THE FTC HAS A DOG IN THE PATENT MONOPOLY FIGHT: WILL ANTITRUST'S BITE KILL GENERIC CHALLENGES?

JENNIFER D. CIELUCH[†]

ABSTRACT

Antitrust laws have been notoriously lenient in the patent realm, the underlying reason being that patents' grant of exclusion create monopolies that defy antitrust laws in order to incentivize innovation. Thus, antitrust violations have rarely been found in the patent cases. But after the Supreme Court's holding in FTC v. Actavis, brand name pharmaceutical companies may need to be more cautious when settling Hatch-Waxman litigation with potential patent infringers. Both brand-name drug manufacturers and generic drug manufacturers have incentives to settle cases by having the brand-name pay the generic in exchange for delaying their entry into the market. While courts usually found that these reverse-payment settlements did not violate antitrust laws, the Supreme Court recently held that they sometimes can, even if the settlement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. The Court tried to take the middle ground after rejecting several bright line rules promulgated by appellate courts, including the Third Circuit's "quick look" presumption against reverse payment settlements and the Second, Eleventh, and Federal Circuit's "scope of the patent" test. This note finds that the Supreme Court's ruling will make the Hatch-Waxman legal landscape murky and, therefore, difficult for district courts to rule on the legality of reverse-payment settlements in the future. The ruling may hinder generics from challenging brand-name manufacturers, a result that would certainly contravene the principle purpose behind the Hatch Waxman Act.

INTRODUCTION

The battle between antitrust and patent affects everyone, though it is not readily apparent. Take the regular drug store visit to pick up a

[†] Duke University School of Law, J.D. candidate, 2015; Rice University, B.S. in Bioengineering, 2009. I gratefully acknowledge the comments and guidance of Professor Arti Rai throughout the development of this student note without suggesting that Professor Rai agrees with the statements made in this note. All mistakes are my own.

remedy for any common ailment, for example. When looking for a pain reliever, does one choose Advil® or the store's generic brand based on the same chemical compound, ibuprofen? For itchy watery eyes, does one choose Clartin® or any drug with the active ingredient loratadine? What makes a customer choose one over the other? Surely, we are swayed somewhat by brand loyalty, the attractive packaging, and advertisements, but mostly, it all boils down to the price seen on the shelves.

Congress passed the Hatch-Waxman Act[1] in order to prescribe special procedures for identifying and resolving patent disputes between brand-name and generic drug manufacturers.[2] The Hatch-Waxman Act was designed to further drug competition by promoting the availability of low-cost generic drugs through expedited introduction to the market.[3] Under the Act, generic manufacturers must simply show that their drug has the "same active ingredients as" and is "biologically equivalent" to the already approved brand-name drug[4] in order to bypass the lengthy and expensive clinical trials and FDA approval process for a new drug.[5] This Act reflects the careful balance between properly creating incentives for innovation and providing value to consumers. The patent system rewards brand-name manufacturers with a patent for the considerable funds they invest in research and development, their resultant inventions, and the creation of a beneficial drug for society, but limits the amount of time the brand-name manufacturer can have a monopoly in order to allow cost-effective generics to enter the market and provide lower healthcare costs for consumers.

The enactment of the Hatch-Waxman Act created an unintended by-product: reverse payment settlements,[6] or pay-to-delay settlements, between brand-name and generic drug manufacturers.[7] Reverse payment

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[1] Officially, the Drug Price Competition and Patent Term Restoration Act.

[2] *See* H.R. Rep. NO. 98-857, pt. 1, at 14–17 (1984) (discussing the need to change how the drug patent process works).

[3] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

[4] *Id*. (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv) (2012)).

[5] *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) (allowing applicants to use "bioequivalence" in lieu of conducting animal and human studies when introducing a new drug).

[6] The term "reverse" refers to the fact that the patent holder is paying the alleged infringer, rather than vice versa. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 205 (2d Cir. 2006). Reverse payments are also sometimes referred to as "pay-for-delay agreements," "exclusion payments," or "brand payments."

[7] FED. TRADE COMM'N, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 3 (2010) [hereinafter FTC, PAY FOR DELAY REPORT], *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

settlements are agreements under which the brand-name manufacturer pays a rival generic manufacturer to delay their market entry.[8] Such agreements have created tension between antitrust law and patent law and have spurred many heated debates about their legality.[9] The Federal Trade Commission (FTC) has asserted that "'[p]ay-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," but consumers will "miss out on generic prices that can be as much as 90 percent less than brand prices."[10] Even Congress has recognized this issue and has made several modest attempts at rectifying this loophole.[11] However, some courts have allowed reverse payments as long as the exclusion of generics falls within the patent's scope, meaning that the settlement does not keep the generic drug off the market past the brand name's patent expiration.[12] Recently, the Third Circuit declined to follow this approach and applied a presumption against any settlement involving delayed entry into the market, creating a split between the circuits.[13]

Because of the circuit split and Congress's failure to act, the Supreme Court granted certiorari to review the reverse payment settlement

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[8] *See id.* at 1.

[9] C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1555–56 (2006) (summarizing the "stark" conflict between the means of antitrust law and those of patent law).

[10] FTC, PAY FOR DELAY REPORT, *supra* note 7, at 1.

[11] *See, e.g.,* Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012) (proposed bill that would have prohibited pay-for-delay agreements).

[12] *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1335–36 (Fed. Cir. 2008) (discussing holdings of several circuit courts that allowed reverse payments as long as the exclusion of generics fell within the patent's scope). Under the "scope of the patent" test, reverse payment settlements are deemed permissible so long as (1) they do not exceed the scope of a patent, (2) the patent holder's patent infringement claim was not objectively baseless, and (3) the patent was not procured by fraud. *See id*.

[13] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *cert. granted*, *judgment vacated sub nom.* Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013) *and cert. granted, judgment vacated sub nom.* Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013) *reinstatement granted*, No. 2-01-cv-01652, 2013 WL 5180857 (3d Cir. Sept. 9, 2013). The Third Circuit employed the stricter "quick look" rule of reason analysis to find that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] prima facie evidence of an unreasonable restraint of trade." *Id.*

issue in *FTC v. Actavis*.[14] The Supreme Court found a middle ground, holding that reverse payments were not presumptively illegal, but that reverse payment settlements in patent infringement litigation could sometimes violate the antitrust laws—even if the agreement's anticompetitive effects fell within the scope of the exclusionary potential of the patent.[15] The Supreme Court also outlined a standard comprised of considerations for allowing antitrust law analysis to determine if a reverse payment settlement is illegal.

This Note will analyze the Supreme Court's ruling in *FTC v. Actavis* and how lower courts should apply the Supreme Court's standard by examining patent and antitrust law principles and the history of reverse payment settlements. Part I delivers a background on reverse payment settlements, including the circuit split on the legality of reverse payment settlements and the viewpoints of the FTC and the Department of Justice (DOJ) on the illegality of reverse payment settlements. Part II provides a detailed analysis of the judicial standards adopted by the Supreme Court and the strengths and weakness of that approach. Part II also addresses the procedural complications of the Supreme Court's ruling. Part III analyzes the public policy implications of the Supreme Court's ruling. Part IV offers proposed solutions to help mitigate any negative effects from the ruling, including how lower courts should apply the Supreme Court's ruling and legislative reform.

I. REVERSE PAYMENT SETTLEMENTS

The Hatch-Waxman Act requires the pioneer brand-name drug manufacturer to list the "number and the expiration date" of any relevant patent in its New Drug Application (NDA),[16] and it requires the generic drug manufacturer to assure the Food and Drug Administration (FDA) that the generic will not infringe the brand-name's patents in its Abbreviated New Drug Application (ANDA).[17] The generic manufacturer can provide this assurance by requesting approval to market beginning when any still-in-force patents expire, certifying that the brand-name manufacturer has not listed any relevant patents or that any relevant patents have expired.[18]

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[14] F.T.C. v. Watson Pharm., Inc., 133 S. Ct. 787 (2012). The case was formally known as *FTC v. Watson Pharmaceuticals*. The case name changed because generic drug manufacturers Watson Pharmaceuticals, Inc. had since changed its name to Actavis.

[15] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

[16] *See* 21 U.S.C. § 355(b)(1) (2012) (discussing what needs to be included in an application for a new drug).

[17] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

[18] See 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

Alternatively, the generic manufacturer can also seek Paragraph IV[19] certification by claiming that any listed or relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the ANDA.[20] A Paragraph IV challenge would automatically count as patent infringement under the statute[21] and often "means provoking litigation."[22]

Further, the Act encourages generic manufactures to take the Paragraph IV route by giving the first-to-file company 180 days of generic exclusivity starting from the first commercial marketing of its drug.[23] Because no other generic drugs can be marketed during the exclusivity period, the generic manufacturer's potential profits mostly materialize during this period and can be worth several hundred million dollars.[24] The Act also incentivizes the brand-name drug manufacturer to respond to the generic's Paragraph IV certification by providing an automatic stay of FDA approval of the ANDA for 30 months if the brand-name files a patent infringement lawsuit.[25] The brand-name drug manufacturer is also motivated to challenge Paragraph IV certification because of its patent and, more importantly, its profits have been put at risk.

The Hatch-Waxman Act unintentionally created an incentive structure for brand-name drug manufacturers and generic drug manufacturers to settle patent infringement claims through reverse payments, where the brand-name manufacturer pays the generic manufacturer to delay a generic's market entry.[26] Because of the significant difference between monopoly and competitive drug prices, both manufacturers are encouraged to settle litigation through reverse payments in the current landscape.[27] Generic manufacturer profits are much less than what brand-name manufacturers stand to lose, which allows brand-name manufacturers to settle litigation by offering generic manufacturers a split of the monopoly profits—an offer that ends up costing more money than what the generic manufacturer would have made by entering the market.[28] Both the FTC and DOJ, the federal antitrust enforcement agencies, have steadfastly maintained that reverse payments are a violation of antitrust laws

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[19] Because it stems from the fourth paragraph of this statute's section, this type of challenge is commonly known as the "Paragraph IV" route, which requires the generic drug manufacture to certify that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug.
[20] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).
[21] *See* 35 U.S.C. § 271(e)(2)(A) (2006 & Supp. V 2011).
[22] Caraco Pharm. Labs, 132 S. Ct. at 1677.
[23] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2012).
[24] Hemphill, *supra* note 9, at 1579.
[25] 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

as the settlement extends the patent holder's monopoly.[29] Furthermore, the agencies argue that the delay of generic drugs produces a negative economic impact on pharmaceutical drug consumers due to the monopoly pricing set by the brand-name drug manufacturers.[30] Nevertheless, courts have generally found that reverse payment settlements do not violate antitrust laws so long as they do not extend the brand-name's monopoly past patent expiration.[31] By contrast, the Third and Sixth Circuits have adopted a vastly different approach and found reverse payment settlements to be presumptively illegal.[32] While Congress could resolve this by

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[26] *See* FTC, PAY FOR DELAY REPORT, *supra* note 7, at 3.

[27] *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 635–36 (2009) (discussing the drug manufacturer's incentive to settle).

[28] *Id.*

[29] *See* FTC, PAY FOR DELAY REPORT, *supra* note 7, at 1–2; *Confirmation Hearings on Federal Appointments: Hearings Before the S. Comm. on the Judiciary*, 111th Cong. 618 (2009) (statement of Christine Varney, nominee for Assistant Att'y Gen., Antitrust Division, United States Department of Justice) (stating DOJ's full support of the FTC's position against reverse payment settlements).

[30] Consumers will "miss out on generic prices that can be as much as 90 percent less than brand prices" and "[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices." FTC, PAY FOR DELAY REPORT, *supra* note 7, at 1–2.

[31] *See, generally,* FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012) *and rev'd and remanded sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (holding that absent sham litigation or fraud in obtaining patent, reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within scope of exclusionary potential of patent); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (holding that brand-name manufacturer acted within its rights as patentee when it agreed to make payments to generic manufacturers in exchange for an agreement not to market generic version of drug until patent expired); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (requiring patent holder to make reverse payments to generic drug manufacturer in a settlement agreement would not be unlawful under Sherman Act even if it required reverse payments in an amount more than either party anticipated generic manufacturer would earn by winning lawsuit); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1296 (11th Cir. 2003) (finding that brand-name manufacturer's agreements with generics manufacturers to not market generic version until patents expired or were held invalid, in exchange for cash payments, was not a per se violation of Sherman Act prohibition on contracts in restraint of trade).

[32] *See In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012) (applying the rule of reason test to find the reverse payment agreement at issue per se illegal); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (same).

amending the Hatch-Waxman Act, they have yet to pass any legislative solutions.

In order to better understand how the reverse payment system was created, section A will outline the incentives that Congress provided generics in the Hatch-Waxman Act. To understand why reverse payments arrive at such disparate analysis by the courts, section B will analyze the clash between antitrust law and patent law and section C details the FTC's and DOJ's view that started the litigation in the first place. Section D will analyze the circuit split and the two main tests employed by the courts before *Actavis*, which caused tension as to whether a settlement was allowed under patent law and antitrust law.

A. The Creation of Reverse Payment Settlements

Pharmaceutical manufacturers must function within the framework of the Federal Food, Drug, and Cosmetic Act.[33] In order for a pharmaceutical drug to be approved by the FDA, the manufacturer must submit a New Drug Application (NDA), which demands a multitude of information on the drug's safety, efficacy, and method of production, and disclosure of any patents related to its composition or methods of use.[34] This is an extensive, time-consuming review process that requires significant development costs and intensive, multi-phase clinical trial testing.[35] Before the Hatch-Waxman Act, a generic drug manufacturer could not legally develop a generic version of a brand-name drug until the patent expired.[36] Furthermore, once the patent expired, the generic drug would have to obtain FDA approval through the same extensive NDA process.[37] The duplicative nature of this process eroded the incentives for manufacturers to develop generics.[38]

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[33] 21 U.S.C. § 355(a) (2006).

[34] *See* 21 U.S.C. § 355(b) (describing what must be contained in application to introduce a new drug into interstate commerce).

[35] 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") 20 (2005).

[36] *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).

[37] SCHACT & THOMAS, *supra* note 35, at 20.

[38] *See id.* (noting that generic drug manufactures would have to undertake significant costs to get generic drugs on the market).

1. Congress's Incentive Structure to Promote Generics.

In order to promote the research and development of competing drugs, Congress passed the Hatch-Waxman Act, giving generic drug manufacturers three major incentives: the safe-harbor provision, the ANDA, and the 180-day exclusivity period.[39] The safe-harbor provision under Title II of the Act allows manufactures to use the patented invention "solely for uses reasonably related to the development and submission of information" to the FDA without infringing the patent.[40] This allows the generic drug manufacturer to conduct testing to establish bioequivalency—the same active ingredients, route of administration, dosage form, strength, etc.—before the patent expires so that the generic can be launched quickly after the patent's expiration.[41] The second benefit under the Hatch-Waxman Act, ANDA, allows generic manufacturers who establish bioequivalency to rely on, or "piggyback,"[42] the FDA's finding of safety and efficacy for that drug.[43] By not having to go through the costly and time-consuming NDA approval process, the manufacturer's initial investment into developing a generic drug decreases dramatically.[44]

Finally, generic manufacturers have an incentive to challenge the brand-name drug's patents[45] in order to receive exclusivity against other competing drugs from entering the market for 180 days[46] with minimal risk.[47] Known as the "Paragraph IV" route,[48] the first-to-file ANDA

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[39] FTC, PAY FOR DELAY REPORT, *supra* note 7, at 3. The Hatch-Waxman Act was passed as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2006); 21 U.S.C. §§ 301-360 (2006); 28 U.S.C. § 2201 (2006); 35 U.S.C. §§ 156, 271, 282 (2006)).

[40] 35 U.S.C. § 271(e)(1) (2006).

[41] *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.").

[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) (2012).

[44] *See* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 617–18 (2011) (estimating the cost of preparing and filing an ANDA to be $1 million).

[45] *See id*.

[46] 21 U.S.C. § 355(j)(5)(B)(iii)(IV)(iv)(I).

[47] As long as the generic manufacturer does not market the product, it will face minimal liability for infringement because there generally are no damages if the product was never sold. *See* Emily Michiko Morris, *The Myth of Generic*

applicant certifies that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug.[49] Once initiated, the patent owner has forty-five days to initiate infringement litigation and if the patent owner fails to respond, the ANDA applicant can market the drug without infringing on the underlying patent.[50]

2. 180-day Exclusivity Period: A Perverse Incentive.

While the Hatch-Waxman Act theoretically created notable incentives for greater production of generic drugs, the 180-day exclusivity period eventually pushed both the generic manufacturer and brand-name manufacturer to settle using reverse payments. The exclusivity period drives the generic manufacturer because the exclusivity period begins after the first-to-file generic manufacturer markets the drug or after a court finds that the patent is invalid or not infringed.[51] The brand-name manufacturer is spurred to settle because the grant of exclusivity does not expire.[52] This means that the reverse payment settlement scheme not only delays the first-to-file generic manufacturer's entry into the market, but also prevents any other generic manufacturer from entering the market until after the patent expires unless they go through the FDA's NDA process, which is cost prohibitive.[53] Other generic manufacturers could also file a subsequent Paragraph IV challenge, but this rarely, if ever, happens. The second-comers have little incentive to file a subsequent Paragraph IV challenge without a grant of exclusivity as a possible reward because of the high cost and risk associated with patent litigation.

The brand-name manufacturers settle litigation by offering the first-to-file generic manufacturer significant monetary compensation, more than the profitability of generics and less than the loss of the brand-name's market share, in exchange for the generic to delay entry into the market and

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Pharmaceutical Competition Under the Hatch-Waxman Act, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 264 (2012).

[48] This is referred to as the "Paragraph IV" route because it falls under the fourth paragraph of the relevant statutory section, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012). Alternatively, the ANDA applicant can file under paragraphs I-III, where the applicant certifies that the brand-name manufacturer failed to file the relevant patents, the patents expired, or approval is being sought effective on a date after patent expiration. *See* 21 U.S.C. §355(j)(2)(A)(vii)(I)-(III) (2012).

[49] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

[50] *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iii)(IV)(iv)(I) (2012); 35 U.S.C. § 271(e)(1) (2012).

[51] 21 U.S.C. §355(j)(5) (2012).

[52] *See* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1755 (2003).

[53] *See id.*

to "park" its grant of 180-day exclusivity.[54] In the end, this incentive causes a brand-name manufacturer to settle *only* with a generic manufacturer that has been approved for the 180-day exclusivity period because the first-to-file generic can exercise its exclusivity period *whenever* they want.

B. The Clash Between Patent Law and Antitrust Law

The Sherman Antitrust Act (Sherman Act) prohibits businesses from contracting, combining, and conspiring to restrain trade or commerce to encourage competitive markets and promote consumer welfare.[55] On the other hand, a patent grants "the right to exclude others from profiting by the patented invention"[56] and is an exception to the general rule against monopolies and to the right of access to a free and open market.[57] Patents therefore grant patent holders a time-limited monopoly without fear of antitrust liabilities.[58]

The Sherman Act prohibits only "unreasonable restraints on competition" under the rule of reason standard, whereby the company's behavior is analyzed under an "elaborate inquiry into the reasonableness" in context of a particular industry.[59] Because the rule of reason standard is not a bright-line rule and consumes considerable time and resources to litigate, the Supreme Court has ruled certain agreements *per se* illegal under the Sherman Act.[60] These standards have been imported into how the circuit courts decided antitrust violations in the Hatch-Waxman context by creating the "scope of the patent" test and "quick look" rule of reason test explained in section D.

In the patent law realm, a patent is presumptively valid and the burden of proving invalidity rests on the challenging party.[61] In the Hatch-Waxman context, the generic manufacturer filing the ANDA must show

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[54] *See id.*
[55] *See* 15 U.S.C. § 1 (2006) (proscribing all contracts, combinations, or conspiracies in restraint of trade).
[56] Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).
[57] 35 U.S.C. § 154(a)(1) (2012).
[58] *See* United States v. Gen. Elec. Co., 272 U.S. 476, 485 (1926) ("It is only when [the patentee] . . . steps out of the scope of his patent rights . . . that he comes within the operation of the [Sherman] Act.").
[59] 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)).
[60] N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (holding that "there 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.").
[61] 35 U.S.C. § 282(a) (2012).

that the brand-name patent is invalid by clear and convincing evidence.[62] Therefore, implications related to the enforcement of antitrust laws only apply when the settlement of Hatch-Waxman litigation falls outside of the rights granted by the patent or when the patent is invalid. Because of the major difference between the two spheres of law, it is possible that antitrust laws might not provide the most suitable vehicle for policing reverse payment agreements.

C. FTC and DOJ's Stance on Reverse Payment Settlements

The FTC has long been aware of reverse payment settlements and always opposed their potential to be over-extended, but it was not until recently that the FTC was concerned with the anticompetitive implications of reverse payments.[63] Insisting that "[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices[,]" the agency has strenuously opposed pay-to-delay deals as anticompetitive and ultimately harmful for US consumers.[64] The FTC has equated reverse payment agreements with horizontal market allocation agreements, which are ordinarily *per se* antitrust violations when no patent is involved.[65] Therefore, the FTC views reverse payment settlements as presumptively illegal.

The FTC has said that any exemption from antitrust law that patent settlements receive normally do not apply if the patent is invalid or does not cover the restricted activities.[66] The FTC has demonstrated its skepticism regarding the presumption of patent validity, stating a firm "certain that a patent was valid . . . would have no incentive whatsoever to pay another

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

[63] Reverse payment settlement agreement in the Hatch-Waxman context is not a new phenomenon. For example, the FTC Generic Drug Study identifies one that was executed in March 1993, and there were probably prior reverse payment settlements. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 31 (2002).

[64] FTC, PAY FOR DELAY REPORT, *supra* note 7, at 2.

[65] *See, e.g.*, Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49 (1990) (quoting *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972) (observing that an agreement between competitors to allocate territories with no purpose other than to reduce competition is a "classic example" of a per se violation of the Sherman Act)).

[66] Schering-Plough Corp., No. 9297, slip op. at 30 (FTC Dec. 18, 2003), *available at* http://www.ftc.gov/sites/default/files/documents/cases/2003/12/031218commissionopinion.pdf, *vacated*, 402 F.3d 1056 (11th Cir. 2005); *see also* Petition for Writ of Certiorari at 14, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273) [hereinafter FTC Petition for Certiorari].

firm to stay out of the market."[67] Therefore, the FTC's rule "would make almost any settlement involving a payment illegal."[68]

On the other hand, the Antitrust Division of the DOJ initially approved of reverse payment settlements, viewing the payments as a legitimate enforcement of the patent holder's rights.[69] Due to changes in the administration and department leadership, in 2008, the DOJ finally adopted a similar stance to that of the FTC's, opposing reverse payment settlements.[70] The DOJ asserted that "[t]he anticompetitive potential of reverse payments . . . is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act."[71] The DOJ further stated that "[l]iability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect."[72]

Currently, the government has a strong cohesive stance against reverse payment settlements. The FTC, with the support of the DOJ and the executive branch, will undoubtedly continue to strongly pursue cases involving reverse payment settlements under its position that reverse payment settlements are *per se* violations of antitrust law.

D. The Circuit Splitting Headache that Has Tormented Settlements

The case law regarding reverse payment settlements is definitively split between patent rights and antitrust concerns. This divergence is illustrated by the clashing positions taken by the Third Circuit and the Eleventh Circuit on the **same** reverse payment settlement for the **same** drug patent, K-Dur. Three other circuits—the Second, Sixth, and the Federal Circuits—have ruled on this issue, also disagreeing on the proper balance between the rights of the patent holder and the importance of enforcing antitrust law's purpose.

1. "Scope of the Patent" Test.

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[67] *See* FTC Petition for Certiorari, *supra* note 66 at 18 (quoting 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046, at 339 (Supp. 2004)).
[68] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005).
[69] Brief for the United States as Amicus Curiae at 8–9, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273).
[70] Brief for the United States in Response to the Court's Invitation at 9–10, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)).
[71] *Id.*
[72] *Id.*

The Second, Eleventh, and Federal Circuits evaluate antitrust claims concerning reverse payment settlements under the "scope of the patent" test.[73] These courts allowed reverse payment settlements as long as the settlement's terms fell within the exclusionary scope of the brand-name manufacturer's patent.[74] Under this analysis, reverse payment settlements are deemed permissible so long as (1) they do not exceed the scope of a patent, (2) the patent holder's patent infringement claim was not objectively baseless, and (3) the patent was not procured by fraud.[75]

The courts reasoned that a patent holder could contract within the patent's term because a patent grants its owner the right to exclude others from making or selling the invention by statute.[76] Therefore, reverse payment settlements would not usually exceed the patent's scope so long as the generic drug's entry into the market was not delayed longer than the expiration of the patent.[77] Furthermore, settlements would fall within the patent's scope because the essence of the reverse payment agreement was to exclude generic manufacturers from profiting from patented invention.[78] Finally, the courts reasoned that the "scope of the patent" test supported public policy by encouraging settlements and judicial efficiency.[79]

2. "Quick Look" Rule of Reason Test.

Conversely, the Third and Sixth Circuits have adopted the "quick look" rule of reason test.[80] Examining the economic realities of the reverse payment settlement, these courts held that any payment made by the patent holder to the generic challenger who agreed to delayed entry into the market was prima facie evidence of an unreasonable restraint of trade.[81] Therefore, the parties bear the burden to rebut this presumption by showing that the

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[73] *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2005); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).

[74] *See In re Ciprofloxacin*, 544 F.3d at 1335–36.

[75] *See id.*

[76] *See* 35 U.S.C. § 282 (2006 & Supp. V 2011); *see, e.g.*, *In re Ciprofloxacin*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 208–09.

[77] *See In re Ciprofloxacin*, 544 F.3d at 1337; *In re Tamoxifen*, 466 F.3d at 208–09.

[78] *See In re Ciprofloxacin*, 544 F.3d at 1337.

[79] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1072–73 (11th Cir. 2005) (quoting Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976)); *see also In re Ciprofloxacin*, 544 F.3d at 1333.

[80] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003).

[81] *In re K-Dur*, 686 F.3d at 218.

payment was for a purpose other than delayed entry or offered some "procompetitive benefit."[82] An example of a procompetitive benefit is "a modest cash payment that enables a cash-starved generic drug company to avoid bankruptcy and begin marketing a generic drug."[83]

The "quick look" rule of reason analysis followed the approach that was initially suggested by the D.C. Circuit and supported the court's 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 . . . ."[84] This test relies upon antitrust law's scrutiny of anticompetitive behavior, which stands in stark contrast to the "scope of the patent" test, which relies on patent law's exclusionary rights and presumption of patent validity.[85] The Third Circuit justified this approach by reasoning that it would protect consumers from unjustified monopolies and align with Hatch-Waxman's public policy objectives.[86] Unlike the Second, Eleventh, and Federal Circuits, the Third Circuit determined that Hatch-Waxman's intent to protect consumers overrode a judicial preference for encouraging settlements.[87]

II. *FTC V. ACTAVIS*: ANTITRUST NOW HAS A BITE TO GO WITH ITS BARK

Because of the circuit split, the Supreme Court granted certiorari in *FTC v. Actavis* in order to find a middle ground between the two juxtaposing viewpoints. This section will outline the Court's holding and the considerations employed in its ruling. Then, the Court's opinion is analyzed for its effective and practical outcomes. While the Supreme Court's attempt to strike an appropriate balance between patent law and antitrust law is laudable, its holding leaves much more to be desired, as the test it employed is open-ended and leaves the lower courts with a nebulous path to fumble through.

A. The Supreme Court's "Rule of Reason" Test

In *FTC v. Actavis*, the FTC challenged the reverse payment settlement between the brand-name manufacturer and generics manufacturer of a synthetic testosterone sold under the name AndroGel as an antitrust violation. Under the settlement agreement, the brand-name

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[82] *Id.*
[83] *Id.*
[84] Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 808 (D.C. Cir. 2001) (internal quotation marks and citation omitted).
[85] *See In re K-Dur*, 686 F.3d at 218; *In re Ciprofloxacin*, 544 F.3d at 1337.
[86] *See In re K-Dur*, 686 F.3d at 217–18.
[87] *See id.*

manufacturer agreed to pay the generics manufacturers millions of dollars in exchange for the generics not entering into the market for 65 months, when the AndroGel patent expired.[88] This was a classic reverse payment settlement case where large sums of money were exchanged for the generics' delayed market entry.

The Supreme Court attempted to find the middle ground between the disparate "scope of the patent" and "quick look" rule of reason tests promulgated by the circuit courts. The court held that the desirability of settlements is outweighed by considerations related to anticompetitive effects:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.[89]

While the Court expressly overruled the "scope of the patent" test, the Court also did not accept the premise that the payment settlement was *per se* illegal or was prima facie evidence of anticompetitive behavior. But, the Court did accept the Third Circuit's reasoning that the legality of the settlement should be measured by "procompetitive antitrust policies," rather than "patent law policy."[90]

The Court outlined five considerations under an antitrust law analysis to determine the legality of a reverse payment settlement:

(1) the reverse payment's "potential for genuine adverse effects on competition;"

(2) whether the reverse payment's "anticompetitive consequences . . . prove unjustified;"

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[88] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).
[89] *Id.*
[90] *Id.*

(3) "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee['s] . . . power to bring that harm about in practice;"

(4) administrative efficiency;[91]

(5) the ability for the parties to settle their lawsuit without a reverse payment[92].[93]

The Court ruled that the rule of reason test should be used as in other antitrust cases, but also implicitly suggested that the full rule of reason approach associated with *Chicago Board of Trade*[94] may not be necessary.[95] Further, the Court left the decision to the lower courts as to which considerations to use and how those considerations should be weighed in applying the rule of reason analysis.[96] While the Court clearly overruled the "scope of patent" test and held that antitrust laws should measure the payment's legality rather than patent law policy, it nevertheless created a murky standard that could deem a reverse payment illegal under antitrust law, even if the settlement's anticompetitive effects fell within the scope of the exclusionary potential of the patent.

B. Uncertainty Will Lead to Inconsistent Rulings

The question left unanswered by the Supreme Court is how lower courts should apply the *Actavis* ruling in future reverse payment settlement cases. All of the circuit courts' approaches were rejected, and the Court did not develop any concrete replacement. The Court left too much unclear with its vague holding that reverse payment settlements should be analyzed somewhere in between the "quick look" rule of reason and "scope of the patent" tests. Primarily, lower courts are left with the decision on how they should use the five considerations and how those considerations should be

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[91] The Court states consideration four as whether "an antitrust action is likely to prove more feasible administratively." *Id.*

[92] The Court states consideration five as whether "a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." *Id.*

[93] *Id.* (internal citations omitted).

[94] Chicago Board of Trade v. United States, 246 U.S. 231 (1918).

[95] *Actavis,* 133 S. Ct. at 2237.

[96] *Id.* at 2238 ("[T]rial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.") (internal quotations omitted).

weighed and applied to the existing rule of reason analysis. In addition, the following issues remain unresolved as to how to apply the rule of reason test: when and to what extent the validity of the patent will need to be tested, what types of direct economic evidence to consider when assessing the anticompetitive effects, what indirect evidence will serve as the most useful evidence of anticompetitive effects, whether market definition will play a meaningful role, and how courts will analyze potential efficiencies.

1. The Supreme Court May Have Effectively Adopted the "Quick Look" Rule of Reason.

The majority opinion closed by "leav[ing] to the lower courts the structuring of the present rule-of-reason antitrust litigation."[97] Yet, the Supreme Court definitively asserted that an antitrust solution is appropriate in resolving the issues with reverse payment settlements.[98] Some commentators have noted that, in effect, the Court's decision essentially accepted the "quick look" rule of reason approach.[99] If true, the Court did not do so explicitly because the Court acknowledges, albeit quite skeptically, that not all reverse payment settlements are anti-competitive.

Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro in *Activating Actavis* assert that the Court's ruling means that the parties to the challenged reverse payment settlement must show that the settlement leads to earlier or more competition than a settlement without the reverse payment.[100] If the Court's ruling does force the parties to defend the reverse payment settlement only by demonstrating the procompetitive effects of the settlement, then we really are in a world more like the "quick look" rule of reason approach.[101] But, this simply cannot be the case. Direct evidence of the strength of the patent at issue must be an overarching consideration. If strong evidence of patent validity were not persuasive, then the protections given by patents would no longer be as strong as they have been since the inception of our patent system. Adopting the "quick look" rule of reason approach would not allow consideration of the fact that the brand-name manufacturer is risk-averse and would rather settle litigation than risk their patent to be invalidated. Even when the patent is strong and there's little chance of invalidation, the risk of losing millions of dollars' worth of profits would give any brand-name manufacturer pause to consider splitting some of its profits.

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[97] *Id.* at 2238.
[98] *Id.*
[99] *See* Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 21 (Fall 2013).
[100] *Id.*
[101] *Id.*

Perhaps the Court wanted to draw the line in the middle of the circuit split, but in practice, its ruling can make any patent litigation settlement appear to be a pay-for-delay whenever the generic does not enter the market immediately. This could actually harm the consumers, a result contrary to the Court's intent, because a reverse settlement in the context of a strong patent could actually bring a generic drug to the market sooner than otherwise expected. The generics could be available sooner than the expiration of the patent when there is a high chance of a validity finding with a strong patent. Whatever the underlying intent of the Supreme Court, the holding ultimately leaves the decision to be made by the lower courts. As a consequence, the uncertainty on how these courts will rule could result in another circuit split.

2. The Circuit Splitting Headache Still Exists.

The circuit courts clearly showed a preference for the outliers of the spectrum, which could lead to further inconsistencies between the circuits.[102] District courts may find that their jurisdiction's appellate court will "stick to their guns" and rule as closely to their previous holdings as possible while still falling within *Actavis*, thereby ruling inconsistently across the United States. More troubling, lower courts could struggle to rule consistently against the long-established judicial preference for settling cases.

For example, the Third and Sixth Circuits, which adopted the "quick look" rule of reason approach, can apply strong criteria close to a full-blown rule of reason analysis that would allow the vast majority of reverse payment settlements to be found illegal.[103] On the other hand, the Second, Eleventh, and Federal Circuits, which adopted the "scope of the patent" approach, can apply weaker criteria so as to allow more flexibility in finding reverse payment settlements legal.[104] With different jurisdictions yielding widely disparate results, generic and brand-name manufacturers might agree to litigate—and thereby settle—in reverse settlement preferred jurisdictions and encourage a flood of Hatch-Waxman cases on those jurisdictions' dockets.

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[102] *See supra* Part I.C.
[103] *See supra* Part I.C.2.
[104] *See supra* Part I.C.1.

III. ANTITRUST'S BITE MAY SCARE OFF BAD PATENTS BUT CAN ALSO KILL SETTLEMENTS, EFFICIENCY AND POSSIBLY GENERIC CHALLENGES

Congress enacted the Hatch-Waxman Act to promote consumer access to low cost generics. "Cheaper generic drugs have saved purchasers billions of dollars per year—an estimated $1 trillion in the United States over the past decade, according to an industry-sponsored study—which makes such drugs a powerful way to keep down heath-care costs."[105] The other goal of Hatch-Waxman was to provide incentives for generic manufacturers to challenge brand-name patents in order to clean up the prevalence of bad patents, which damages society as a whole.[106] Reverse payment settlements arguably bypass both of these goals by delaying generics from the market and halting the determination of the validity of the original patents at issue. But, these settlements could also help in the context of stronger patents as Paragraph IV challenges typically are for secondary patents: patents that are not for the original chemical compound or active ingredients of the drug, but for the other improvements of the drug, i.e. dosage amount. By hindering reverse payment settlements, generic manufacturers have no incentive to challenge these arguably stronger patents. Perhaps generic manufacturers would stay out of Paragraph IV challenges completely because of the increased costs associated with the increased chance that the FTC would challenge any settlement.

A. Secondary Patents Are the Major Source of Harm

Brand-name manufacturers attempt to extend the patent exclusivity of their drugs through the process of "evergreening," or filing secondary patents.[107] Secondary patents protect supplementary aspects of drug

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[105] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (2013) (citing to a study conducted by IMS Health for the Generic Pharmaceutical Association); *see also* GENERIC PHARM. ASS'N, GENERIC DRUG SAVINGS IN THE U.S. 1 (2014) (estimating that the savings are over $1.5 trillion over the past decade).

[106] H.R. REP. NO. 98-857, pt. 1, at 28 (1984) (explaining that allowing early generic challenges "fairly balance[d]" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent); *see also* Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101 (2006).

[107] *See* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 959–62 (2011) ("This practice became known as 'evergreening' because the patentee could refresh

innovation, such as particular drug formulations and compositions, beyond the fundamental protection of a novel active ingredient given by the primary (traditional) patent. The rise of the total number of patents is in large part due to the rise of secondary patents, but unfortunately, they are also responsible for the increasing number of bad patents.[108]

While secondary patents do, in large part, provide great societal value and promote improvements and further innovations, they are less likely to meet legal standards of patent validity. Therefore, generic manufacturers target these "bad" or "weak" secondary patents in order to enter the market before patent expiration.[109] Secondary patents are seen as less onerous bars for generics to entry into the market, and consequently, it is beneficial for generics to challenge secondary patents under Hatch-Waxman, to release generic drugs on the market when they are supposed to be, and to help eliminate bad patents from our system.[110] By allowing generic manufacturers to challenge secondary patents, the system enables the often-overloaded U.S. Patent and Trademark Office (USPTO) to review bad patents by allowing for a second look after the bad patents' initial approval.

B. Generics' Entry into the Market Could Even Be Delayed, Contrary to the Act's Entire Purpose

Reverse payment settlements, without a doubt, have negative effects on consumers if the generic manufacturer can defeat the brand-name manufacturer's patent; however, this perspective is just one side of the coin. Often, the brand-name manufacturer wins the patent infringement litigation, which results in generic entry only after patent expiration.[111] Of the cases that go to trial and do not settle, the brand-name manufacturer wins 92% of the time when the litigation involves a primary patent and 32% of the time

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its stay by periodically adding a new patent to the Orange Book, no matter how weak the patent or how little it related to the defendant's product").

[108] Carlos Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective viii (Jan. 2007) (working paper) (noting that "in the 12-years period 1989-2000, just 153 (15%) of all new drug approvals were medicines providing a significant clinical improvement") (internal citation omitted) (*available at* http://www.ictsd.org/sites/default/files/research/2008/06/correa_patentability20guidelines.pdf).

[109] Hemphill & Sampat, *supra* note 105, 1386–87.

[110] *Id.*

[111] PRICEWATERHOUSECOOPERS, PATENT LITIGATION STUDY 20–21 (2014); *see also* ADAM GREENE & D. DEWEY STEADMAN, RBC CAPITAL MKTS., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 4 (2010).

when it involves a secondary patent.[112] So, for the vast majority of primary patent cases and a sizeable number of secondary patent cases, a reverse settlement payment could have allowed the generic to come on the market sooner than they would have under the patent life.

Using the *Actavis* case as the poignant example, AndroGel is protected by a patent that expires in 2021 and settlement in that case allowed the generic to be available in 2015.[113] The settlement allowed consumers to be able to access the generic six years earlier than if the brand-name manufacturer won at trial, and the brand-name manufacturer had a strong possibility of doing so. AndroGel's patent was arguably strong. The FDA approved the NDA for AndroGel in 2000.[114] In January 2003, the USPTO issued U.S. Patent No. 6,503,894 ('894 patent), which expressly disclosed the AndroGel formulation.[115] AndroGel has become a great medical and commercial success, providing needed treatment to millions of patients and generating nearly $875 million in sales in 2011.[116] Furthermore, the patent in that dispute was not a secondary patent, which is the strongest argument for support of the reverse payment settlement in this case. In settlements where substantial probability of patent validity exists such as the one in *Actavis*, reverse payment settlements may benefit consumers by providing the generic challenger with a market entry date much earlier than the patent's expiration.

C. Litigation, Settlements, and Innovation Will Be Chilled if Waters Remain Murky

The murkiness brought on by *Actavis* may discourage generic drug companies from bringing Paragraph IV challenges. Moreover, if the generics still decide to challenge brand-names' patents, litigation settlements would be chilled due to fear of antitrust liability as the FTC and DOJ now have more ammunition to challenge even more agreements. Undoubtedly, the FTC will express no hesitation in challenging any patent settlement that has any hint of anticompetitive behavior in the wake of *Actavis*, particularly given its position that transferring anything of value from the brand-name drug manufacturer to a generic competitor should merit antitrust scrutiny.[117] In addition to forcing brand-name manufacturers

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[112] Hemphill & Sampat, *supra* note 105, at 1386–87.
[113] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).
[114] *Id*.
[115] *Id*.
[116] ABBOTT LABS., ABBOTT 2011 ANNUAL REPORT 52 (2011), *available at* http://media.corporate-ir.net/media_files/irol/94/94004/Proxy_Page/AR2011.pdf.
[117] *See* Brief for the Petitioner, FTC v. Actavis, 133 S. Ct. 2223 (Jan. 22, 2013) (No. 12-416).

to defend even their strong patents, the FTC's fighting power gives brand-name manufacturers little incentive to settle cases with generic manufacturers because the best defense to an antitrust challenge is to establish the validity of the patent, which can only be established through patent litigation.

Reverse payment settlements have been a common part of patent litigation over the last ten years or more, and in the 2012 fiscal year, the FTC reported there were 40 reverse payment agreements among 140 "final resolutions" of ANDA litigation.[118] Uncertainty could lead to a different litigation dynamic, in which generic challengers are less able to seek or obtain settlements that they would consider beneficial to their business. Further, there would be no incentive to settle if, immediately after settling, the parties would have to go through the whole rigmarole again and litigate the same issue of the patent's validity to defend against an antitrust suit. Simply put, there is essentially no advantage to settling when the law is murky. The landscape post-*Actavis* forces parties to litigate their cases fully through time-consuming trials, thereby incurring greater costs and risk that deters rather than incentivizes generic challenges.[119]

Patent litigation is particularly complex, costly, and uncertain. Generally, if a patent case goes to trial, legal fees alone will cost each side $1.5 million.[120] But a generic challenging a brand-name patent case costs about $10 million per suit on average.[121] Settlements can provide efficient resolutions to otherwise lengthy, complex, and costly trials. Reverse

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[118] FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FISCAL YEAR 2012, at 2 (2013), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

[119] *See* Kelly Casey Mullally, *Legal* (*Un)certainty, Legal Process, and Patent Law*, 43 LOY. L.A. L. REV. 1109, 1125 (2010).

[120] 1 H. HOVENKAMP ET AL., IP AND ANTITRUST § 7.1c, 2014 WL 3738869, at *2 n.6 (Nov. 2013) (But, "[t]oday that number is in excess of $5 million per side." (citing Am. Intell. Prop. L. Ass'n, REPORT OF THE ECONOMIC SURVEY, 34 (2013)); *see also* Chris Neumeyer, *Managing Costs of Patent Litigation*, IP Watchdog (Feb. 5, 2013) ("[T]he cost of an average patent lawsuit, where $1 million to $25 million is at risk, is $1.6 million through the end of discovery and $2.8 million through final disposition") *available at* http://www.ipwatchdog.com/2013/02/05/managing-costs-of-patent-litigation/id=34808/.

[121] Michael R. Herman, note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1832 n. 41 (2011) (*citing* MARC GOODMAN ET AL., MORGAN STANLEY EQUITY RESEARCH, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS 9 (2004)).

payment settlements provide these same benefits and more. Of the cases that proceed to trial, the brand-name manufacturer often wins.[122] This means that a reverse payment settlement in those situations would have allowed a generic to come on the market sooner than they would have under the patent life. As discussed earlier, in the *Actavis* case, AndroGel is protected by a patent that expires in 2021.[123] Settlement in that case allowed the generic to be available in 2015, six years earlier than if the case went to trial and the patent was found to be valid.[124] It is important to keep in mind that these patents are presumed to be valid in the first place, and "a valid patent excludes all except its owner from the use of the protected process or product."[125]

Given the Hatch-Waxman Act's reallocation of litigation risk, reverse payment settlements can be efficient resolutions to the otherwise lengthy and complex trials in Paragraph IV disputes.[126] If reverse payment settlements are no longer an option to parties, in this time of uncertainty, cases are more likely to go to trial or generics might not file under Paragraph IV at all, opting for easier, cheaper, and less risky administrative alternatives which would cause generics to not be available until the patent was due to expire anyway. If cases proceed to trial more often, generic manufacturers' profits may not be able to cover the continuing legal bills and brand-name manufacturers may not have enough profits to feed back into the growing costs of research and development for new drugs.[127]

D. The Actavis *Ruling Could Hinder Settlement Incentives in Other Contexts*

The *Actavis* opinion has broader implications for the basic intersection of antitrust and patent law. Reverse payment settlements can

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[122] GREENE & STEADMAN, *supra* note 111, at 4.
[123] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).
[124] *Id.*
[125] United States v. Line Material Co., 333 U.S. 287, 308 (1948).
[126] *See* 21 U.S.C. § 355(j) (2006 & Supp. IV 2010); FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1300 (11th Cir. 2012) (describing patent litigation as an "infamously costly and notoriously unpredictable process"); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005) (stating that "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation"); Mullally, *supra* note 119, at 1125.
[127] *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 18 (2007) (statement of Billy Tauzin, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America).

also arise in the context of patent interference disputes.[128] Under a broad reading of *Actavis*, any settlement agreement between generics and brand-name manufacturers could be subject to antitrust challenge: a lower court could reasonably read the decision as indicating that any settlement by which the challenging generic obtained benefits that it otherwise would not have gained should be subject to antitrust evaluation. This could even affect licensing agreements, where terms and conditions, especially "field of use" restrictions, will face greater scrutiny from antitrust review.

On the beneficial side, the opinion fuels support for the FTC to increase antitrust scrutiny against "patent trolls," also known as patent assertion entities or non-practicing entities. Patent trolling is probably the hottest issue in intellectual property law today, and these entities have an adverse impact on competition and consumers.[129] The *Actavis* decision could mean that agreements with patent holders to acquire or pool their patents would be subject to antitrust review based on two parts of the Court's reasoning. First, that patent protection from antitrust challenge turns "in important part" on "the public interest in granting patent monopolies [that] exist[] only to the extent that the public is given a novel and useful invention in consideration for its grant."[130] Second, that antitrust laws might be violated by a cross licensing agreement among patent holders even if the patents are valid and enforceable if the patent holders had "curtailed the manufacture and supply of an unpatented product."[131] Because patent trolls are in its essence entities that do not practice their patents, this may be an important tool to curtail patent trolling by allowing the FTC to ask whether the patent troll, in acquiring rights to a patent, is furthering the public interest in the "novel and useful invention" or harming the public interest by curtailing "the manufacture and supply of an unpatented product."

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[128] *See, e.g.*, Medimmune, Inc. v. Genentech, Inc., 427 F.3d 958 (Fed. Cir. 2005), *rev'd on other grounds and remanded*, 549 U.S. 118 (2007).

[129] *See* David L. Schwartz & Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425, 426 (2014) (discussing the seismic change in patent litigation in large part due to the rise of "patent troll" cases).

[130] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2232 (2013) (quoting *United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963)) (internal quotations removed).

[131] *Id.* at 2233 (quoting *Standard Oil Co. v. United States*, 283 U.S. 163, 174 (1931)).

IV. JUDICIAL AND LEGISLATIVE PROPOSALS TO MOVE FORWARD

The Supreme Court basically punted and left it all to the lower courts to decide how to apply its considerations outlined in *Actavis* to the rule of reason test in order to identify whether a reverse payment settlement withstands antitrust scrutiny. This Note will explore how the lower courts should indeed apply the Court's rule of reason analysis by balancing both patent and antitrust values even though the real solution should come from Congress. Congress can institute legislation to help clean up the bad patents, which is the entire purpose of the Paragraph IV challenge in the first place. Furthermore, Congress should realign the incentive structure in the Hatch-Waxman Act itself in order to close the unintentional loophole.

A. How Lower Courts Should Apply the Rule of Reason Test

The lower courts are now burdened with the task of analyzing the specific facts of each case to determine whether the proposed reverse payment settlement is permissible under the Supreme Court's rule of reason analysis. This will be a demanding process, requiring the fact-finder to weigh the anticompetitive effects against the procompetitive justifications. As explained in the previous section, this leeway will generate inconsistent decisions and create uncertainty for those parties trying to craft a reverse payment settlement, or potentially any settlement in any patent litigation case, that can withstand antitrust scrutiny.

This Note argues that lower courts should focus on applying a consistent approach in analyzing reverse payment settlements by implementing a stepwise approach in a "structured rule of reason" test. This would be consistent with the burden-shifting approach referenced by the Supreme Court in *California Dental*.[132] Under this analysis, the FTC would have the burden of establishing a prima facie case of anticompetitive effect. Once proven, the burden would shift to the defendants to establish cognizable procompetitive justifications. Assuming the defendant offered procompetitive justifications, the FTC would then have the burden of attacking such justifications as pre-textual or a sham. If the FTC cannot do so, the FTC must show that the anticompetitive effects outweigh the procompetitive benefits. The FTC can successfully establish that the justifications are pre-textual or a sham without having to introduce evidence of the relevant market and market shares. But, in most instances, proving anticompetitive effects will require the FTC to show a relevant antitrust market and market shares.

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[132] California Dental Ass'n v. FTC, 526 U.S. 756 (1999).

The anticompetitive effects can be proven by direct evidence of the settlement's purpose, but, of course, that would be very difficult to do in practice. In order to prove anticompetitive effects by circumstantial evidence, the *Actavis* Court provided examples to provide the lower courts some guidance, including the size of the reverse payment, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.[133] The Court further suggested that the two most important factors from the above list are the size of the payment and its justifications.[134] In the Court's view, "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects."[135] An example would be where the brand-name manufacturer pays a generic "a sum even larger than what the generic would gain in profits if it won the [infringement] litigation and entered the market."[136] Such a payment "cannot in every case be supported by traditional settlement considerations" and, therefore, provides "strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[137]

This stepwise, burden-shifting approach has support from the courts already.[138] Therefore, it would be easy to implement, easy for the parties to follow because of pre-existing case law, and produce more consistent results. District courts should apply this analysis as part of a process for approving the settlement of the patent case, and could employ a special master or invite the FTC to participate in the proceedings. Determining antitrust legality before a reverse payment settlement becomes effective promotes judicial efficiency by bringing the patent and antitrust issues into a single forum to be decided at the same time, which would provide additional incentive for both the brand-name and generic manufacturers to settle and avoid a costly, time-consuming trial.

B. Congress Should Step In to Filter the Murky Waters

Congress originally enacted Hatch-Waxman to promote the public welfare by encouraging prompt market entry of generic drugs and fair

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[133] *Actavis*, 133 S. Ct. at 2237.
[134] *Id.*
[135] *Id.*
[136] *Id.* at 2235.
[137] *Id.*
[138] *See* Polygram Holding, Inc. v. FTC, 416 F.3d 29, 36 (D.C. Cir. 2005); Agnew v. NCAA, 683 F.3d 328, 336 (7th Cir. 2012); *In re* Sulfuric Acid Antitrust Litig., 703 F.3d 1004, 1007–08 (7th Cir. 2012).

competition, but the Act, unintentionally, created the incentives for both brand-name and generic drug manufacturers to settle litigation through the reverse payment arrangement. Reverse payment settlements have been described as atypical settlements "that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme."[139] If this truly goes against Congress's underlying intent of the statute, then Congress must act in order to rectify the current misinterpretations of the statutory meaning and intent of the Hatch-Waxman Act.[140]

1. Prior Legislative (In)Action.

Congress has attempted to amend the Hatch-Waxman Act several times. Recently, the Protecting Consumer Access to Generic Drugs Act of 2012 was presented by Congressman Waxman and Congressman Rush "[t]o prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes."[141] Unfortunately, this bill does not differ meaningfully from past failed efforts to regulate reverse payment and, therefore, is susceptible to the same criticisms.[142] Congressional attempts to regulate reverse payment settlements have been unsuccessful due to the feared negative effects on generic manufacturers, including the significantly reduced incentives to file ANDA challenges under Hatch-Waxman.[143] Congress has yet to strike the appropriate balance between lowering costs of drugs for consumers and allowing for patent holders to settle cases within their rights of their patent. Each of the proposed legislation has focused on the short-term goal of reducing prices without really solving the underlying problem of reverse payment settlements because lawful reverse payments can actually reduce costs for consumers in the long run when dealing with stronger patents (as explained above) and avoid wasteful investment by innovator companies in litigation rather than innovation.

In order for Congress to successfully modify the Hatch-Waxman Act and its progenies, Congress must recreate the incentives for settlement

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[139] Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 84 (2009).
[140] *See* H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.
[141] Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012).
[142] *See* H.R. 3995; Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009); Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2007, H.R. 1902, 110th Cong. (2007).
[143] See H.R. 3995 §§ 2(c), 3 (2012).

for the brand-name and generic drug manufacturers. There are many different suggestions on how to do so, but Congress should focus on the following three aspects: (1) strengthening the patent system, (2) enhancing predictability of patent validity disputes; and (3) reinforcing the public policy of encouraging private settlements.

2. Creating Clarity by Cleaning Up Patents.

A patent should continue to be presumed valid in the absence of clear evidence proving otherwise. The prevalence of bad patents and the resulting uncertainty creates costly, drawn out patent litigation. Patents should be reviewed more closely at the outset, and the new changes with administrative proceedings under the America Invents Act[144] may help to review patent validity more efficiently and effectively.[145] Challenging the validity of patents through these new administrative review proceedings promises to be faster and less costly than litigation. The statute provides that the administrative courts issue a decision within a year of instituting the action and, in the majority of cases,[146] it appears that the board is on track to make a final determination of validity within about 18 months from the date the petition is filed.[147] Because of the compressed timeline and the structure of the proceedings, the total cost is estimated to fall in the range of thousands of dollars instead of millions.[148] Furthermore, challenging the validity of a bad patent in an administrative proceeding should have a

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[144] The America Invents Act was a huge shift in the patent world, changing our patent system from a first-to-invent system to match the rest of the world's first-to file system. The new patent system now rewards the inventor that first files for its patent instead of proving to have actually invented the innovation first. In addition, the Act puts forth new administrative procedures for examining the validity of a patent, including *ex parte* review, *inter partes* review, transitional program for covered business method patents and post grant review proceedings.

[145] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

[146] *Id.*

[147] *See* PATENT TRIAL AND APPEAL BOARD AIA PROGRESS STATISTICS (2014), *available at* http://www.uspto.gov/ip/boards/bpai/stats/aia_statistics_01_30_2014.pdf.

[148] According to a survey by the American Intellectual Property Law Association, a patent lawsuit where $1 million to $25 million is at risk will cost each party on average $1.7 million through the end of discovery and will cost each party on average $2.8 million through trial not including any damages awarded. *See* Am. Intell. Prop. L. Ass'n, REPORT OF THE ECONOMIC SURVEY (2013). In comparison, total costs for each party in an *inter partes* review are currently estimated at around $150,000 to $300,000. Susan Decker, *Google, NetApp Sidestep Courts to Combat Patent Claims*, Bloomberg (Oct. 14, 2013), *available at* http://www.bloomberg.com/news/2013-10-14/google-to-netapp-sidestep-courts-to-combat-patent-claims.html.

higher likelihood of success than challenging its validity in federal court. The USPTO uses a lower evidentiary standard when determining invalidity because a challenged patent at the USPTO is not presumed to be valid as it is in federal court.[149] Furthermore, the USPTO uses a broader interpretation of patent claims when assessing whether the invention was already known or obvious.[150] The use of these proceedings, especially *inter partes* review, has been popular for all of the stated reasons,[151] but it is too early to tell if these changes were successful, and the efficacy and effects of these proceedings should be evaluated in future publications.

In addition to the new administrative procedures, the FDA and USPTO could review the validity of patents when the patents are placed on the Orange Book[152] when the new drug is applying for FDA approval.[153] Alternatively, Congress could adopt the European system and eliminate the American patent linkage system of listing relevant patents on the Orange

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[149] The PTO uses a "preponderance of the evidence" standard for adjudicating patentability. An examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable. MPEP § 706.I.

[150] The PTO determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re* Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004). The rules of the PTO require that claims "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

[151] *See* Robert Siminski, *6 Reasons Inter Partes Review Was Popular In 2013*, LAW 360, Dec. 17, 2013, *available at* http://www.law360.com/articles/495709/6-reasons-inter-partes-review-was-popular-in-2013.

[152] The "Orange Book" is the commonly known name for FDA's publication, "Approved Drug Products With Therapeutic Equivalence Evaluations." This publication "identifies drug products approved on the basis of safety and effectiveness by the [FDA]" and lists all patents covering a new drug or the methods of using the drug. U.S. Food and Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, U.S. Dept. of Health and Human Servs. (Feb. 24, 2015), http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm.

[153] A pioneering drug manufacturer must obtain FDA approval for its new drug by submitting a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a), (b) (2012). As part of the NDA process, the manufacturer must report to the FDA all patents covering its drug or the methods of using the drug, "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1), (c)(2) (2012). The FDA lists all such patents in the "Orange Book."

Book, allowing generic manufacturers to launch "at risk" instead of having to jump through the Hatch-Waxman hoops.[154] This would allow the access to generic drugs throughout the litigation and incentivize only those generics that believe they will be successful at trial to launch. This could result in generics only attacking those brand-name drugs in which they believe the patents are weak. While these proposed solutions alone will not help solve the reverse payment settlement problem, it will create more clarity for patent litigation and clear up bad patents at the same time.

3. Aligning Incentives with Congressional Intent by Adjusting Exclusivities.

The other main underlying issue of reverse payments stems from the Act's 180 days generic exclusivity grant to the first generic manufacturer to file for FDA approval, regardless of whether or not that generic manufacturer succeeds in invalidating the patent or finding a way to avoid infringement.[155] This gives both brand-name and generic manufacturers the incentive to settle. The brand-name manufacturer buys off the first generic entrant, delaying its entry to the market, and prevents any other generics from entering the market until after the exclusivity period has expired.[156] Meanwhile, the generic manufacturer settles a risky patent suit and retains its valuable period of generic exclusivity, which is where the manufacturer can often make more than half of their total profits on a drug.[157] Essentially, both parties get to have their cake and eat it too at the expense of the consumers.

While Congress purposely gave the first-to-file generic 180 days of exclusivity in order to induce Paragraph IV challenges to clean up bad patents, perhaps Congress should adjust the exclusivity approval procedures. One suggestion is for generics to forfeit exclusivities if settlement is reached. Scholars have suggested that the first generic should only be entitled to the 180-day exclusivity period "if it successfully defeats the patent owner (for example, by invalidating the patent or by proving that it did not infringe that patent), obtains a settlement that permits entry

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[154] A recent study of litigation in the European Union revealed that even when disputes are few in number, they exert a strong chilling effect on generic entry as a result of the mere risk of interim injunctions, leading the authors to conclude the chilling effect of even a small number of proceedings "illustrates the strength of the link between patent-related exchanges and patent litigation." EUROPEAN COMM'N, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT 200–09 (2009).

[155] *See supra* Part I.A.2.

[156] *Id*.

[157] Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 BIOTECH. L. REP. 525, 525–26 (2006) (finding "[i]n general, most generic drug companies estimate that 60% to 80% of their potential profit for any one product is made during this exclusivity period").

without delay, or can enter the market without delay because the patent holder does not sue for infringement."[158] Another suggestion is for subsequent generic challengers who are ultimately successful in invalidating the brand-name's patents to obtain generic exclusivity. These suggestions have their issues, of course, but both paths give Congress a start to the discussion on how to provide incentives that are more in line with the original statutory intent.

Meanwhile, changes made to the patent system in the America Invents Act may also be alleviating the current problem. The post-grant review and *inter partes* review procedures seem to be gaining strides and utilization by second Paragraph IV challengers because the two procedures are much cheaper and quicker than traditional litigation.[159] Increased secondary generic challengers using the new post grant review and *inter partes* review procedures could break the logjam created by the first generic challenger's settlement. By having the patent invalidated through the administrative procedures, there would be no barrier to entry by any generic. As soon as the administrative court rules the patent invalid, the generic could launch with no risk of litigation. Perhaps we would not even need to shift the exclusivity incentives built into Hatch-Waxman at all. Nevertheless, we will have to wait to see the full extent of the results stemming from the America Invents Act.

CONCLUSION

> "[T]he logical method and form flatter that longing for certainty and for repose which is in every human mind. But certainty generally is illusion, and repose is not the destiny of man."[160] — Justice Oliver Wendell Holmes

The pharmaceutical companies, or rather their lawyers, desire certainty. After the Supreme Court's ruling in *FTC v. Actavis*, however, very little is certain. The lower courts have a significant task ahead of them—to agree on how to decide whether each individual reverse payment settlement violates antitrust laws. Until the legal landscape is made more certain by consistent case law set by all of the jurisdictions, pharmaceutical companies may not want to settle at all, or worse, generic drug manufacturers may find it too risky to challenge the brand-name manufacturers' patents. This would undermine the ability for generic drugs to enter the market as quickly as possible, the primary purpose behind the

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[158] Hemphill & Lemley, *supra* note 107, at 949.
[159] *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat 284 (2011).
[160] Oliver Wendell Holmes, Jr., *The Path of the Law*, 10 HARV. L. REV. 457, 465 (1897).

Hatch-Waxman Act. If Congress cannot legislate on the matter, which could provide ultimate clarity, perhaps the Supreme Court will need to rule on this issue again in the very near future.