitted).

this approach, the FTC would have the burden of proving that Solvay was unlikely to prevail in the underlying patent infringement litigation. According to the FTC, since Solvay's AndroGel patent was "vulnerable" at the time of the settlement, it was "unlikely to prevail" in the patent infringement suit and the FTC could state an antitrust claim.²³⁸

The Eleventh Circuit rejected the FTC's approach for several reasons.²³⁹ First, it declared that the FTC's position is inconsistent with the circuit's precedents. "Our decisions focus on the *potential* exclusionary effect of the patent, not the *likely* exclusionary effect."²⁴⁰ In other words, so long as the patent for the drug was active, the court refused to inquire into its actual exclusionary power. Second, the court decided that "retroactively predicting from a past perspective a future that never occurred is . . . perilous."²⁴¹ It reasoned that assessing the infringement claim as of the time of settlement would impose a profound burden on litigants and scarce judicial resources, and would be unreliable anyway.²⁴²

Finally, *Watson* explained that the FTC's approach would require the circuit courts to make substantive determinations for which they are not institutionally equipped.²⁴³ "We are ill-equipped to make a judgment about the merits of a patent infringement claim The FTC's approach is in tension with Congress' decision to have appeals involving patent issues decided by the Federal Circuit."²⁴⁴ The Federal Circuit has exclusive appellate jurisdiction over patent cases.²⁴⁵ Thus, the court struck down the FTC's approach for (1) being inconsistent with precedent, (2) promoting unstable judicial policy, and (3) generating tension with Congress's decision that the Federal Circuit hears patent appeals.²⁴⁶

²³⁸ *Id.* at 1313.

²³⁹ *Id.*

²⁴⁰ *Id.* at 1312–13.

²⁴¹ *Id.* at 1313.

²⁴² *Id.* at 1314.

²⁴³ *Id.* at 1315.

²⁴⁴ *Id.*

²⁴⁵ *Id.* at 1314 (citing 28 U.S.C. § 1295(a)(1)).

²⁴⁶ *See id.* at 1313–15.

Instead, the court reiterated the scope of the patent test. “[A]bsent sham [Hatch-Waxman patent infringement] 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.”²⁴⁷ Because the FTC’s complaint attempted to state an antitrust claim by retroactively assessing, as of the time of the settlement, the likelihood Solvay would prevail in the underlying patent infringement suit, it did not state a plausible federal antitrust claim.²⁴⁸ The court granted the defendants’ Rule 12(b)(6) motion to dismiss²⁴⁹ and later denied the FTC’s petition for a rehearing en banc.²⁵⁰

The FTC filed a petition for a writ of certiorari on October 4, 2012,²⁵¹ presenting the question of “[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).”²⁵² In its petition, the FTC argued that the Supreme Court should overturn *Watson* because its approach “effectively equates a brand-name manufacturer’s *allegation* of infringement with a judgment in the manufacturer’s favor.”²⁵³ It explained that this outcome is incorrect for several reasons. First, defendants usually win patent infringement suits.²⁵⁴ In the cases litigated to final judgment, generic competitors prevail seventy-five percent of the time.²⁵⁵ Second, Congress clearly intended through the Hatch-Waxman Act and subsequent amendments for brand-name drug companies and generic manufacturers to use the judicial process to resolve patent

²⁴⁷ *Id.* at 1312.

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 1315.

²⁵⁰ Petition for Writ of Certiorari at 10, *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), (No. 12-416).

²⁵¹ Petition for Writ of Certiorari, *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), (No. 12-416).

²⁵² *Id.* at I.

²⁵³ *Id.* at 11.

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 18 (citing 2002 FTC STUDY, *supra* note 103, at 19–20).

infringement claims.²⁵⁶ Third, federal antitrust laws condemn “naked agreements not to compete”²⁵⁷ as per se unreasonable under Section 1 of the Sherman Act.²⁵⁸

C. The “Quick Look” Rule of Reason Test

The petition described *Watson* as a superior vehicle for resolving the circuit split because *Watson* involves a federal agency enforcement action, which gives the government greater control over the litigation.²⁵⁹ *K-Dur*, on the other hand, is a private class action.²⁶⁰ Moreover, FTC Commissioner J. Thomas Rosch has remarked that *Watson* is superior because it was decided on a motion to dismiss, and therefore “presents a pure issue of law,” unlike *K-Dur*, which was decided on summary judgment.²⁶¹

In re K-Dur Antitrust Litigation marked a distinct split in the circuit courts’ trend toward the “scope of the patent” test.²⁶² The Third Circuit rejected this test because it “assumed away” the question being litigated in the underlying patent suit.²⁶³ Instead, the court advocated a “quick look” rule of reason analysis. Under this test, the fact finder treats “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, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”²⁶⁴

The Third Circuit derived its approach to reverse payment settlements from the conventional “rule of reason” analysis in

²⁵⁶ *Id.* at 11.

²⁵⁷ *Id.*

²⁵⁸ See 15 U.S.C. § 1 (2006); Petition for Writ of Certiorari at 22, *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), (No. 12-416)..

²⁵⁹ See *id.* at 12 (“This case is a superior vehicle for addressing the question presented because it is brought by an agency charged by Congress with challenging unfair methods of competition . . .”).

²⁶⁰ See *id.*

²⁶¹ See Rosch, *supra* note 225, at 15.

²⁶² See Carrier, *Why the “Scope of the Patent” Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 4 (2012).

²⁶³ *K-Dur*, 686 F.3d at 214.

²⁶⁴ *Id.* at 218.

antitrust jurisprudence.²⁶⁵ Classically, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors.”²⁶⁶ This involves, according to *K-Dur*, three parts:

First, the plaintiff must show that the challenged conduct has produced anti-competitive effects within the market. If the plaintiff meets the initial burden, “the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.” Finally, the plaintiff can rebut the defendant’s purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective.²⁶⁷

The quick look test under the rule of reason represented a compromise between the rule of reason test, under which plaintiffs must “make a full showing of anticompetitive effects in the market,” and the per se rule, where market effects need not be examined. The quick look rule of reason test is used when “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” by virtue of their nature.²⁶⁸ Here, the court justified applying this test by “embrac[ing]” the “common sense conclusion that a payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement.”²⁶⁹

While admitting that the quick look test does not encourage settlement to the same degree as the scope of the patent test, the court stated that “the judicial preference for settlement . . . should not displace countervailing policy objectives or, in this case, Congress’s determination . . . that litigated patent challenges are

²⁶⁵ *Id.* at 209 (citing *State Oil v. Khan*, 552 U.S. 3, 10 (1997)).

²⁶⁶ *Id.*

²⁶⁷ *Id.* (quoting *United States v. Brown Univ.*, 5 F.3d 658, 668–69 (3d Cir. 1993)).

²⁶⁸ *Cal. Dental Ass’n v. Fed. Trade Comm’n*, 526 U.S. 756, 770 (1999).

²⁶⁹ *K-Dur*, 686 F.3d at 218 (internal quotation marks omitted) (quoting *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001)).

necessary to protect consumers from unjustified monopolies by brand name drug manufacturers.”²⁷⁰ In light of Hatch-Waxman’s structure and legislative record, Congress’s objective was to increase litigated challenges to pharmaceutical patents, an aim reverse payment settlements frustrate.²⁷¹

The court was also skeptical of *Tamoxifen*’s conclusion that subsequent ANDA-IV filers would restore competition after a reverse payment settlement.²⁷² It noted that only the first ANDA-IV challenger is eligible for the 180-day exclusivity period.²⁷³ Moreover, a brand-name drug company’s profit margin could be wide enough to “pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation.”²⁷⁴ Contrary to the *Tamoxifen* panel, the Third Circuit believed settlements likely reduced subsequent generic competition.

III. RESOLUTION: A PATENT-CENTRIC STANDARD OF ANTITRUST REVIEW

A. *The Hatch-Waxman Act Neither Prohibits nor Endorses Settlements*

The Hatch-Waxman Act does not expressly prohibit settlements in a patent infringement suit. Congress enacted the Act for two competing policy reasons: (1) to increase the availability of low cost generic drugs, and (2) to increase incentives for innovation in the pharmaceutical industry.²⁷⁵ To promote generic competition, the Act provided generic firms a safe harbor provision, an Abbreviated New Drug Application for streamlined FDA approval, and a 180-day marketing exclusivity period for the first applicant to submit to the FDA a “substantially complete” ANDA-IV.²⁷⁶ To promote innovation in the pharmaceutical

²⁷⁰ *Id.* at 217.

²⁷¹ *Id.*

²⁷² *Id.* at 215.

²⁷³ *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iv)).

²⁷⁴ *Id.* (citing *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521–22 (E.D. Pa. 2010), *abrogated by K-Dur*, 686 F.3d 197).

²⁷⁵ *See supra* Part I.B.1.

²⁷⁶ *See supra* Part I.B.1.a.

industry, the Act provided a patent term extension to allow patent proprietors time to recoup their research and development costs, non-patent marketing exclusivity to the first NDA applicant to obtain approval for an NCE, and a thirty-month stay of FDA approval for a patent infringement challenge to a generic firm's ANDA-IV.²⁷⁷ It did not, and still does not, prohibit settlements in a patent infringement suit.²⁷⁸

The Act reflects a careful balance struck by Congress, a balance that some commentators fear has been upset by reverse payment settlements.²⁷⁹ But the six prominent provisions in Hatch-Waxman that this Note has highlighted are each designed to remedy a preexisting, congressionally identified problem.²⁸⁰ Congress provided the patent term extension, for instance, to restore patent terms that had then been effectively eroded by FDA requirements and approval processes.²⁸¹ It introduced the ANDA to streamline the FDA approval process for generics and avoid “needlessly costly, duplicative” clinical trials.²⁸² It provided non-patent marketing exclusivity to drugs that introduce new active ingredients to encourage research and development,²⁸³ while granting a 180-day marketing exclusivity period to the first ANDA-IV applicant to encourage generic challenges.²⁸⁴ Finally, it granted generic firms safe harbor while they conduct experiments reasonably related to FDA approval,²⁸⁵ while providing an automatic thirty-month stay of FDA approval to patent holders who bring timely patent infringement suits.²⁸⁶ In 2003, when Congress amended the Hatch-Waxman Act, it only required settlements to be filed with the FTC and DOJ for review.²⁸⁷

B. The Circuits Have Not Resolved the Conflict Between Patent

²⁷⁷ See *supra* Part I.B.1.b.

²⁷⁸ See *supra* notes 54–59 and accompanying text.

²⁷⁹ See *supra* notes 13–14 and accompanying text.

²⁸⁰ See *supra* Part I.B.1.

²⁸¹ See *supra* Part I.B.1.b.i.

²⁸² See *supra* Part I.B.1.a.ii.

²⁸³ See *supra* Part I.B.1.b.ii.

²⁸⁴ See *supra* Part I.B.1.a.iii.

²⁸⁵ See *supra* Part I.B.1.a.i.

²⁸⁶ See *supra* Part I.B.1.b.iii.

²⁸⁷ See *supra* note 125 and accompanying text.

and Antitrust Law

The Third Circuit's presumptive illegality approach in *K-Dur* is unsuitable in light of Hatch Waxman's silence regarding settlements.²⁸⁸ The court improperly forces the parties in the patent infringement suit to litigate their case to final judgment or settle without a reverse payment.²⁸⁹ But the uncertainty of litigation and potential consequences of an adverse outcome to the plaintiff-patent proprietor, relative to the potential consequences of an adverse outcome to the defendant-patent challenger, help explain how a reverse payment can be rational, rather than unreasonable.²⁹⁰

On the other hand, the Second Circuit's "scope of the patent" test approach in *Tamoxifen* is no more satisfactory. As *K-Dur* correctly criticizes, the *Tamoxifen* test effectively "assumes" that the underlying patent is valid, and asks instead whether the parties' settlement falls within the "scope of the patent."²⁹¹ If an agreement falls within the scope of the patent, it poses no antitrust concern; if it does not, then the court applies antitrust scrutiny.²⁹² But if the patent is not valid in the first instance, then it has no scope at all.²⁹³ The primary beneficiaries of this test are those who hold weak patents.²⁹⁴

C. The Supreme Court Should Adopt a Patent-Centric Standard of Antitrust Review

Appropriate antitrust analysis of reverse payment settlements must subject the patent to scrutiny. The quick look test disregards the patent and the scope of the patent test assumes its validity. Only Judge Pooler's test, articulated in her dissent in *Tamoxifen*, recommends evaluating the strength of the patent at the time of the reverse payment settlement.²⁹⁵ After evaluating the patent's

²⁸⁸ See *supra* note 59 and accompanying text.

²⁸⁹ See *supra* notes 262–274 and accompanying text.

²⁹⁰ See *supra* notes 143–149 and accompanying text.

²⁹¹ See *supra* note 263 and accompanying text.

²⁹² See *supra* notes 200–205 and accompanying text.

²⁹³ See *supra* notes 208–209 and accompanying text.

²⁹⁴ See *supra* note 199 and accompanying text.

²⁹⁵ See *supra* notes 206–210 and accompanying text.

strength, a court could then conclude whether the reverse payment settlement terms were unreasonable under the Sherman Act.²⁹⁶ This approach harmonizes the exclusive principles of patent law with the procompetitive principles of antitrust law.

The *Tamoxifen* case presented a relatively simple evaluation of the strength of the patent—there, at the time the parties entered into the settlement at issue, the district court had recently ruled that Zeneca’s tamoxifen patent was invalid because the NDA filer had withheld critical testing information from the PTO.²⁹⁷ The question remains how Judge Pooler would have evaluated the strength of the patent in the absence of the district court’s ruling, as she does not offer a test for how to evaluate strength of a patent.

Evaluating the strength of a patent is difficult to pinpoint with precision and may be unknowable to the patentee itself, who may enter into multimillion-dollar settlements to insure against random outcomes.²⁹⁸ But the strength of a patent is critical to determining whether an agreement is anticompetitive.²⁹⁹ An evaluation of patent strength is therefore a necessary feature to any standard of antitrust review for reverse payment settlements. Determining which factors are relevant to the evaluation should be left to case-by-case adjudication.

The court of competent jurisdiction to review patent strength is the Court of Appeals for the Federal Circuit. The Federal Circuit has exclusive appellate jurisdiction over all patent cases. This grant of exclusive jurisdiction reflects a congressional choice to have experts evaluate questions pertaining to technical evidence.

CONCLUSION

The decade-long debate over the legality of reverse payment settlements has had its day in Court. This Note has argued that any standard of antitrust review for reverse payment settlements must involve an evaluation of the patent’s strength at the time of

²⁹⁶ See *supra* Part I.B.4.

²⁹⁷ See *supra* notes 181–192 and accompanying text.

²⁹⁸ See, e.g., *supra* notes 179–185.

²⁹⁹ See *supra* note 207 and accompanying text.

settlement. The Federal Circuit is the proper court to review patent strength evaluations given Congress's decision to have appeals involving patent issues reviewed by the Federal Circuit. This would give effect to the legislative intent of the Hatch-Waxman Act while preserving a meaningful place for patent law and antitrust law in the pharmaceutical industry.