BALANCING ACCESSIBILITY AND SUSTAINABILITY:

HOW TO ACHIEVE THE DUAL OBJECTIVES OF THE HATCH-WAXMAN ACT WHILE RESOLVING ANTITRUST ISSUES IN PHARMACEUTICAL PATENT SETTLEMENT CASES

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TABLE OF CONTENTS

I. INTRODUCTION

Brand-name pharmaceutical companies invent innovative medicines patients need. Due to the high cost associated with the research and development (R&D), the innovative medicines are expensive. To make the innovative medicines cheaper and more affordable to the public, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act,[1] to encourage the generic competition. Not only can the generic companies begin developing a generic version of a brand-name drug before the patent expires, they can also use safety and efficacy data in the brand-name company's original New Drug Application (NDA).[2] Furthermore, the Hatch-Waxman Act also gives an attractive incentive for generic drug companies to challenge brand-name drug companies' patents before the patent expiration.[3] As a result, patent challenges in the court are intensified. Like any other types of litigation, patent litigation between a brand-name drug company and a generic drug company often settles so that both parties can minimize risk of financial damages.

According to a study by the Federal Trade Commission (FTC) in 2002,[4] there are three types of settlement agreements between a brand-name pharmaceutical company and a generic company: (a) a license agreement, in which the generic company obtains a "non-exclusive, royalty-bearing license" to use the brand-name company's patent prior to the patent expiration; (b) a supply agreement, which allows the generic company to market the brand-name product as a generic product under the brand-name company's NDA instead of the generic company's Abbreviated New Drug Application (ANDA); and (c) an agreement involving a payment from the brand-name company to the generic company, which typically requires the generic company to delay launching its generic product.[5] In each of these cases, the failure of the first

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984); WENDY H. SCHACHT & JOHN R. THOMAS, CONGRESSIONAL RESEARCH SERVICE, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS (2004), *available at* http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-4052:1.

[2] FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY ii, 3–5 (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf [hereinafter FTC STUDY].

[3] *Id.* at 7, 57.

[4] *Id.* at 1.

[5] *Id.* at 28, 30–31.

generic applicant to launch its generic product would create a bottleneck that forestalls entry by other generic competitors. However, the anticompetitive effects of the three types of agreements have been treated differently by the FTC and commentators. Agreements of type (c) have been particularly scrutinized by the FTC and criticized by commentators.[6] More prominently, some type (c) agreements have caused the top federal legislators to conduct hearings on the anti-competitive effects of the agreements.[7]

An FTC study found that about half of the settlements are of type (c),[8] and a recent study showed the similar percentage of this type of settlement.[9] Because the payment is made by a patent holder to a patent challenger, it is often called "reverse payment."[10] Since the payment appears to serve the purpose of excluding the generic entry, the payment is also called "exit payment," "exclusion" payment, or other similar terms.[11] The

[6] *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557–59, 1561–62, 1570 (2006); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1752, 1755 (2003).

[7] *See*, *e.g.*, *Deals Delaying Market Entries Blasted*, CHAIN DRUG REV., June 26, 2006, at 254, *available at* 2006 WLNR 11920107 (stating that Sen. Charles Schumer (D-N.Y.) and Rep. Henry Waxman (D-Cal.) asked the Generic Pharmaceutical Association (GPhA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) to oppose agreements to delay market entry for generic medications); *Senate Committee Ponders Generic Drug Maze*, WORLD GENERIC MARKETS, Aug. 7, 2006, *available at* 2006 WLNR 13623849; *Senate to Weigh Generics Policy (Special Report)*, CHAIN DRUG REV., Feb. 19, 2007, at 72, *available at* 2007 WLNR 3830225; Jon Leibowitz, Comm'r, Oral Statement at the Hearing of the Senate Judiciary Comm. 1–3 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf.

[8] FTC STUDY, *supra* note 2, at 17.

[9] *FTC Reports on Pharmaceutical Company Settlements as Senate Introduces Payoffs Bill*, WORLD GENERIC MARKETS, Jan. 30, 2007, *available at* 2007 WLNR 1792133 (reporting twenty-eight settlements of patent litigation between a brand and a generic company received by the FTC in FY 2006, fourteen of which included "some form of compensation from the branded company and restrictions on the generic firm's ability to enter the market with its product").

[10] JOHN R. THOMAS, CONGRESSIONAL RESEARCH SERVICE, PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS: IMPLICATIONS FOR COMPETITION AND INNOVATION 1–2 (2006), *available at* http://www.ipmall.info/hosted_resources/crs/RL33717-061103.pdf (quoting Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789, 1795–96 (2003)).

[11] THOMAS, *supra* note 10, at 1 (quoting Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309 (11th Cir. 2003); Herbert Hovenkamp et al.,

payments range from $1.75 million to $132.5 million, depending on the sales of drugs and length of delay.[12]

The court decisions on the legality of these settlements have not been consistent.[13] While the Court of Appeals for the Sixth Circuit held that a settlement agreement involving a reverse payment is *per se* invalid under the antitrust law,[14] the Eleventh and Second Circuits declined to categorically condemn the existence of a reverse payment in a pharmaceutical patent settlement as a *per se* antitrust violation.[15] The antitrust implications of the patent settlements involving reverse payments have been hotly debated among commentators. Some argue that these reverse payments make the settlements anticompetitive, because without the payments, the consumers might be able to enjoy early generic entry,[16] and therefore, propose that the patent settlements involving reverse payments should be barred as "*per se* illegal."[17] Some propose presumptive, but rebuttable, illegality.[18] Others suggest that the settlements should be analyzed by a balanced approach.[19] In particular, several articles and notes seem to suggest that the size of a reverse payment is an indication of how questionable the validity of the underlying patent is, and therefore, is the key factor to determining the legality of a settlement.[20]

Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments, 88 MINN. L. REV. 712, 714–15 (2004)).

12 FTC STUDY, *supra* note 2, at 31–32.

13 THOMAS, *supra* note 10, at 2, 12–13.

14 *Id.* at 13.

15 *Id.* at 13, 15–20.

16 *E.g.*, Hemphill, *supra* note 6, at 1553, 1557, 1564; Hovenkamp et al., *supra* note 6, at 1720–21, 1724, 1763.

17 *See, e.g.*, Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1339, 1342, 1348–49 (2001); Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, 16 ANTITRUST 53, 54 (2002).

18 Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1071, 1090–94 (2004); Cotter, *supra* note 10, at 1793–94.

19 *See, e.g.*, Kelly A. Gidcumb, *Rethinking the Hatch-Waxman Act: Balancing Both Sides of the Equation*, 6 WAKE FOREST INTELL. PROP. L.J. 23, 30, 43 (2006); Douglas A. Robinson, Note, *Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?* 81 WASH. U. L.Q. 829, 856–57 (2003); *see also* Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 308 (1987).

20 *E.g.*, Hovenkamp et al., *supra* note 6, at 1758–59; Carl Shapiro,

This Article argues that a patent allows a legitimate monopoly within the statutorily prescribed timeframe. Whether a patent settlement constitutes "anticompetitive horizontal restraints," therefore violating Section One of the Sherman Antitrust Act,[21] is a complicated issue. The antitrust implications of any settlement agreement should be analyzed within the reach of the patent law in the context of the Hatch-Waxman Act. This Article favors the Eleventh and Second Circuits' approaches and proposes that the mere existence of a reverse payment should not be used to determine against the legality of a settlement agreement; nor does the size of a payment have any legal bearing on the validity of the patent in dispute. A "*per se* illegal" rule would have ignored the innovator's exclusionary rights under the patent law. If the size of a payment is considered in the analysis of the antitrust issues, the total sales of the drug product the brand-name drug company would be able to generate should be used as the basis for the analysis. Other factors, such as the length of the remaining term of the patent and business risks associated with the patent litigation, should also be considered.

Previous articles that condemned the settlements involving a reverse payment as *per se* violation of antitrust law were based upon some questionable presumptions. They include: (1) that without a generic entry, a patented drug product would lack competition; (2) a generic entry competes with the brand-name drug on a leveled ground in the marketplace; and (3) the earlier the generics enter the market, the more the public would benefit. This Article intends to help clear up these misconceptions by giving a more realistic picture of the competition in the pharmaceutical industry in the Hatch-Waxman context. To maintain the sustainability of the pharmaceutical industry, this Article urges lawmakers, antitrust agencies, and courts to adopt a more balanced approach in resolving the complex litigation created by the Hatch-Waxman Act.

In this Article, section II will introduce the statutory framework of the Hatch-Waxman Act of 1984 and its 2003 Amendments, the Medicare Act. Section III will analyze the impact of the Hatch-Waxman Act and its 2003 Amendments on the pharmaceutical industry. Section IV will introduce basic tenets of the antitrust law and the patent law. Section V will

Antitrust Analysis of Patent Settlements Between Rivals, ANTITRUST 70, 72 (2003), *available at* http://faculty.haas.berkeley.edu/shapiro/settle_am.pdf.

[21] 15 U.S.C. § 1 (2004).

discuss and comment on judicial treatments of some patent settlement agreements between the brand-name and the generic pharmaceutical companies. Section VI will discuss how to balance different interests by providing some practical considerations in the competitive market of the pharmaceutical industry. Section VII will render some policy considerations on how to reduce clashes between the antitrust law and the patent law in the Hatch-Waxman context, in particular how to ensure a sustainable innovative cycle of the drug development to benefit the public.

II. THE HATCH-WAXMAN ACT AND ITS STATUTORY FRAMEWORK

A. Hatch-Waxman Act of 1984

In 1984, Congress enacted the Hatch-Waxman Act to streamline the process for the FDA in approving generic versions of brand-name drugs.[22] The Act allows a generic drug company to prepare and file an Abbreviated New Drug Application (ANDA) by relying on the data in the original NDA filed by a brand-name drug company before the expiration of the latter's patent.[23] Because a generic drug company does not incur the expenses associated with the lengthy, expensive clinical trials and safety studies, as required of an NDA filer, generic drugs can be sold at lower prices than their brand-name counterparts.[24]

A generic drug company starts developing a generic by selecting a brand-name drug from the Approved Drug Products with Therapeutic Equivalence Determinations, also known as the "Orange Book" of the FDA, which lists all approved drugs and the corresponding patent information.[25] Pursuant to the safe harbor provision in the Patent Act, a generic drug company can

[22] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 15 U.S.C. §§ 68b–68c (1984), 70b; 21 U.S.C. §§ 301, 355, 360cc (2007); 28 U.S.C. § 2201(1993), and 35 U.S.C. §§ 156, 271, 282 (2003)).

[23] FTC STUDY, *supra* note 2, at 5.

[24] *Id.* at 5, 9.

[25] FDA, CENTER FOR DRUG EVALUATION AND RESEARCH, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (28th ed. 2008), *available at* http://www.fda.gov/cder/orange/obannual.pdf; 21 U.S.C. § 355(j)(7)(A)(i)(I) (2007); s*ee also* Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 196–97, 200 (1999); Brian J. Malkin, *FDA's Role in Administering the Hatch-Waxman Act*, 54 FOOD & DRUG L.J. 211, 211–12 (1999).

develop a generic version of a branded drug protected by the NDA holder's patent without worrying about infringement.[26] In an ANDA application, the generic drug company can use the safety and efficacy data in the original NDA, and only needs to generate data to demonstrate that the generic version is "bioequivalent" to the branded drug.[27] However, the generic company must submit a certification "with respect to each patent that claims the listed drug."[28] The statute provides four grounds upon which the certification can be made: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug" for which approval is sought.[29] The four types of certifications are commonly known as the paragraph I, II, III, or IV certification, respectively.[30]

An ANDA with a certification under paragraph I, II, or III does not implicate any patent infringement and, therefore, is usually approvable immediately if all of the relevant scientific and regulatory requirements are met.[31] But the generics cannot be sold until the brand-name patent expires in the case of the paragraph III certification.[32] However, the filing of an ANDA under the paragraph IV certification automatically constitutes an act of patent infringement because the generic company seeks approval from the FDA to begin selling the drug before the

[26] 35 U.S.C. § 271(e)(1) (2003); *see also* Brian D. Coggio & F. Dominic Cerrito, *The Safe Harbor Provision of the Hatch-Waxman Act: Present Scope, New Possibilities, and International Considerations*, 57 FOOD & DRUG L.J. 161, 162–63 (2002).

[27] 21 U.S.C. § 355(j)(2)(A)(iv) (2007). A generic drug is considered "bioequivalent" to a listed drug if, under similar experimental conditions,

(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 . . . or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug . . . 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.

§ 355(j)(8)(B).

[28] 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.53(f) (2004).

[29] 21 U.S.C. § 355(j)(2)(A)(vii).

[30] Jacob S. Wharton, *"Orange Book" Listing of Patents under the Hatch-Waxman Act*, 47 ST. LOUIS U. L.J. 1027, 1033 (2003).

[31] 21 U.S.C. § 355(j)(5)(B)(i)–(iii); Wharton, *supra* note 30, at 1033.

[32] Wharton, *supra* note 30, at 1033.

expiration of the NDA holder's patent.[33] Thus, the NDA holder has the right to sue for the infringement in the United States District Court. The statute gives the patent holder a window of forty-five days to start the infringement action following the date on which an ANDA is filed.[34] The FDA study showed that NDA holders had filed patent infringement action against the ANDA filers seventy-two percent of the time within the forty-five day window following the ANDA filers' paragraph IV certifications.[35]

Upon filing a patent infringement action, an NDA holder gets an automatic thirty-month stay of the FDA approval on the ANDA under the Hatch-Waxman Act.[36] Despite the lawsuit, the FDA's evaluation of the ANDA continues to proceed.[37] However, the final approval to market the generic drug does not become effective until either (1) the patent expires, or (2) a court renders a decision on the infringement case in favor of the ANDA applicant.[38]

A strong incentive the Hatch-Waxman Act provides for a generic company to become the first ANDA filer under the paragraph IV certification is the potential 180-day market exclusivity.[39] Under the Act, the first ANDA filer to obtain a paragraph IV certification, i.e., proving either invalidity or non-infringement of the patent, would be awarded a 180-day exclusivity period, during which only the first ANDA applicant can sell a generic version of the listed drug.[40] "[S]ubsequent ANDA applications cannot be approved for a period of 180 days from the earlier of (i) the date of a court decision holding the patent invalid or not infringed (the so-called 'court decision trigger'); or (ii) the date the [first ANDA applicant] begins commercial marketing of the [generic] drug (the so-called 'commercial marketing trigger')."[41]

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33 35 U.S.C. § 271(e)(2) (2003); Wharton, *supra* note 30 at 1033–34.

34 21 U.S.C.A. § 355(j)(5)(B)(iii).

35 FTC STUDY, *supra* note 2, at 14.

36 21 U.S.C. § 355(j)(5)(B)(iii).

37 John Fazzio, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property and Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POL'Y 1, 10 (2006).

38 § 355(j)(5)(B)(iii).

39 § 355(j)(5)(B)(iv); Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287, 288 (2004).

40 21 U.S.C. § 355(j)(5)(B)(iv).

41 M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON

During the 180-day market exclusivity period, the first ANDA applicant enjoys a market duopoly along with the NDA holder; therefore, the market exclusivity is a "highly lucrative" reward for the generic drug company.[42]

Although the Hatch-Waxman Act was enacted in 1984, "[t]he FDA did not implement finalized regulations governing the 180-day exclusivity period provisions until 1994."[43] According to the FDA regulation, a generic drug company is entitled to the 180-day exclusivity only when it is the first to file an ANDA under the paragraph IV certification and successfully defends the patent infringement suit.[44] "In addition to the successful defense requirement, the 1994 regulation" also required the ANDA filer to be involved in the patent infringement lawsuit.[45] Both the "successful defense" and involvement in the "patent infringement suit" requirements were invalidated by the court in *Mova Pharm. Corp. v. Shalala.*[46] In December 1994, Mova Pharmaceutical Corporation filed an ANDA with a paragraph IV certification for micronized glyburide, a drug to treat type II diabetes.[47] The NDA/patent holder, Pharmacia & Upjohn Co., sued within the forty-five day window.[48] The Court of Appeals for the District of Columbia Circuit held that the 180-day exclusivity period was not contingent on the existence of litigation with the NDA holder, and that under 21 C.F.R. § 314.107, the first ANDA filer is entitled to the 180-day exclusivity period regardless of the outcome of the patent infringement suit against the ANDA filer.[49]

L. REV. 359, 386 (2002).

[42] Reid F. Herlihy, Note, *The Federal Circuit's Interpretation of the Hatch-Waxman Act: Allowing Generics to Induce Infringement*, 15 FED. CIR. B.J. 119, 136 (2005); *see also* Sarah M. Yoho, Note, *Reformation of the Hatch-Waxman Act, an Unnecessary Resolution*, 27 NOVA L. REV. 527, 534–35 (2002).

[43] Brian Porter, Comment, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177, 195 (2005); *see also* Lietzan, *supra* note 39, at 294.

[44] 21 C.F.R. § 314.107(c)(1) (2000); Porter, *supra* note 43, at 195.

[45] Porter, *supra* note 43, at 195–96; *see also* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,352–53 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314).

[46] Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066–74 (D.C. Cir. 1998); *see also* Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1205 (D.C. Cir. 1998).

[47] *Mova Pharm. Corp.*, 140 F.3d at 1065.

[48] *Id.* at 1062.

[49] *Id.* at 1066–74; 21 C.F.R. § 314.107 governs the award of 180-day

Under *Mova Pharm. Corp.*, the first ANDA filer's failure to challenge the patent or to launch its product would not trigger the clock of the exclusivity period.[50] Once the first generic company files an ANDA under the paragraph IV certification, it owns the right to a 180-day exclusivity period while the patent infringement suit is pending in the court.[51] To trigger the clock of the 180-day exclusivity period, a second ANDA filer must win its own patent infringement suit with the NDA holder before the first ANDA filer.[52] The first ANDA filer's 180-day market exclusivity would be preserved even after a settlement agreement is reached between the ANDA filer with the NDA holder.[53] Consequently, a settlement agreement between an NDA holder and the first ANDA filer, in which the latter agrees not to launch its product until a future date, would effectively prevent all other generic entry.[54]

B. The Medicare Act of 2003

The Hatch-Waxman Act of 1984 allows an automatic thirty-

market exclusivity and reads in relevant part,

(c) Subsequent abbreviated new drug application submission. (1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier: (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

21 C.F.R. § 314.107(c)(1) (2000).

[50] *Mova Pharm. Corp.*, 140 F.3d at 1067.

[51] *See* Lietzan, *supra* note 39, at 290–91.

[52] Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410, at *2 (4th Cir. Apr. 3, 1998); *see also* Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003, 1005 n.3 (D.C. Cir. 1999) (requiring the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). For a full discussion of *Granutec*, see Colman B. Ragan, *Saving the Lives of Drugs: Why Procedural Amendments in Hatch-Waxman and Certification of Markman Hearings for Interlocutory Appeal Will Help Lower Drug Prices*, 13 FED. CIR. B.J. 411, 419–22 (2003).

[53] Lietzan, *supra* note 39, at 305–06.

[54] *See id.* at 289. The 180-day exclusivity period does not begin until the first generic applicant's commencement of marketing the generic product or a final judicial determination favorable to the ANDA applicant. *Id.* at 288–89. If there is a settlement, no final judicial determination has taken place.

month stay of the FDA approval on an ANDA based on the mere filing of a patent infringement action by the brand-name drug company.[55] The duration of the stay may be modified by the court if the court finds that either party has "failed to reasonably cooperate in expediting the action."[56] These provisions were intended to give an NDA holder "time to vindicate its patent in court before the generic competitor is allowed entry into the market."[57] Under the Act, an NDA holder could obtain multiple thirty-month stays by strategically listing its patents related to a drug product in the Orange Book.[58] A new patent listed in the Orange Book could enable the NDA holder to bring a new infringement suit against the ANDA filer and to cause further delay of the approval, even if the patent turned out to be "invalid or inapplicable."[59] Thus, the Act created a substantial incentive for an NDA holder to list its patents in the Orange Book, even if the validity of the patents is questionable.[60]

In response to the FTC study showing that brand-name drug companies had been abusing the thirty-month stay provision to delay generic entry, the FDA amended its rules in early 2003 to allow only one thirty-month stay.[61] Subsequently, Congress codified the FDA rules in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Act") to eliminate multiple thirty-month stays.[62]

Besides limiting the number of automatic thirty-month stays to only one, [63] the Medicare Act of 2003 also included several other

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55 21 U.S.C. § 355(j)(5)(B)(iii) (2007); *see also* Yoho, *supra* note 42, at 534.

56 21 U.S.C. § 355(j)(5)(B)(iii); *see also* Yoho, *supra* note 42, at 534.

57 Morse, *supra* note 41, at 385 (quoting Mova Pharm. Corp., 140 F.3d at 1064).

58 *Id.* at 364–65.

59 *See* William Shieber, *One View from the Road: State Antitrust Enforcement in Pharmaceutical Cases*, 18 ANTITRUST 74, 75 (2004); Porter, *supra* note 43, at 191.

60 Porter, *supra* note 43, at 190.

61 *Id.* at 190–91; Richard J. Smith, *Hatch-Waxman 2003—Patented v. Generic Drugs: Regulatory, Legislative and Judicial Developments*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 695, 701–02 (2004).

62 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101, 117 Stat 2066, 2071 (codified as amended at 21 U.S.C. § 355(j) (2007)) (modifying § 505(j) of the Federal Food, Drug, and Cosmetic Act); *see also* Robert Pear & Robin Toner, *Senate Votes to Give Consumers Faster Access to Generic Drugs, Amending Medicare Bill*, N.Y. TIMES, June 20, 2003, at A18, *available at* 2003 WLNR 5668235.

63 21 U.S.C. § 355(c)(3)(C)(i) (2007); SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686, 691 n.3 (E.D. Pa. 2004); Porter, *supra* note 43, at 191.

important modifications to the Hatch-Waxman Act of 1984. Of particular importance in the Medicare Act of 2003 are the modified provisions governing the 180-day market exclusivity period.[64] Under the new provisions, the 180-day exclusivity period is forfeited if the first ANDA filer fails to market the generic version by the later of: (1) seventy-five days after the effective approval of its application, or thirty months after it was submitted, whichever is earlier; or (2) seventy-five days after the date on which a court decision has held that the NDA holder's patent is invalid or is not being infringed upon, a settlement has been approved by the court, or the NDA holder has withdrawn its patent information.[65]

The first ANDA applicant also forfeits the 180-day exclusivity period if it: (1) "withdraws its application"; (2) "withdraws its paragraph IV certification"; (3) "does not receive [the] approval of its ANDA within thirty months after [the ANDA] was filed"; or (4) "enters into an agreement with another party, such as the patent holder," and the agreement is found by the FTC or a court to be in violation of the federal antitrust laws.[66] In forfeiture provision (4), "Congress sought to prevent . . . anti-competitive agreements by employing FTC scrutiny."[67] The parties that reach an "agreement involving the 180-day exclusivity period or the sale or marketing of a brand name or generic drug . . . must file the agreement with the FTC and the Attorney General within ten business days of the agreement's execution."[68] The exclusivity period, however, would be forfeited if the FTC determines that the settlement agreement has violated the federal antitrust laws.[69] "[B]y expanding the forfeiture provisions in the Medicare Act of 2003, Congress intended to prevent the practice of 'parking' the exclusivity period and 'force generic [drug companies] to market [generic drugs] promptly.'"[70]

The Medicare Act of 2003 also allows a generic drug company

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64 21 U.S.C. § 355(j)(5)(B)(iv); Teva Pharm. Indus. v. FDA, 355 F. Supp. 2d 111, 114 n.5 (D.D.C. 2004); Porter, *supra* note 43, at 191.

65 21 U.S.C. § 355(j)(5)(D).

66 Porter, *supra* note 43, at 193–94; 21 U.S.C. § 355(j)(5)(D); Lietzan, *supra* note 39, at 289.

67 Porter, *supra* note 43, at 194; Diane Green-Kelly, *FTC, Split Circuit Courts Raise Questions about Legality of Pharmaceutical Patent Suit Settlements*, MONDAQ, May 14, 2004, *available at* 2004 WLNR 12288800.

68 Porter, *supra* note 43, at 194.

69 *Id.*, *see also* 21 U.S.C. § 355(j)(5)(D(i)(V).

70 Porter, *supra* note 43, at 194 (quoting Lietzan, *supra* note 39, at 313–14).

to bring an action in federal courts to seek a declaratory judgment that the patent either is invalid or will not be infringed by the generic version, if the NDA holder brings a timely patent infringement suit.[71] In addition, the generic drug company may also bring a counterclaim requesting the delisting of a patent from the Orange Book.[72] Although a generic drug company can bring a counterclaim for delisting of the patent only when it is sued for patent infringement,[73] instead of bringing the claim as an independent cause of action, this provision could help the generic drug company "circumvent the need to confront the presumption of validity that a patent enjoys."[74] If successful on the counterclaim, the generic drug company may get the thirty-month stay lifted, and therefore, clear its way towards the approval of its ANDA by the FDA.[75] Thus, the addition of the counterclaim and declaratory judgment provisions in the Medicare Act enables generic drug companies to challenge the listed patents more effectively and to obtain faster approval of their ANDAs with a paragraph IV certification.[76]

III. IMPACT OF THE HATCH-WAXMAN ACT

The Hatch-Waxman Act was enacted to serve "two seemingly contradictory objectives": first, to make generic drugs more accessible and affordable to consumers; second, to preserve "adequate incentives to invest in the development of new drugs."[77] The success of the Act in serving the first objective is phenomenal in light of the fast-growing market share of generic drug companies and the resultant savings by consumers.[78]

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71 21 U.S.C. § 355(j)(5)(C)(i); Teva Pharm. U.S.A., Inc. v. Pfizer Inc., 395 F.3d 1324, 1329 (Fed. Cir. 2005).

72 21 U.S.C. § 355(j)(5)(C)(ii).

73 *Id.*

74 Mark Feldman, *Medicare Improvement Act of 2003–Much More than Just a Prescription Plan*, MONDAQ, Apr. 30, 2004, *available at* 2004 WLNR 12287822.

75 *Id.*; Porter, *supra* note 43, at 195.

76 Porter, *supra* note 43, at 195; Feldman, *supra* note 74.

77 Daniel Goldberg, *Cornering the Market in a Post-9/11 World: The Future of Horizontal Restraints*, 36 J. MARSHALL L. REV. 557, 560 (2003) (quoting Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have they Outlived their Usefulness?*, 39 IDEA 389, 389 (1999)). "[T]he two goals of the Hatch-Waxman Act are at the very least mutually inconsistent and are possibly mutually exclusive." *Id.* at 576.

78 *See* Melissa K. Davis, *Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357, 365 (1995) (stating that the market share of generic drug companies increased from eight

However, the success in serving the second objective has been controversial at best.

A. Pharmaceutical Market before the Hatch-Waxman Act

Before the Hatch-Waxman Act of 1984, the brand-name pharmaceutical companies had enjoyed virtually no competition from the generic drug companies. The brand-name drug market monopoly could last several years after the patent expiration, owing to the high regulatory barriers for generics to enter the market.

Under the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938,[79] drugs were approved based on safety only.[80] "[F]or drugs approved prior to 1962, generic versions could be approved with a 'paper' new drug application (NDA) . . . [that] was based solely on published scientific or medical literature" that demonstrated the safety of the compound.[81] Triggered by the safety problem of Thalidomide associated with infants, Congress amended the FDCA in 1962.[82] The 1962 amendments to the FDCA required for the first time that pharmaceutical companies prove the efficacy of a new drug through tests on humans, commonly called "clinical trials," when submitting an NDA to the FDA.[83] Generic drug companies seeking to market a generic version of a branded drug were subject to the same requirements, i.e., proving both safety and efficacy.[84] Furthermore, generic drug companies could not begin testing or seek regulatory approval for their generic versions until after the expiration of the patents covering the branded drug products,[85] which would unavoidably delay the

percent in 1984 to thirty-three percent in 1989 and that "switching from a brand-name drug to a generic drug results in a savings of between thirty and fifty percent").

79 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq.).

80 Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

81 *Id.*

82 *Id.*

83 Drug Amendments of 1962, Pub. L. 87-781, § 102(d), 76 Stat. 780, 781 (1962) (codified as amended at 21 U.S.C. §§ 321, 331–32, 348, 351–53, 355, 357, 372, 374, 376, 381).

84 *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864 (Fed. Cir. 1984).

85 *Id.* at 862–65 (holding that mere use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the patent period is an act of patent infringement—subsequently superseded by the Hatch-Waxman Act).

actual marketing activities by several years.[86] As a result, by 1984, more than 150 brand-name drugs still enjoyed the market exclusivity without a generic rival, even after the expiration of the underlying patents.[87]

B. The Pharmaceutical Market after the Hatch-Waxman Act

The Hatch-Waxman Act changed the landscape of the pharmaceutical industry dramatically. As described succinctly by Gongola, "[g]enerics flourish as a result of the Hatch-Waxman Act."[88] When the Act took effect, "generics flooded the FDA with 800 applications in the first seven months."[89] Today, generic copies are available almost as soon as, if not before, an innovator's patent expires.[90] Since 1984, the generic industry's share in the prescription drug market has jumped from less than twenty percent to almost fifty percent in 2003.[91] "[O]f the

[86] *See, e.g.*, Janet A. Gongola, Note, *Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787, 816 (2003) (citing *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 51 (2001), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_house_hearings&docid=f:73735.pdf (statement of Dr. Gregory Glover on behalf of Pharmaceutical Researchers and Manufacturers of America)).

[87] FTC STUDY, *supra* note 2, at 4; Mossinghoff, *supra* note 80, at 187; *see also* NAT'L ACAD. OF ENG'G, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 79–80 (National Academy Press 1983), *available at* www.nap.edu/openbook/0309033969/html/79.html (monitoring the trend in decreasing life spans of effective drug patents from 1966 to 1981).

[88] Gongola, *supra* note 86, at 816.

[89] *Id.*; Sheryl Gay Stolberg & Jeff Gerth, *How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, *available at* http://www.nytimes.com/library/national/science/health/072300hth-generic-drugs.html.

[90] *See* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 325 (2000) (stating "[t]oday, nearly 100% of the top-selling drugs with expired patents have generic versions available, versus only thirty-six percent in 1983," and that "the generic share of prescription drug volume has increased by almost 150% since enactment of the Hatch-Waxman Act in 1984").

[91] Chris Adams & Gardiner Harris, *Drug Makers Face Battle to Preserve Patent Extensions*, WALL ST. J., Mar. 19, 2002, at A24; Goldberg, *supra* note 77, at 581 (stating "market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled in [sic] the last decade, from approximately [nineteen] percent to [forty-three] percent" (quoting Greater Access to Affordable Pharmaceuticals Act of 2002, S. 812, 107th Cong. § 102(a)(7) (2002))).

approximately 10,000 brand name prescription[] drugs available, 9,000 have generic equivalents."[92] The Congress Budget Office (CBO) studied twenty-one brand-name drugs that faced competition from generic drugs between 1991 and 1993.[93] "For seven of those drugs . . . generics had gained [sixty-five] percent or more of the innovator's market by 1994."[94] CBO's data indicates that the market share of generic drugs in the "total quantity of prescriptions sold for multiple-source drugs" increased from around thirteen percent in 1980 to fifty-eight percent in 1994.[95] Although a handful of patent lawsuits have occupied a majority of press coverage due to the settlements involving "reverse payments," those cases often belie the true picture of the pharmaceutical industry.[96] Since the Hatch-Waxman Act took effect in 1984, "[o]f the 8,000 drugs that have come off patent . . . [ninety-four percent] moved from brand-name to generic without a patent dispute."[97] As a result, pharmacists are filling over one billion prescriptions with generic drugs each year, and the generic companies are increasingly sharing a large portion of profits with the brand-name drug companies.[98]

Along with the generic prosperity, brand-name pharmaceutical companies are facing an increasing number of patent challenges. The Act allows generic drug companies to start developing generic versions of brand-name drugs many years before the NDA holders' patents expire, often soon after the brand-name drugs start to enter market.[99] The 180-day exclusivity associated

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92 Gongola, *supra* note 86, at 816 (quoting Marjorie Wertz, *Consumers Question Generic Drugs; Doctor Knows Best*, PITTSBURGH TRIB.-REV., Feb. 4, 2002, *available at* http://www.pittsburghlive.com/x/tribune-review/health/s_15624.html).

93 CONG. BUDGET OFFICE, A CBO STUDY: HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xiii (July 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf [hereinafter CBO STUDY].

94 *Id.* at 28.

95 *Id.* at 37.

96 *See, e.g.*, Posting of Sheppard Mullin to Antitrust Law Blog, *available at* http://www.antitrustlawblog.com/article-reverse-payment-patent-settlements-the-second-circuit-speaks-out.html (Dec. 7, 2005) (offering examples of press attention to a few federal cases regarding reverse patent settlements).

97 Herlihy, *supra* note 42, at 135 (quoting Yoho, *supra* note 42, at 549 (quoting Julie Appleby & Jayne O'Donnell, *Consumers Pay as Drug Firms Fight Over Generics*, USA TODAY, June 5, 2002, at 2A, *available at* http://www.usatoday.com/money/health/2002-06-06-generic-drugs.htm)).

98 Gongola, *supra* note 86, at 816; Wertz, *supra* note 92.

99 *See* 35 U.S.C. § 271(e)(1) (2003); *see also* Coggio & Cerrito, *supra* note

with an ANDA with paragraph IV certification is a tempting financial incentive that has enticed generic drug companies to race to the FDA to become first ANDA filers, and to "either commercially market a generic product or receive a favorable court decision in a patent infringement action."[100]

The generic companies that lose the race to become the first ANDA filers also have incentives to become subsequent ANDA filers because any favorable court ruling would trigger the 180-day exclusivity period.[101] In the event that the second ANDA filer succeeds in the patent infringement suit ahead of the first ANDA filer, the exclusivity period starts to run and the first filer would unlikely be able to use it, thus creating an incentive for the first filer to sell its position with regard to the infringement challenge.[102] This dilemma, resulting from the decision in *Granutec, Inc. v. Shalala*,[103] "created a virtual race among subsequent generic filers to secure a final judgment."[104] Therefore, "multiple challenges to the same patent have become commonplace."[105] "Three, four, or sometimes five generics may line up to challenge patents on blockbuster drugs, even though only the first generic to challenge is eligible for the exclusivity."[106] Although steps necessary to prepare an ANDA do not constitute infringement of an NDA holder's patent under the Hatch-Waxman Act, the actual filing of an ANDA with a paragraph IV certification is deemed a statutory act of patent infringement.[107] Therefore, the number of lawsuits between

26, at 161–62.

100 Gongola, *supra* note 86, at 820.

101 *Id.* at 820–21.

102 Fazzio, *supra* note 37, at 12–13.

103 Granutec, Inc. v. Shalala, No. 97-1873, 1998 WL 153410, at *6–7 (4th Cir. Apr. 3, 1998); *see also* Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003, 1005 n.3, 1338 (D.C. Cir. 1999) (requiring the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period).

104 Fazzio, *supra* note 37, at 12; *see also* FTC STUDY, *supra* note 2, at 35–37, 39 (detailing results where first and second applicants either reached agreements or settled with the brand-name company with regard to the 180-day exclusivity period).

105 Engelberg, *supra* note 77, at 416; *see also* Gongola, *supra* note 86, at 820.

106 Gongola, *supra* note 86, at 820 (citing *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals*, *supra* note 86, at 14 (statement of Rep. W.J. "Billy" Tauzin, Chairman, House Comm. on Energy and Commerce).

107 35 U.S.C. § 271(e)(2) (2003).

brand-name and generic drug companies has increased significantly since the enactment of the Hatch-Waxman Act.[108]

The brand-name pharmaceutical companies are often dragged to court to defend their patents in order to recoup their investments.[109] The patent challenges are occurring at increasingly early stages—often as early as four years after a product launch.[110] For example, Bayer obtained the patent covering Cipro, the widely used antibiotic ciprofloxacin hydrochloride, in June 1987 and obtained the FDA approval of the drug in October 1987.[111] In October 1991, Barr filed an ANDA for a generic version of Cipro.[112] After Eli Lilly & Co. launched Zyprexa, a schizophrenia treatment drug, three generic challengers filed ANDAs within five years, even though the patent covering the drug in the United States would not expire until 2011.[113] Similarly, after Sanofi-Synthelabo, Inc. and its U.S. partner Bristol-Myers Squibb Co. obtained FDA approval of their blood-thinning drug Plavix in November 1997, Apotex, a Canadian generic drug company, filed its ANDA for the FDA's approval of a generic version in November 2001, although the patent would not expire until November 2011.[114] Such a short period of time would not be enough for a brand-name drug company to recoup its development costs for the drug in dispute, let alone the total costs and expenses incurred in research and development.

In patent litigation under the Hatch-Waxman Act, even when an NDA holder prevails, the remedy is very limited. If the court determines that the patent is invalid or is not infringed, the FDA would be able to approve the ANDA,[115] and the generic drug company would be able to market its generic drug and grab the

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[108] Brief of AARP as Amicus Curiae Supporting Petitioner at 8, Teva Pharm. USA, Inc. v. Pfizer, Inc., 546 U.S. 958 (2005) (No. 05-48), 2005 U.S. S. Ct. Briefs LEXIS 1142 (stating that "[a]s of August 1, 2005, generic drug manufacturers [sic] have 303 pending ANDAs containing paragraph IV patent certifications, certifying that their generic version will not infringe a brand name manufacturer's listed patent or that such patent is invalid").

[109] Gongola, *supra* note 86, at 820.

[110] *Id.*

[111] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 743 (E.D.N.Y. 2001); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 194 (E.D.N.Y. 2003).

[112] *In re Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 194.

[113] Gongola, *supra* note 86, at 820.

[114] Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 322 (S.D.N.Y. 2006).

[115] 21 U.S.C. § 355(j)(5)(B)(iii) (2007).

market share rapidly from the brand-name drug company.[116] Even if the court "ultimately upholds the validity of the challenged patent," the NDA holder would still suffer loss of profits in many ways, due to depressed pricing power and loss of loyalty of the patient population.[117] Although by law the brand-name drug company could force the generic drug company to withdraw its infringing product from the market, in reality, the brand-name drug company would unlikely resort to such an action.[118] One reason for this is that a straight enforcement by the brand-name drug company would hurt the patients who by then have relied on the lower-cost generic,[119] which in turn could hurt the brand-name drug company's public image and reputation.

In contrast, a generic drug company could obtain a windfall if it wins a patent suit, while if it loses, it will incur no significant economic risks under the Hatch-Waxman Act. The high profitability potential, coupled with low litigation risks created by the Hatch-Waxman Act, makes generic drug companies willing to "invest literally millions of dollars in these patent challenges."[120]

The brand-name drug companies are struggling to fill the financial holes resulting from patent expirations or early generic entry. Faced with patent challenges from generic drug companies at increasingly early stages of patent terms, brand-name pharmaceutical companies have been trying to protect their exclusive rights for the brand-name drugs and often have to make large compromises in negotiating patent settlement terms with the generic counterparts. The "reverse payment" is just one form of these compromises.

In short, the Hatch-Waxman Act has made generic companies flourish and intensified patent challenges. The intensified patent challenges and early entry of generics have adversely affected financial stability of the brand-name pharmaceutical industry.

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116 CBO STUDY, *supra* note 93, at xiii.

117 Gongola, *supra* note 86, at 819.

118 *Id.*

119 *Id.*

120 *Id.* at 820 (quoting *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals*, *supra* note 86, at 60 (statement of Bruce L. Downey, Chairman and CEO, Barr Laboratories).

IV. LEGAL FRAMEWORK OF ANTITRUST LAW AND PATENT LAW

A. Antitrust Law

Sections 1 and 2 of the Sherman Act prohibit unfair restraint of trade and monopolization, respectively.[121] Specifically, section 1 states that "[e]very contract . . . or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."[122] Section 2 states that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony."[123]

On its face, an agreement between a brand-name pharmaceutical company and a generic drug company, requiring the latter to delay marketing its product, would violate Section 1 of the Sherman Act, because the agreement would create a bottleneck for other generic entry. The agreement seemingly would also violate Section 2 of the Sherman Act, because by making the generic drug company delay launching its product, the brand-name pharmaceutical company would effectively extend the market monopoly of its branded drug. It has also been argued that the agreement has both "horizontal elements" and "vertical elements" of restraint of trade because the "two groups compete against each other to secure market share," and in the meantime the generic drug company relies on the brand-name company's research and development in developing generic drugs.[124]

However, the existence of patents for the branded drug complicates the analysis of antitrust issues regarding the agreement. At a minimum, an agreement to preserve a patent holder's market monopoly within the valid patent term has been widely recognized to be not violating antitrust laws even among the commentators criticizing the anticompetitive effects of the settlements involving reverse payments.[125]

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121 15 U.S.C. §§ 1–2 (2004).

122 15 U.S.C. § 1.

123 15 U.S.C. § 2.

124 Fazzio, *supra* note 37, at 36.

125 *See, e.g.*, Hemphill, *supra* note 6, at 1589; Hovenkamp et al., *supra* note 6, at 1749–60.

B. Patent Law

The U.S. Constitution empowered Congress to enact the patent legislation to promote scientific progress.[126] A patent awards a patentee a monopoly of limited duration in exchange for the patentee's timely disclosure of the invention to the public.[127] It gives a patentee the right to exclude others from making, using, offering to sell, or selling the patented invention within the United States or importing into the United States the patented invention.[128]

Different theories have been proposed to justify the patent monopoly; for example, "incentive to invent," "incentive to disclose," and incentive to invest in "innovation" theories.[129] In other words, there are four principal rationales of patent protection: "Invention Motivation," "Invention Dissemination," "Invention Commercialization," and "Orderly Cumulative Development of Invention."[130] Regardless of which theory justifies the patent monopoly, giving an inventor far too short a period of time to recoup his initial investment would serve as a disincentive for invention.[131] The patent system could certainly overcompensate some inventors; however, it remains the best method to provide incentives for investment in research and development.[132]

V. PHARMACEUTICAL PATENT SETTLEMENT CASES IN THE HATCH-WAXMAN CONTEXT

A. Patent Settlement Cases

In addressing the antitrust issues of the patent settlement agreements between brand-name and generic pharmaceutical

126 U.S. CONST. art. I, § 8, cl. 8.

127 Edwin D. Garlepp, *Baxter v. Cobe: Public Use or Secret Prior Art?*, 4 J. INTELL. PROP. L 381, 381 (1997).

128 35 U.S.C. § 271 (2003).

129 Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024, 1028, 1036–37 (1989).

130 PHILIP NELSON ET AL., A.B.A. TASK FORCE, SECTION OF ANTITRUST LAW, THE ECONOMICS OF INNOVATION: A SURVEY 10 (2002), *available at* www.ftc.gov/opp/intellect/0207salabasrvy.pdf.

131 Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 368 (2000).

132 *Id.* at 368–69.

companies, the federal courts have adopted two different approaches.[133] The Court of Appeals for the Sixth Circuit held that a settlement agreement between a brand-name drug company and a generic drug company to delay marketing until resolution of the patent infringement case in exchange for a "reverse payment" is classical restraint of trade and *per se* illegal.[134] The Eleventh and Second Circuits rejected this "*per se* rule" but instead considered the exclusionary power of the patent and addressed whether the settlement agreements exceeded the exclusionary power awarded by the patent law.[135]

1. Sixth Circuit

HMRI-Andrx Settlement (Cardizem)

In a patent case settlement between Hoechst Marion Roussel, Inc. ("HRMI") and Andrx Pharmaceuticals, Inc. ("Andrx"), HRMI is the patent holder and manufacturer of the prescription drug Cardizem CD, a widely used treatment for angina, hypertension, and prevention of heart attacks and strokes.[136] Andrx filed an ANDA seeking approval to manufacture and sell a generic version of Cardizem CD along with a Paragraph IV certification that the generic form would not infringe HMRI's patents.[137] HMRI filed a timely suit against Andrx for patent infringement.[138] During the thirty-month stay period, the FDA issued a tentative approval of Andrx's ANDA.[139] Nine days later, HMRI and Andrx entered into an agreement, in which HMRI was going to pay Andrx $40 million per year, payable quarterly, beginning on the date Andrx's generic version received FDA approval and ending on the date Andrx either began to sell its generic version or was adjudged liable for patent infringement.[140] The agreement would defer the trigger of the 180-day exclusivity period and would in effect keep subsequent ANDA filers from

133 *See* Gary Young, *Antitrust Violation Not Patently Clear*, 26 NAT'L L.J. 15 (Sept. 22, 2003) (noting Eleventh Circuit disagreement with the approach taken by the Sixth Circuit).

134 THOMAS, *supra* note 10, at 13–14.

135 *Id.* at 13, 15–19.

136 Louisiana Wholesale Drug Co., et al., v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 901 (6th Cir. 2003).

137 *Id.* at 902.

138 *Id.*

139 *Id.*

140 *Id.* at 902–03.

entering the generic market.[141]

The U.S. Court of Appeals for the Sixth Circuit focused on the anticompetitive nature of the agreement and found it "a classic example of *per se* illegal restraint of trade," and thus, presumptively illegal.[142]

2. Eleventh and Second Circuits

Abbott-Geneva Settlement (Hytrin)

The Eleventh Circuit has followed a different approach with respect to the antitrust actions against the patent settlement cases.[143]

Abbott Laboratories ("Abbott") is the patent holder and manufacturer of prescription drug Hytrin, the brand-name for terazosin hydrochloride salt, for treatment of hypertension and enlarged prostates.[144] Abbott obtained FDA approval of its NDA for Hytrin in 1987, and Geneva Pharmaceuticals ("Geneva") filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents.[145] Invoking the 30-month stay of FDA approval of Geneva's ANDAs, Abbott brought infringement suits under 35 U.S.C. § 271(e).[146] Geneva then filed two additional ANDAs based on Hytrin: one for generic terazosin HCl tablets and the other for generic terazosin HCl capsules, both with paragraph IV certifications.[147]

Abbott sued for patent infringement based on Geneva's submission of the tablet ANDA, however, negligently failed to file suit based on the submission of the capsule ANDA.[148] Consequently, the FDA stayed the review of Geneva's tablets pursuant to the 30-month stay provision of the Hatch-Waxman Act but approved Geneva's capsules.[149] Upon Geneva's threat that it would launch its product unless it was paid by Abbott not to enter the market, Abbott agreed to pay Geneva $4.5 million per month on the condition that Geneva would not bring its

141 *Id.* at 902.
142 *Id.* at 908.
143 *See* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).
144 *Id.* at 1298.
145 *Id.* at 1298–99.
146 *Id.*
147 *Id.* at 1299.
148 *Id.*
149 *Id.* at 1300.

generic capsules or tablets to market until the district court ruled on the patent infringement issue or another generic terazosin HCl entered the market.[150] In addition, Geneva also agreed to not transfer, assign, or relinquish its 180-day exclusivity right.[151]

The purchasers of the patented drug brought consolidated antitrust suits against both the patent holder and the generic drug company, alleging that the defendants' agreements not to compete violated the Sherman Act.[152] The District Court for the Southern District of Florida ruled that the agreement was a *per se* violation of Section 1 of the Sherman Act.[153] The Eleventh Circuit reversed the district court's ruling and held that the agreements, to the extent that they had no broader exclusionary effect than that provided by the disputed patents, were not *per se* unlawful.[154]

Based on the conclusion that the district court had failed to consider the exclusionary power of Abbott's patent in the antitrust analysis,[155] the Eleventh Circuit remanded the case to the district court so that the court may consider whether the settlement is within the patentee's exclusionary right and to what extent the agreements exceed the scope of the exclusionary potential of the patent, thereby resulting in anticompetitive effects.[156]

Schering-Upsher Settlement (K-Dur 20)

Another widely publicized patent settlement agreement under the Hatch-Waxman context that was adjudicated in the Eleventh Circuit is the agreement between Schering-Plough Corp. ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher").[157]

Schering was the patent holder and manufacturer of two brand-name drugs, K-Dur 20 and K-Dur 10, which helped restore

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150 *Id.*

151 *Id.*

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

153 *Id.* at 1354.

154 *Valley Drug Co.*, 344 F.3d at 1311.

155 *Id.* at 1306.

156 *Id.* at 1311–12. Upon remand, the District Court, Seitz, J., again held that the agreements exceeded the exclusionary scope of the patent and constituted horizontal restraint of trade that was *per se* violation of the Sherman Act. *In re* Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 (S.D. Fla. 2005).

157 Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005); *see also* Geraldine M. Alexis & Zorah Braithwaite, *FTC Administrative Judge Rejects Commission's View of Drug Patent Settlements*, 18 ANDREWS INTELL. PROP. LITIG. REP. 23 (2003).

potassium levels typically in patients taking heart medications.[158] K-Dur 20 was the most frequently prescribed potassium supplement with a patent that would expire on September 5, 2006.[159] In 1995, Upsher filed an ANDA to market a generic version of K-Dur 20 with a paragraph IV certification.[160] Schering subsequently sued Upsher for patent infringement.[161] In 1997, prior to trial, Schering and Upsher entered into settlement discussions and eventually reached an agreement ("the Schering-Upsher agreement") to settle the patent litigation, in which (1) Upsher agreed not to enter the market with any generic K-Dur competitor drug until September 2001; (2) Schering agreed to grant Upsher a license to market its generic version of K-Dur 20 in September 2001, five years before the expiration of Schering's patent; (3) Upsher agreed to license to Schering five Upsher products; and (4) Schering agreed to pay Upsher $60 million.[162] The effect of the settlement, pursuant to the Hatch-Waxman Act, was that Upsher's 180-day exclusivity period would begin to run in September 2001.[163]

In 1995, ESL Lederle, Inc. ("ESI"), another drug manufacturer, filed a subsequent ANDA for a generic version of K-Dur 20, called "Micro-K 20," with a paragraph IV certification.[164] Schering sued ESI in the United States District Court.[165] After mediation by a court appointed magistrate judge, Schering and ESI eventually reached a settlement agreement in June 1998, in which Schering agreed to pay ESI $5 million representing legal fees in addition to $10 million contingent on the FDA approval of ESI's ANDA.[166] In addition, Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.[167]

In March 2001, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home

158 *Schering-Plough Corp.*, 402 F.3d at 1058.
159 *Id.* at 1058, 1059.
160 *Id.* at 1058.
161 *Id.* at 1059.
162 *Id.* at 1059–60.
163 *Id.* at 1073–74.
164 *Id.* at 1060.
165 *Id.*
166 *Id.* at 1060–61, n.8.
167 *Id.* at n.8.

Product ("AHP", now "Wyeth").[168] The FTC's complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements restraining trade, violating Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and Section 1 of the Sherman Act, 15 U.S.C. § 1.[169] After trial, before an Administrative Law Judge ("ALJ"), the ALJ found that the presence of payments did not make the settlements *per se* anticompetitive.[170] However, the full Commission of the FTC reversed the ALJ's decision and issued its opinion that Schering's settlements with Upsher and ESI had violated the FTC Act and the Sherman Act.[171] Upon petition to the Eleventh Circuit for review by Schering and Upsher, the court held that the settlement agreements did not unreasonably restrain competition beyond exclusionary effects of the patent.[172] The Court reiterated the law established in *Valley Drug* that "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law."[173]

Zeneca-Barr Settlement (Tamoxifen)

The Second Circuit essentially adopted the Eleventh Circuit's approach.[174] The Zeneca-Barr Settlement concerns Tamoxifen, the most "widely prescribed drug for the treatment of breast cancer."[175] Imperial Chemical Industries, PLC ("ICI") was the owner of the tamoxifen patent, and Zeneca, a former subsidiary of ICI, sold tamoxifen under the trade name Nolvadex®.[176] In December 1985, four months after ICI was awarded the patent, Barr Laboratories, Inc. ("Barr") filed an ANDA with the FDA for a generic version of tamoxifen and later, in September 1987, amended its ANDA to include a paragraph IV certification.[177] In November 1987, ICI filed a patent infringement action against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. ("Heumann"), within

168 *Id.* at 1061.
169 *Id.*
170 *Id.*
171 *Id.* at 1062.
172 *Id.* at 1076.
173 *Id.*
174 *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 374 n.1 (2d Cir. 2005), *amended by* 466 F.3d 187 (2d Cir. 2006).
175 *Tamoxifen*, 466 F.3d at 193.
176 *Id.*
177 *Id.*

the forty-five-day requirement of Barr's amendment of its ANDA.[178] In April 1992, the District Court for the Southern District of New York declared ICI's tamoxifen patent invalid due to ICI's withholding of information from the USPTO "regarding [the] tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug."[179] ICI appealed to the Court of Appeals for the Federal Circuit.[180] While the appeal was pending, the parties entered into a confidential settlement agreement in 1993.[181]

In the agreement, Barr agreed to change its ANDA from the paragraph IV certification to a paragraph III certification and to not market its own generic version of tamoxifen until Zeneca's patent on the drug expired in 2002.[182] Barr did this in return for $21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the U.S. under Barr's label.[183] Zeneca also agreed to pay Heumann $9.5 million immediately and additional $35.9 million over the following ten years.[184] "The parties further agreed that if the [ ] patent were to be subsequently declared invalid or unenforceable in a final and . . . unappealable judgment," Barr would be allowed to revert to a paragraph IV ANDA certification.[185] The Second Circuit, agreeing generally with the Eleventh Circuit's reasoning in *Valley Drug*, affirmed the district court's holding that the settlement did not violate the antitrust laws merely because of the existence and the size of the reverse payment.[186]

The FTC brought enforcement actions challenging all the Abbott-Geneva, HMRI-Andrx, and Schering-Upsher patent settlements, alleging that the agreements had the effect of keeping the first ANDA filers' generics out of the market and forestalling other generic competition.[187] After the Eleventh Circuit reversed the FTC full Commission's opinion over the Schering-Upsher settlement agreement, the FTC petitioned to the United States Supreme Court for a writ of certiorari

178 *Id.*
179 *Id.*
180 *Id.*
181 *Id.*
182 *Id.*
183 *Id*.
184 *Id.* at 194.
185 *Id.*
186 *Id.* at 212–13.
187 Morse, *supra* note 41, at 360–61.

unsuccessfully,[188] so the law in this area is still unsettled.

B. Analysis and Comments

Antitrust law proscribes formation of monopolistic corporate powers by improper ways such as making "certain agreements tending to restrict output and elevate prices and profits above the competitive level."[189] Patent law, on the other hand, gives an inventor a limited duration of market monopoly in exchange for a prompt disclosure of the invention.[190] A patent holder is subject to antitrust liability if the patent holder acts to acquire monopolistic power beyond the scope granted by the patent law;[191] but as long as the patent holder acts within the scope of the patent grant, there is no antitrust law violation.[192] This is because a patent grant is "an exception to the general rule against monopolies."[193] A patent holder is entitled to engage in actions that would otherwise be considered illegal under the antitrust law.[194]

In the pharmaceutical industry, because of the particular importance of patents, brand-name pharmaceutical companies often try to preserve their patent monopolies on their brand-name drugs when facing potential generic competitions, thereby resulting in clashes between the antitrust law and the patent law. Nevertheless, analysis of the anticompetitive effects of a patent settlement should always be conducted within the reach of the patent law; otherwise, the "exclusionary right" pursuant to a patent grant would be rendered meaningless.

Many commentators propose that any settlement agreements involving a reverse payment, requiring a generic drug company

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188 F.T.C. v. Schering-Plough Corp., 126 S.Ct. 2929, 2929 (2006).

189 Richard D. Chaves Mosier & Steven W. Ritcheson, *In re Cardizem and Valley Drug: A View from the Faultline Between Patent and Antitrust in Pharmaceutical Settlements*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 497, 510 (2004).

190 *See* 35 U.S.C.A. § 154(a)(2) (2002); Mosier & Ritcheson, *supra* note 189, at 510.

191 Mosier & Ritcheson, *supra* note 189, at 510; *see also* Hovenkamp et al., *supra* note 6, *passim*, 1743 (detailing various patent settlement provisions from least to most problematic under antitrust laws).

192 Michael A. Sanzo, *Antitrust Law and Patent Misconduct in the Proprietary Drug Industry*, 39 VILL. L. REV. 1209, 1228 (1994).

193 Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)).

194 Mosier & Ritcheson, *supra* note 189, at 510.

to delay launching its product, should be labeled as "*per se* illegal."[195] Some even proposed such drastic solutions as imposing on the settling parties a "duty to litigate" to judgment.[196] However, imposition of a "duty to litigate" is contrary to the public policy of favoring settlements.[197] A cursory look into the nature of a patent lawsuit between a brand-name pharmaceutical company and its generic counterpart can reveal that imposition of a "duty to litigate" would not work to consumers' benefit but more likely work to their detriment.

First, brand-name pharmaceutical companies and generic drug companies, though competing with each other apparently, are *de facto* business partners; that is, the generic drug companies heavily relying on the brand-name drug companies' continuing success in developing innovative drugs. Brand-name drug companies' loss would hurt their ability to develop more innovative medicines, which would in turn translate into fewer generic drugs in the future. Second, the outcome of patent litigation is unpredictable. After a pharmaceutical patent is held valid, it would be more difficult for subsequent ANDA filers to challenge the same patent. Consequently, consumers would more likely have to wait for the patent to expire before gaining access to the generic products. Third, patent litigation is extremely expensive. A generic drug company often does not have the same financial strength as a brand-name drug company does. Imposition of a "duty to litigate" may hurt a generic drug company's return on investment or, even worse, jeopardize its survivability. Moreover, the additional cost associated with the patent litigation would eventually be borne by the consumers and make both innovative and generic medicines more expensive.

Therefore, this Article argues that in order to give consumers speedier access to more innovative medicines, a balanced approach must be adopted in resolving antitrust issues

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195 *See, e.g.*, Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, 16-SUM ANTITRUST 53, 55 (Summer 2002); Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1253–54 (2001).

196 Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 1 (2004).

197 *See Schering-Plough*, 402 F.3d at 1072–73 (stating that the patent settlements clearly enhance efficiency and public policy favors settlement to litigation).

associated with the patent settlement cases. The analysis will start from some realistic considerations on the competitive marketplace in pharmaceutical industry.

1. Is a pharmaceutical product a monopoly?

Pursuant to a patent grant, a pharmaceutical company can often set the price of a brand-name drug product, but the company does not have a monopoly power in its true sense.

An antitrust analysis of a patent case should start from the question: what is the relevant market?[198] "Defining the market is critical in evaluating whether [a patentee in fact has the] market power in [the] relevant antitrust market . . . not solely over a particular patented product."[199] If the "relevant market" refers to a single product protected by a patent, a settlement agreement over the patent dispute can probably be said to implicate antitrust issues. However, if the "relevant market" refers to all products substitutable for the patented product, antitrust issues should not be implicated because the patented product is not a true monopoly. The patentee does not have an unfettered monopoly power to price its patented product, as the price is disciplined by competition from substitutes. As the Antitrust Guidelines for the Licensing of Intellectual Property (promulgated by the Department of Justice (DOJ) and the FTC in April 1995) stated, "[a]lthough the [patent] right confers the power to exclude with respect to the *specific* product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power."[200]

In pharmaceutical cases, as has been suggested, "it is important to draw a distinction between the monopoly right in [a pharmaceutical] product . . . and a monopoly in the treatment of a particular disease."[201] The patent protection for a particular pharmaceutical product does not grant the patentee monopoly in the treatment of the disease for which the drug is intended.[202] The pricing power of a pharmaceutical company over a drug

198 Singham, *supra* note 131, at 369.

199 *Id.* at 371.

200 DEPARTMENT OF JUSTICE & FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 2.2 (Apr. 6, 1995), *available at* http://www.usdoj.gov/atr/public/guidelines/0558.htm.

201 Singham, *supra* note 131, at 369.

202 *Id.*

product is disciplined by other therapeutic substitutes; therefore, the monopoly issue is relevant only when there is no other therapeutic substitute available for a particular disease.[203] "In other words, [an antitrust issue comes into play only when] the relevant product market . . . [is] the single patented drug *where no other products are substitutable*."[204] However, given any disease area, there are "different chemical entities" offered as different brands that could be used for the treatment.[205] Many pharmaceutical companies constantly work on different new chemical therapeutic methods targeting the same diseases.[206] These alternatives, either currently available or in development, constitute an effective "price discipline" on the behavior of the patentee.[207]

In addition, although the patentee has the right to exclude others to use the invention, the patent law confers the public right to improve over or design around the invention, which can also inherently discipline the patentee's pricing power. Therefore, a monopoly pursuant to a valid patent should rarely, if ever, implicate antitrust issues.

2. Does a reverse payment make a settlement agreement more anticompetitive?

The "market power alone is not enough to violate [the] antitrust laws,"[208] especially when it comes from a patent grant. The antitrust laws are not triggered unless a patentee "company with the market power uses its power unreasonably with respect to its patent right."[209] This Article argues that a reverse payment in a patent settlement case in the Hatch-Waxman context merely represents a voluntary compromise a brand-name pharmaceutical company makes in order to preserve its limited monopoly power over its patented product.

First, a settlement involving a reverse payment is almost unavoidable in patent cases in the Hatch-Waxman context. On one hand, a brand-name drug company has a statutory right to

203 *Id.* at 370.
204 *Id.*
205 *Id.*
206 *See id.* (discussing how multiple companies create multiple chemical entities for multiple therapeutic possibilities).
207 *Id.*
208 *Id.* at 370–71.
209 *Id.* at 371.

exclude pursuant to its patent grant; on the other hand, a generic drug company has a statutory right to challenge the patent without incurring significant economic risks. As a result, in order to make the generic drug company delay launching its generic product before a court decides on the patent validity issue, the brand-name drug company often has to pay for the hypothetical loss the generic drug company would incur. Whether this type of settlement agreement violates antitrust laws does not have an easy answer before the Supreme Court or the Congress speaks directly to the issue, but a "*per se* illegal" rule clearly will not benefit consumers.

As has been suggested, how two parties settle a patent case depends on various factors, such as, *inter alia*, "their business relationship, [] financial strength, [and] appetite for risk."[210] The settlement payment could "flow in either direction, [and] the direction the payment ultimately flows depends on the parties' bargaining power in the settlement negotiations."[211] The Hatch-Waxman Act provides generic drug companies not only with a strong incentive to challenge the NDA holder's patent but also with a tremendous bargaining power in settlement negotiations.

Second, existence of a reverse payment is irrelevant to the patent validity, and thus, does not have legal bearing on the antitrust issue. It is generally agreed that in the presence of a valid patent, a settlement agreement between an NDA holder and an ANDA filer is likely not only anti-competitive,[212] but may actually benefit consumers by providing additional funds to the ANDA filer for developing other generic drugs and becoming stronger competitors.[213] But if the patent were invalid, then an agreement not to compete would likely violate antitrust laws.[214] However, the validity of a patent is not readily ascertainable, [215] even by a court. For sound policy reasons, to determine antitrust issue of a patent case settlement, in the absence of a viable and

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[210] Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 775 (2002).

[211] *Id.* at 774.

[212] Gongola, *supra* note 86, at 823.

[213] *Id.*

[214] *Id.*

[215] *Id.*; *see also* Thomas B. Leary, Comm'r, Fed. Trade Comm'n, Speech at the Am. Bar Assoc. Antitrust Healthcare Program: Antitrust Issues in the Settlement of Pharmaceutical Disputes, Part II (May 17, 2001), *available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm (stating the lack of capacity for the FTC to ascertain the validity of a patent).

reliable method to ascertain the validity of the patent, the benefit of the doubt should be given to the patent holder. A settlement involving a reverse payment should be presumed to be the patent holder's lawful practice to preserve its market exclusivity over its invention under the patent law.

Third, a settlement agreement, even if involving a reverse payment, has pro-competitive effects and eventually will benefit the consumers. Uncertainty aside, patent litigation is a complex, expensive endeavor for both the NDA holder and its generic counterpart. By settlements, both brand-name and generic drug companies reduce their operating and litigation costs and the savings can eventually be passed on to the consumers. The brand-name pharmaceutical company can expend more resources on developing new innovative medicines, which would translate into more new medicines available to consumers. The savings by the generic drug company, plus any reverse payment from the brand-name drug company, can help the generic drug company develop more generic drugs and make generics more accessible and affordable by the consumers. Thus, the society would be enriched and consumers would ultimately benefit, which is exactly what the Hatch-Waxman Act was intended for. In contrast, a categorical ban on a settlement merely because it involves a reverse payment, as Judge Posner has pointed out, "would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."[216]

Despite the reverse payment, in a patent settlement between an NDA holder and an ANDA filer, the delay of the generic product launch almost never goes beyond the patent term.[217] Because most agreements allow generic entry months or years before the patent expiration, consumers actually could enjoy early entry of generics in the absence of the ANDA filers' clear victory of the patent cases.[218] If the ANDA filers had to litigate the suits to judgment, whether consumers could enjoy the same

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[216] Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[217] John M. Coster, *The Waxman-Hatch Generic Drug Law: 23 Years Later*, US Pharmacist (2007), *available at* http://www.uspharmacist.com/index.asp?show=article&page=8_2052.htm; *see also* Hemphill, *supra* note 6, at 1553, 1607 (discussing pay-for-delay settlements and patent duration).

[218] *See id.* (discussing the effect of pay-for-delay settlements on consumers).

benefits would be far less certain.

Moreover, even if a patent is eventually declared invalid, it does not necessarily mean the patent holder had violated antitrust law if the patent holder had a good faith belief in the validity of its patent. Except for in rare cases that involve presence of clearly anticipatory prior acts or involve a patentee's fraudulent act during prosecution of the patent, the validity or enforceability of a patent is not readily ascertainable, if it is ascertainable at all. Most times, the patent validity issue is a subjective one, and given the same set of facts, different judges could interpret it differently. Therefore, it would be unfairly burdensome for a patent holder to ensure that the patent is valid, assuming he has the ability to do so, before exercising his exclusionary right to settle with a patent challenger. Thus, for sound policy reasons, upon issue, a patent should be presumed valid.[219] Presumptive illegality of any settlement agreement involving a reverse payment would be contradictory to this sound policy behind the patent law long established by the Congress.

Finally, the anticompetitive effect of patent settlements is overstated. A survey covering the period from 1984 to January 2001 suggests that the total number of patent challenges under Hatch-Waxman Act is small relative to the total number of ANDA applications filed.[220] Among the 8259 ANDA applications, "only 478 . . . raised a patent issue, either challenging patent validity or claiming non-infringement,"[221] among which "only fifty-eight court decisions involving [] forty-seven patents [were] issued to resolve the . . . [patent] challenges."[222] Out of these patent disputes, only three settlement agreements were challenged by the FTC, specifically Abbott/Geneva, Aventis/Andrx, and Schering/Upsher-Smith/ESI Lederle.[223] In other words, only about 0.3-0.4% of ANDA applications filed in the seventeen-year period resulted in settlements challenged by the FTC. Based upon these statistic data, the antitrust concern expressed by the media, the FTC, and the commentators about these patent settlement cases is overly pessimistic.[224]

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219 *See* Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1555 n.1 (Fed. Cir. 1985) (stating that an issued patent is presumed valid).

220 Gongola, *supra* note 86, at 822.

221 *Id.*

222 *Id.*

223 *Id.*

224 *Id.*

3. Is the size of a reverse payment indicative of patent validity?

The absolute size of a reverse payment in a patent case settlement has no bearing on the legality of the settlement, let alone the validity of the patent itself. Using the size of a payment to determine or presume the illegality of a settlement is too simplistic and deemed error-prone.[225]

In *Fromson*, the Federal Circuit stated in a footnote that "[t]here is never a need or occasion" to declare a patent valid.[226] "Patents are born valid and remain so until proven otherwise."[227] The Federal Circuit also declared that "[t]he validity of a patent is always subject to plenary challenge on its merits."[228] Therefore, on one hand, a patentee seems to be able to enjoy the presumptive validity of a patent; on the other hand, the patentee can never be sure about the validity of a patent. One alleged infringer's unsuccessful challenge of a patent in the court does not prevent others from challenging the same based upon new evidence or new grounds.

In a patent settlement case, the size of a reverse payment, similar to whether a reverse payment exists in the first place, depends on many factors. First, patent litigation characteristically has uncertain outcomes.[229] Empirical studies of patent cases have shown that about half of all patents litigated to judgment on validity issues have been invalidated by courts.[230] The FTC's survey showed even a higher risk for brand-name drug companies to litigate a patent case to judgment.[231] With these statistics as the backdrop, it is not surprising that a great

225 *Cf., e.g.*, Hovenkamp et al., *supra* note 6, at 1722 (discussing the need for heightened scrutiny of settlement agreements).

226 *Fromson*, 755 F.2d at 1555 n.1.

227 *Id.*

228 Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997).

229 Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: a Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 11 (2006) ("A survey of judicial decisions addressing infringement during 2003 showed that courts found the patent not infringed 75% of the time. A more optimistic study still shows patentees losing litigation 42% of the time.").

230 *Id.* (noting that "nearly all written, final validity decisions by the district courts and the U.S. Court of Appeal for the Federal Circuit from 1989 through 1996 found that 46% of patents challenged in litigation were invalidated") (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated patents*, 26 AIPLA Q. J. 185, 187, 205 (1998)).

231 It found that the generic drug companies prevailed 73% of the thirty cases litigated to judgment over a ten-year period by proving either invalidity or non-infringement. FTC Study, *supra* note 2, at 16.

majority of patent infringement cases have resulted in settlements in which the NDA holders often make huge compromises, including making reverse payments to mitigate the risk of losing market exclusivity on the brand-name drugs.[232]

Second, a patent suit settlement is not just settling a legal matter, but is more making business compromises between two parties, especially when the stake is so high that it could affect the brand-name drug company's business sustainability. Similar to other high profile cases, patent litigation over a blockbuster drug is often highly publicized, which puts tremendous pressure on the brand-name pharmaceutical company's management. Patent litigation is also notoriously lengthy and costly, and the outcome is unpredictable. All these factors could press the brand-name company's management to settle the case by making a relatively high reverse payment in return for the business stability.

Third, pharmaceutical business is complex in many respects. Development of new drugs is extremely expensive, yet never a sure thing,[233] and the sales vary considerably from one drug to another. Pharmaceutical companies rely on a small number of the so-called "blockbuster" drugs to recoup the research and development costs invested in not only these drugs themselves, but also other less successful or failed drug candidates.[234] The amount of reverse payments varies not because of varying litigation costs, but more because of varying profitability of the disputed drugs and the different risks the negotiating parties can bear. Litigation in the Hatch-Waxman context often involves patents covering these highly profitable drugs. The reverse

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[232] *See infra* notes 236–44 and accompanying text; Anne-Marie C. Yvon, Note, *Settlements Between Brand and Generic Pharmaceutical Companies: A Reasonable Antitrust Analysis of Reverse Payments*, 75 FORDHAM L. REV. 1883, 1898–99, 1900, 1903 (2006).

[233] Tufts Center for the Study of Drug Development (CSDD), *Analysis and Insight Into Critical Drug Development Issues*, 5 IMPACT REPORT 3, (May/June 2003) [hereinafter "Tufts Study"], *available at* http://csdd.tufts.edu/InfoServices/ImpactReportPDFs/ImpactReportSummaryMayJune2003.pdf.

[234] PHRMA, DELIVERING ON THE PROMISE OF PHARMACEUTICAL INNOVATION: THE NEED TO MAINTAIN STRONG AND PREDICTABLE INTELLECTUAL PROPERTY RIGHTS 8 (April 22, 2002), *available at* http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf (estimating that the cost of research and development for a single new drug would be between $500-$600 million (citing Boston Consulting Group, *Sustaining Innovation, in U.S. Pharmaceuticals: Intellectual Property Protection and the Role of Patents* 35–36 (1996))).

payments, usually in the range of tens of millions of dollars a year, may constitute just a fraction of the profits the drug could potentially generate. Because the reverse payments are almost always higher than potential litigation costs, using potential litigation costs as the yardstick to determine the legality of a settlement, as recommended by some commentators,[235] would be tantamount to a "*per se*" rule. Such a rule is at best a too simplistic and error-prone approach to assessing the patent validity and antitrust issues.[236]

Finally, mere existence or the size of a reverse payment has no legal bearing on the validity of the patent at issue, which has been well-demonstrated by a recent patent settlement case between generic drug maker Apotex, Inc. ("Apotex") and brand-name drug makers Sanofi-Aventis SA ("Sanofi") and its U.S. partner Bristol-Myers Squibb Company ("BMS").[237]

Plavix, the brand-name antiplatelet agent, is the most widely prescribed blood-thinning drug in the world, preventing platelets in blood from aggregating around obstructions in arterial passageways.[238] "The active ingredient of Plavix is clopidogrel bisulfate" for which Sanofi obtained a patent on July 11, 1989.[239] "The *patent* is exclusively licensed to the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership and expires on November 17, 2011".[240] In November 2001, Apotex filed an ANDA with the FDA for approval "to manufacture and sell

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[235] *See, e.g.*, Abbott & Michel, *supra* note 229, at 14–15 (concluding that "the purpose and effect of the payments is to purchase the generic's guaranteed exclusion from the market"); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004) (stating that "as the payment becomes larger, going into several millions of dollars, then something else must be going on," and "the infringement plaintiff must have significant doubts about the validity of its patent or the defendant's status as an infringer.").

[236] Hovenkamp, *supra* note 235, at 28 ("A firm willing to pay roughly $75 million per year to keep an alleged infringer out of the market when a successful preliminary injunction would have done the same thing for the cost of obtaining the injunction indicates that the prospects for a preliminary injunction were very poor.").

[237] *See generally* Sanofi-Synthelabo v. Apotex, Inc., 488 F. Supp. 2d 317 (S.D.N.Y. 2006) (discussing the relation of size of reverse payment on patent validity).

[238] *Id.* at 321; *see also*, John Carreyrou, *States Reject Deal On Plavix, In Blow to Bristol-Myers*, WALL ST. J., July 29, 2006, at A2 (stating that Plavix was the second best-selling drug in the world, with $5.9 billion sales globally in 2005).

[239] *Sanofi-Synthelabo*, 488 F. Supp. 2d at 322.

[240] *Id.*

clopidogrel bisulfate tablets before" the patent expired and "certified that it believed Sanofi's patent to be invalid."[241] Sanofi and BMS filed a patent infringement suit against Apotex in March 2002, which trigged an automatic 30-month stay until May 2005.[242] The FDA approved Apotex's ANDA in January 2006.[243]

Several days before approval of the ANDA, BMS, Sanofi and Apotex started settlement negotiations trying to resolve the litigation.[244] A final agreement was reached between the parties in May 2006.[245] In the agreement, BMS and Sanofi reportedly agreed to pay Apotex "a minimum of $40 million to delay its launch of a generic version of Plavix until 2011—the year the patent protecting Plavix expires."[246] Upon disapproval of the agreement by the FTC, Apotex launched its generic clopidogrel bisulfate product after the agreed five-day period passed.[247] Pursuant to the agreement, five business days after the generic launch, Sanofi filed its motion for a preliminary injunction action against Apotex in the United States District Court for the Southern District of New York.[248] After a two-day evidentiary hearing, the district court granted the motion for injunctive relief.[249] The district court essentially upheld the validity of the patent by concluding that Apotex had failed to provide substantial evidence to invalidate Sanofi's patent on both anticipation and obviousness grounds,[250] which was affirmed by the Court of Appeals for the Federal Circuit.[251] Later, both the

241 *Id.*

242 *Id.* at 322–23.

243 *Id.* at 323.

244 *Id.*

245 *Id.* at 324.

246 Carreyrou, *supra* note 238, at A2.

247 The agreement also contained a number of terms that were to enter into force if the agreement would fail to get approval from the FTC, including: (1) "[u]ntil five business days after the date on which Regulatory Denial is effective . . . Apotex will not launch a generic clopidogrel bisulfate product, and Sanofi would not launch an authorized generic product and . . . will not seek a temporary restraining order or a preliminary injunction," and (2) after the expiration of the period, Sanofi "will not file for a preliminary injunction until Sanofi gives Apotex five business days notice . . . of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product." *Sanofi-Synthelabo*, 488 F. Supp. 2d. at 324–25.

248 *Id.* at 325.

249 *Id.* at 350.

250 *Id.* at 327–38.

251 Sanofi–Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1385 (Fed. Cir. 2006).

validity and enforceability of the patent protecting Plavix were upheld in the full-fledged litigation to judgment.[252]

In summary, in a patent settlement case, the existence and size of a reverse payment have no legal bearing on the validity of the patent at issue, nor should they be used alone to conclude antitrust violations.

VI. BALANCING DIFFERENT INTERESTS: PRAGMATIC CONSIDERATIONS

"[T]wo goals of the Hatch-Waxman Act are at the very least mutually inconsistent and are possibly mutually exclusive."[253] The same can be said about the relationship between the antitrust law and the patent law. Whether a settlement agreement has exceeded the scope of the patent holder's exclusionary rights rarely has a clear answer; however, it is clear that when an NDA holder has a valid patent the antitrust law is not offended as long as the agreement does not require the generic drug company to delay launching its product beyond the patent term. Thus, the antitrust question in the Hatch-Waxman context often becomes "one of prioritization," that is, how to balance between a brand-name drug company's right to capitalize on its patent and the consumer's interest in early access to cheaper generics.[254]

1. Reliance of the Brand-Name Drug Industry on the Patent Protection

The pharmaceutical business has been a very profitable one in the past few decades. Part of the profitability of this business is attributable to pharmaceutical companies' ability to develop innovative drugs under the patent protection. However, innovation enjoyed by a pharmaceutical company is a relative term because against any patented drug product there is abundant competition.

Brand-name pharmaceutical companies compete with each other constantly in potential therapeutic areas, especially those with a high market demand.[255] Companies race to develop "first-

252 Sanofi-Synthelabo v. Apotex, Inc., 492 F. Supp. 2d 353, 356 (S.D.N.Y. 2007).

253 Goldberg, *supra* note 77, at 576.

254 *Id.*

255 *See* Prescription Access Litigation (PAL) Project: Learn More,

in-class" drug candidates[256] because a "first-in-class" medicine has a previously un-met medical need and is usually highly profitable. Once a company succeeds in developing the "first-in-class" drug product, other companies race to develop a better compound, i.e., one with higher efficacy and/or lower side effects, the so called "best-in-class."[257] As a general rule, pharmaceutical companies can make big profits usually only by developing either "first-in-class" or "best-in-class" compounds.[258] Profitability of the rest, or the so-called "me-too" drugs, is a lot less certain. Due to the fierce intra-industry competition, as a recent CBO study indicates, many me-too drugs developed in the recent years were often in clinical trials before the respective pioneering drugs received approval from the FDA.[259]

available at http://www.prescriptionaccess.org/learnmore?id=0003 (noting that although brand-name drugs do not compete against each other on price, they do compete against each other on arguments of "medical superiority"); *see also* Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 499–500 (2002).

256 A "first-in-class" drug is often referred to the first in a new class of chemical entities that target a specific biological process. *See* Marlynn Wei, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25, 28 (2007).

257 Peter Van Osta, *Drug Discovery and Development—Human Cytome Project*, *available at* http://ourworld.compuserve.com/homepages/pvosta/hcpphrm.htm; *see also* Rick E. Winningham, Chief Executive Officer of Theravance®, discussing strategy targeting "best-in-class" medicines in large market on the company's Investor R&D Day, Feb. 5, 2007, *available at* ir.theravance.com/downloads/InvestorRnDDay.pdf; Trista Morrison, *Gilead Gets Letairis Approval, Potential Best in Class For PAH*, BIO WORLD TODAY, June 19, 2007, *available at* http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioWorld Headlines_article&forceid=44272 (noting factors that may cause a certain drug to become best in class).

258 *See, e.g.*, Eduard M. Holdener, Head of Pharma Development, Roche, Roche Pharma Development: Creating the Best Future Medicine for Each Patient (May 2004), www.roche.com/pages/downloads/investor/pdf/praesentations/irp050504rdd7.pdf (listing Phrama's strategy as: (1) "[p]ioneering 1st-in-class therapy"; (2) "[c]reating best-in-class in areas of established mechanisms"; and (3) "[m]aximizing product lifecycles through innovative development").

259 U.S. CONGRESSIONAL BUDGET OFFICE (CBO), A CBO STUDY: RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 12–13 (Oct. 2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf (citing Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and the Timing of Development*, 22 PHARMACOECONOMICS 2, 2–14 (2004), *available at* http://www.who.int/intellectualproperty/submissions/Submission_DiMasi.pdf).

The fierce competitive nature of the pharmaceutical industry and the low barriers to generic entry under the Hatch-Waxman Act make the patent protection crucial to the survival of brand-name pharmaceutical companies.[260]

First, the brand-name pharmaceutical companies make heavy investments in small molecule drug discovery, and it is impossible for them to protect their inventions by trade secret.[261] Before a drug enters the market, it must go through many years of rigorous clinical trials and multiple regulatory review processes. As soon as a small molecule drug product enters the market, the structure of the active ingredient and the formulation of the drug product are easy to be reverse-engineered by a generic company. As a study suggested, 65% of medicines on the market would not have been developed if the patent protection had not been available, a much higher percentage than in other industries.[262]

Second, developing new brand-name medicines is a very lengthy and risky process, and the cost is extremely high.[263] "For every drug successfully brought to market, there are 5,000–10,000 unsuccessful compounds screened and 250 that undergo preclinical testing."[264] Brand-name pharmaceutical companies constantly have over a thousand new chemical entities (NCE) in the development pipeline, covering a wide range of therapeutic needs.[265] Development of an innovative drug typically takes ten–fifteen years and costs over $800 million,[266] or even $1.7 billion

[260] *See, e.g.*, Henry H. Gu, Note, *The Hatch-Waxman Act and the Declaratory Judgment Action: Constitutional and Practical Implications*, 57 RUTGERS L. REV. 771, 798 (2005); Wilson, *supra* note 255, at 501; Gregory J. Glover, M.D., J.D., Address Before the Federal Trade Commission and the Department of Justice: Competition in the Pharmaceutical Marketplace (Mar. 19, 2002), *available at* http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf.

[261] Gu, *supra* note 260, at 798; Wilson, *supra* note 255, at 501–02.

[262] Singham, *supra* note 131, at 374.

[263] Herlihy, *supra* note 42, at 133.

[264] ERNST & YOUNG, LLP, PHARMACEUTICAL INDUSTRY R&D COSTS: KEY FINDINGS ABOUT THE PUBLIC CITIZEN REPORT 6 (Aug. 8, 2001) (citing *PhRMA, Pharmaceutical Industry Profile* 2001), *available at* http://www.cptech.org/ip/health/econ/phrmaresponse.pdf.

[265] *See id.* at 5–6 (explaining that NCEs play a very significant role in pharmaceutical R&D).

[266] Gu, *supra* note 260, at 798; *Pharmaceutical Industry Profile 2006*, 2006 PHRMA 2, *available at* http://www.phrma.org/files/2006%20Industry%20Profile.pdf; Tufts Study, *supra* note 233.

depending on how one calculates the costs.[267] The vast majority of the cost in developing an innovative drug is incurred during research and development, sequentially in the stages of discovery, development, clinical trial, and regulatory approval,[268] whereas the cost of manufacturing a pill itself is only a fraction of the total cost.[269]

However, the average effective patent life of innovative medicines is significantly shorter than that of other product patents.[270] While other patented products can enjoy average 18.5 years of market exclusivity, the average effective patent term of prescription drugs is only about eleven–twelve years, although ostensibly one objective of the Hatch-Waxman Act is to compensate the lost patent term of prescription drugs due to the regulatory review.[271] The strong incentives provided by the Hatch-Waxman Act for early generic entry have significantly threatened to shorten the market exclusivity period of many top-selling drug products sold by the brand-name pharmaceutical companies.

Third, the pharmaceutical industry, in a sense, competes with itself constantly. Although in the current new drug application (NDA) process, the FDA does not require an applicant to compare its new drug candidate with similar existing drugs,[272] pharmaceutical companies often make such comparisons voluntarily.[273] Without a favorable comparison of the efficacy

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[267] Gu, *supra* note 260, at 798; *see also* BNA, Inc., Research and Development Cost to Develop New Drug Going Up Due to Failure Rate, 1 PHARM. L. & INDUS. REPORT 1326, 1326 (2003).

[268] Wilson, *supra* note 255, at 496–500; Gu, *supra* note 260, at 798.

[269] Gu, *supra* note 260, at 798; Robert H. Ballance, *Market and Industrial Structure*, *in* CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS 96–97 (Peter Davis ed., 1996) (demonstrating that the actual costs for manufacturing brand-name drugs accounted for about 25% of total costs in 1989).

[270] Herlihy, *supra* note 42, at 133.

[271] *Id.*; Parikshit Bansal & Anand Sharma, *Generic Drugs and Their Approval—Part I of II*, MAGAZINE OF INTELL. PROP. & TECH. (July 21, 2005), *available at* http://www.ipfrontline.com.

[272] John H. Barton & Ezekiel J. Emanuel, *The Patent-Based Pharmaceutical Development Process*, 294(16) JAMA 2075, 2081 (2005); Alastair J.J. Wood, *A Proposal for Radical Changes in the Drug-Approval Process*, 355(6) NEW ENG. J. MED. 618, 622 (2006).

[273] *Compare* Design and Development: Overview of Drugs: Merck Manual Home Edition, http://www.merck.com/mmhe/sec02/ch010/ch010b.html (last visited Oct. 8, 2008) (stating that during clinical studies, the new drug is generally compared against an established drug), *with* FDA Center for Drug Evaluation and Research, New Drug Application Process (2007), *available at*

and/or side effects of a new drug candidate with those of existing drugs, the commercial success of the new drug would be far from certain. Especially when the existing drugs have become generic, it is almost certain that a marginally better new drug cannot enjoy a commercial success.

2. Reliance of the Generic Drug Industry on the Brand-Name Drug Industry

Undisciplined emphasis on encouraging early entry of generic drugs into the market has at best only a very short-term effect on reducing the drug prices and increasing the accessibility to the drugs by consumers.

Although a brand-name pharmaceutical company and its potential generic competitor can be characterized as "horizontal competitors,"[274] they are not true competitors in the marketplace. The generic drug companies rely on continuing development of innovative new medicines by the brand-name pharmaceutical companies.[275] When generics enter the market so early that the pioneer pharmaceutical companies are not able to recoup their investment in the drug development, these brand-name pharmaceutical companies will not be able to sustain the high cost of developing innovative drugs. Generic drug companies profit from the research conducted by brand-name drug companies without the need to conduct expensive drug discovery and clinical trials.[276] Under the Hatch-Waxman Act, the barrier for generic entry is low. Because generics are based upon existing drugs, developing generics takes only three–five years, and the approval of generics by the FDA is almost guaranteed.[277]

http://www.fda.gov/cder/regulatory/applications/nda.htm (outlining information requirements for a NDA and not including a comparison to similar existing drugs).

274 *In re* Buspirone Patent Litig., 185 F. Supp. 2d 340, 343 (S.D.N.Y. 2002) (noting that ANDA IV filers are competitors of brand-name manufacturer, who have been seeking to produce or sell generic versions of pioneer drug); *see also* Ciprofloxacin, 261 F. Supp. 2d at 240; *see also Cardizem*, 105 F. Supp. 2d at 701 (finding it "evident" that ANDA IV filer and brand-name manufacturer were competitors from generic manufacturer's ANDA, Paragraph IV Certification and subsequent patent suit); *Terazosin*, 164 F. Supp. 2d at 1349 (finding that filing ANDA IV demonstrated that generic manufacturers were "poised to compete" with brand-name manufacturer at same level of market).

275 Engelberg, *supra* note 77, at 406.

276 Gidcumb, *supra* note 19, at 29–30; *see also* Mossinghoff, *supra* note 19, at 307.

277 Herlihy, *supra* note 42, at 122.

However, generics originate from innovative medicines. When new innovative drugs become scarce, they would become more expensive, and the accessibility of the consumers to these drugs would be diminished. Consequently, too strong an incentive for the early entry of generics in the marketplace could backfire and hurt the public's long-term welfare.

In short, when the investment in the research and development of life saving drugs becomes financially unattractive or infeasible, the availability of innovative medicines will be diminished. So will the generics. Numerous challenging diseases besieging human beings, such as cancers, Alzheimer's disease and Parkinson's disease, may remain with a lack of treatment.

VII. REDUCING UNNECESSARY CLASHES: POLICY CONSIDERATIONS

As has been discussed in Part V, there could be many reasons for an NDA holder to settle its patent case with an ANDA filer by offering a large reverse payment. The two most important reasons are probably: (1) an uncertain outcome of patent litigation; and (2) high stakes in the litigation outcome. When a patent covering a top-selling drug product is under attack, an adverse ruling on the patent validity could devastate the NDA holder's financial stability and jeopardize the sustainability of its high level R&D activities.

In a perfect world, if all patents issued by the USPTO were deemed to be valid, there would be no uncertainty or patent challenges. Generic drug companies would have to wait until NDA holders' patents expire before launching generic products. There would be no patent case settlements, let alone settlements involving reverse payments. Then, the most useful part of the Hatch-Waxman Act would be the safe harbor provision, namely 35 U.S.C. § 271(e), which allows a generic drug company to start developing generic products before an NDA holder's patent expires without infringing the patent. The maximum effect of the Act would probably be to ensure the generics to be available to consumers upon expiration of the NDA holder's patent.

In reality, from both the provisions of the Hatch-Waxman Act and the real world practice, the Act functions as intended by relying on the patent system's imperfectness, that is, a significant portion of patents proven, or held by a court, to be invalid. The difficulty to assess the validity of any patent has

resulted in reverse payment, and in order to reduce the unnecessary clashes between the antitrust law and the patent law in the pharmaceutical industry, this Article urges Congress to focus on the following two aspects when it strives to modify the Hatch-Waxman Act and its progenies: (1) strengthening the patent system and enhancing predictability on patent validity issues; and (2) reinforcing the public policy of encouraging private settlements by declaring a presumed validity of a patent in the absence of clear evidence proving otherwise.

1. Enhancing Predictability on the Validity of Patents

The manufacture of innovative medicines is not difficult to copy, which makes the patent protection particularly crucial in incentivising R&D in this field.[278] When an NDA holder is certain that its patent is valid, it would be less willing to settle a patent case; therefore, enhancing predictability on validity of patents should not only reduce patent litigation in general, but should also reduce settlements involving reverse payments. Because in the long-term, litigation costs will be reflected in the drug prices, less litigation should also help reduce overall drug prices.[279]

Pharmaceutical companies typically rely on a small number of patents, "sometimes . . . a solitary relevant patent," to make profits and sustain the high cost of R&D.[280] These patents "need to function like a gorilla in terms of their strength and effectiveness in terms of standing in the way of a generic copycat."[281] Yet, nothing in the patent system can ensure that

[278] F. M. Scherer, *Antitrust, Efficiency, and Progress*, 62 N.Y.U. L. REV. 998, 1013 (1987) ("Patent protection appears to be a crucial means of appropriating the benefits from innovation in only a few industries such as pharmaceuticals and specialty chemicals."); *The Economics of Innovation: A Survey*, 2002 A.B.A. SEC. ANTITRUST L. 19, *available at* www.ftc.gov/opp/intellect/0207salabasrvy.pdf (July 2002) ("All of empirical work in [the importance of patents] has come basically to the same conclusion—that patents are a particularly important inducement to invention in only a few industries. In pharmaceuticals, for example, patents seem to be an important part of the inducement for R&D.").

[279] Crane, *supra* note 210, at 748 (arguing for the social benefit of the voluntary settlement of disputes because the inefficiency and astronomical cost of patent litigation will ultimately be passed on to consumers).

[280] Robert A. Armitage, *The Conundrum Confronting Congress: The Patent System Must be Left Untouched While Being Radically Reformed*, 5 J. MARSHALL REV. INTELL. PROP. L. 267, 275 (2006).

[281] *Id.*

these important patents will be stronger than other less valuable ones. On the contrary, the number of questionable patents issued is growing fast due to the enormous volume of patent applications and inadequate resources of the USPTO in patent examination processes.[282]

Therefore, Congress should strive to enhance the predictability of the validity of patents by increasing the resources available to the USPTO and strengthening the patent examination processes. A sound policy is to annihilate unworthy applications in the buds, not to "weed out" a weak patent after an enterprise has made huge investments in transforming the patent into a product extremely beneficial to the public health. To provide maximum long-lasting benefits to consumers, a strong patent system needs to be in place to protect innovation and reduce litigation cost.[283]

2. Encouraging Settlements

The sustainability of innovative cycles in the pharmaceutical industry is the key to the accessibility of consumers to more innovative medicines. Given the cost structure of the drug development, this Article argues that a pharmaceutical company should be rewarded for its investment in the development of a successful drug product beneficial to consumers, even when the underlying patent is "weak," or at least considered "weak" in patent terms. In pharmaceutical development, a majority of the cost is incurred in identifying a viable drug candidate and conducting clinical trials, whereas the cost to patent a new chemical entity is only a negligible fraction of the cost for developing the chemical entity into a drug candidate. Allowing a pharmaceutical company to profit from a successful product in spite of a weak patent can encourage the company to focus on identifying drug candidates truly beneficial to the public health. Based upon the same reasoning, a patent settlement between a brand-name pharmaceutical company and its generic counterpart should be encouraged when the validity of the patent is not

[282] *Id.* at 274–75.

[283] *See* James W. Hughes, Michael J. Moore & Edward A. Snyder, "'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," at 3–4 (Nat'l Bureau of Econ. Research, Working Paper No. 9229) (2002) (proving a net loss to consumers due to accelerated generic entry), *available at* http://www.ftc.gov/os/comments/intelpropertycomments/snydermoorehughes.pdf .

readily ascertainable.

A pharmaceutical company's continuing ability to discover new medicines and to deliver them to patients depends on whether and how quickly the pharmaceutical company could recoup its investment. Pharmaceutical companies typically reinvest over 10% of sales in the research and development of new medicines.[284] In the United States, pharmaceutical R&D is estimated to be between 16% and 20.8% of pharmaceutical companies' revenue.[285] Whether a product can be approved for marketing is one thing; profitability of the product is another. A 1994 study found that only 30% of drug products introduced from 1980 to 1984 generated returns higher than their average after-tax R&D costs, and about 70% of returns were generated from the top 20% of products in revenue during this period.[286] Another study also found that about 55% of profits in the pharmaceutical industry came from just 10% of drugs.[287]

These statistics show the importance of the patent protection for the top-selling drugs to the sustainability of the pharmaceutical industry. Unsurprisingly, it is these top-selling drugs that have been the main targets of generic challenges. It is also the patent lawsuits regarding these top-selling drugs that most often result in the settlements causing antitrust actions by the governmental agencies or consumer groups. It is certainly not because these drugs have weaker patents. On the contrary, a company would be willing to expend more resources on the prosecution of these patents and, if possible, make these patents stronger. It is because challenging these top-selling drugs gives a generic drug company the highest potential of profitability, yet the patent system does not enable a higher protection of these important drugs. Considering the reliance of the brand-name pharmaceutical companies on a small number of successful products to finance their continuing R&D, it is not hard to understand why they are willing to pay large sums to settle the patent suits. Therefore, the antitrust agencies and the courts should take a balanced approach in resolving antitrust issues of these important patent case settlements in the Hatch-Waxman

284 Singham, *supra* note 131, at 372–73.

285 *Id.*

286 Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 383 (1994).

287 F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7. J. ECON. PERSP. 97, 106 (1993).

context.

3. The Right Way to Reduce Drug Prices

Twenty-four years have passed since the enactment of the Hatch-Waxman Act, but the prices of prescription drugs have never stopped climbing.[288] This fact suggests that the Hatch-Waxman Act's effect on reducing drug prices is limited. While the Act has affected the prices of the medicines whose patents have either expired or have been successfully challenged by generic drug companies, it has made new prescription drugs more expensive, which is one of many unavoidable ill effects of this well-intended statute. From its inception, the Act has never created a true competition that would result in lower prices.[289]

The U.S. antitrust law is based upon the notion of a free market economy: "freely operating competitive markets will produce the most efficient allocation of a nation's scarce resources, the widest variety of consumer choices, and the lowest product prices possible."[290] In the pharmaceutical industry, because of the Hatch-Waxman Act, the generic competition is not rooted on level ground. Because of the low-cost advantage enjoyed by the generic drug companies pursuant to the Act, brand-name pharmaceutical companies cannot afford to compete with them on prices. The reverse payment in a patent case settlement is essentially an abnormal statutory premium a patentee must pay a potential infringer in order to settle the patent dispute due to the existence of the Hatch-Waxman Act. The statutory premium would increase the cost of developing innovative medicines. This increased cost, in addition to expensive litigation costs, would make the new medicines more expensive. Consequently, the alleged billions of dollars of "savings" by the consumers are deemed to be short-lived. As demonstrated by a recent study by the National Bureau of Economic Research (NBER), future customers would, conservatively, "lose three dollars in benefits of innovation for

288 Gongola, *supra* note 86, at n.287 (explaining that, although the cost of drug development in 1987 was $231 million, merely through the rate of inflation, the cost of drug development in 2000 would have been $318 million) (citation omitted).

289 *See, e.g.*, Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 102–03 (2002).

290 Davis, *supra* note 78, at 358.

every dollar [the existing customers] gain due to easier access" to a medicine.[291]

The judiciary long ago declared a strong public policy in favor of the resolution of disputes among private parties themselves.[292] In light of the expensive litigation in pharmaceutical patent cases and the crowded dockets in federal courts, these settlement agreements should be encouraged because they can lower transaction costs and enhance business certainties for the parties.[293]

Moreover, even without early entry of generics into the market, drug prices will go down after the patents expire. Many studies conclude that drug prices drop to its marginal production cost due to generic competition after patent expiration.[294] While the brand-name pharmaceutical industry is struggling with one of its biggest challenges—patent expiration,[295] allowing this industry some breathing room by settling important patent cases with generic challengers is most opportune.

In summary, a patent case settlement agreement should be presumed to be valid as long as the agreed delay in launching the generic product by the ANDA filer does not go beyond the patent term, regardless of existence of a payment and the flow direction of the payment. Any rule or law that would make an industry so critical to human life and health unsustainable is not only unwise but will hurt the public in the long run.

VIII. CONCLUSION

The Hatch-Waxman Act has changed the landscape of pharmaceutical industry by creating a safe harbor for generic drug companies to start generic drug development before an NDA holder's patent expires. The Act has also created strong incentives for generic drug companies to challenge and design around patents held by brand-name pharmaceutical companies. The Act has achieved tremendous success in encouraging generic

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291 Hughes, *supra* note 283, at 44.

292 Gongola, *supra* note 86, at 822; *see also* Emmons v. Superior Court, 968 P.2d 582, 585 (Ariz. Ct. App. 1998).

293 *See* Gongola, *supra* note 86, at 822.

294 Singham, *supra* note 131, at 386.

295 *See, e.g.*, "Diverse Challenges Await Generics Industry," Pharmaceutical Bus. Rev., July 7, 2006, http://www.pharmaceutical-business-review.com/article_feature.asp?guid=08601A9B-D31C-4409-84E2-7C91A3F24CB8 ("With drugs worth $160 billion in sales coming off patent by 2015, it would seem a good time to be in the generics industry.").

entry into the market and in enabling consumers to access the innovative drugs at lower prices. However, the low-price drugs often come at a high cost for various reasons.

First, the strong incentive for generic drug companies to file ANDAs and to challenge NDA holders' patents in the early stage of patent terms has caused more patent litigation between brand-name pharmaceutical companies and generic drug companies. The pharmaceutical patent litigation in the Hatch-Waxman context is complex, lengthy, and expensive. The high litigation cost borne by both parties will make new medicines more expensive. Second, encouraging early patent challenges from generic drug companies while not providing NDA holders with adequate patent term restoration has in effect shortened the NDA holders' patent terms and weakened the patent protection. The weakened patent protection will reduce incentives for brand-name pharmaceutical companies to invest in developing innovative medicines much needed by the public. Third, encouraging generic entry before an NDA holder has recouped its high R&D cost could jeopardize the sustainability of the innovative cycle in the pharmaceutical industry. When the law tilts too much towards generic industry's favor, the public may end up holding a medicine chest filled only with the existing generics.

In light of the unique situation in pharmaceutical patent cases created by the Hatch-Waxman Act and its progenies, a mechanical application of antitrust law to the patent settlement cases involving reverse payments can only exacerbate the survivability of the innovative pharmaceutical industry. Therefore, this Article has argued that the existence and the size of the reverse payment in the patent infringement settlement cases should not be determinative of the legality of the settlements, let alone the validity of the patents in dispute. Because the Hatch-Waxman Act created an imbalance of the negotiating powers between the two parties, a settlement agreement involving a reverse payment is an expected result under the statute. The reverse payment is nothing but a statutory premium a brand-name pharmaceutical company has to pay its generic counterpart due to the power imbalance.

To sustain a healthy, innovative pharmaceutical industry with an ability to continue delivering innovative medicines, the Congress should enhance, instead of weaken, the patent protection in this field. First, the Congress can make effort to

enhance the predictability of the validity of patents, which would reduce both the patent litigation and the problematic settlement agreements. Second, the Congress can give NDA holders true patent term restoration due to regulatory delays, at a minimum making the effective patent terms of innovative medicines on par with other patents. Third, the Congress can reinforce the public policy of encouraging private settlements of patent litigation. Unless a patent settlement clearly exceeds the patentee's exclusionary rights under the patent law, the settlement should be presumed to be lawful.