TO ACHIEVE CLOSURE OF THE HATCH-WAXMAN ACT'S LOOPHOLES, LEGISLATIVE ACTION IS UNNECESSARY: GENERIC MANUFACTURERS ARE ABLE TO HOLD THEIR OWN

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I. INTRODUCTION

Over twenty years ago, in reaction to the high cost of pharmaceuticals, the lack of lower-costing generic alternatives, and the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*,[1] Congress passed the Hatch-Waxman Act ("Act").[2] The Act comprised a series of amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Patent Act,[3] and effectively lowered the barriers and raised the incentives for market entry by the manufacturers of generic drugs.[4] Under the Act, a 180-day period of market exclusivity is granted to the first in time generic drug maker that successfully files an Abbreviated New Drug Application ("ANDA").[5] The period of exclusivity presents this generic manufacturer an opportunity to capture significant present and future profits: first, by being the sole provider of a lower-cost alternative to the high priced brand-name medication; and second, by granting the opportunity to secure a loyal consumer base before other generics flood the

1 733 F.2d 858 (Fed. Cir. 1984).

2 Narinder S. Banait, *Authorized Generics: Antitrust Issues and the Hatch-Waxman Act*, FENWICK & WEST LLP, at 1-2, Nov. 3, 2005, http://www.fenwick.com/docstore/Publications/Antitrust/Authorized_Generics.pdf.

3 21 U.S.C. § 355 (2006); 35 U.S.C. § 271 (2006).

4 Banait, *supra* note 2, at 2.

5 *Id.* Before 1998, FDA rules stated that the 180-day exclusivity period was to be granted to the first Paragraph IV ANDA filer (or to an ANDA applicant who filed under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) if he was able to successfully defend against the infringement lawsuit that was usually subsequently brought by the brand name pharmaceutical manufacturer. 21 U.S.C. § 355 (2006). But what if the lawsuit were resolved by settlement rather than litigation? Under then-existing FDA guidelines, it was unclear whether the Paragraph IV ANDA applicants that settled were eligible to receive the 180-day exclusivity period. *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005). At least two circuit courts, the D.C. Circuit and the Second Circuit, found the "successful defense" requirement to be "inconsistent with the Hatch-Waxman Act." *Id.* at 376-377. The FDA agreed, and in 1998 amended its regulations, striking out the successful defense requirement. *Id.* For the purposes of this Note, a "successful" ANDA is one that has not been found to infringe on the existing patent, whether as a result of an infringement action or as a result of a settlement, and has consequently been approved by the FDA. An unsuccessful ANDA, thus, would be one that the FDA has rejected.

market.[6] Because the grant of market exclusivity eliminates other low-cost generic manufacturers from the competitive landscape for six months, during that period of time, the recipient of the exclusivity period (the first successful ANDA filer) is able to charge a price that is higher than the price it would be compelled to charge when faced with direct competition from other generics.[7]

Over time, the Hatch-Waxman Act spurred a debate over whether the Act's enactment "encouraged competition as intended or, instead facilitated the use of anticompetitive strategies to delay the marketing of generics."[8] Supporters have emerged on both sides of the argument.[9] Those who are unhappy with the current state of the Hatch-Waxman Act point out that pioneer pharmaceutical companies have found Food and Drug Administration ("FDA") approved loopholes in the Act, including the thirty-month stay provision of the FDCA and the practice of authorized generics, that have been said to frustrate the Act's purpose of furthering competition and innovation.[10] Such maneuvers by brand name drug manufacturers have the potential to essentially deprive the first generic entrant of its 180-day market exclusivity.[11]

In 2003, Congress sought to patch up at least one perceived gap in the Hatch-Waxman Act by targeting it with an amendment, packaged into the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Act of 2003").[12] While this amendment eliminated the practice by brand name manufacturers of using a string of thirty-month stays to keep generic entrants off the market, it did not address the remaining loopholes.[13] These loopholes are still being utilized today by pioneer pharmaceutical companies to artificially extend their patents and to keep generics from entering the marketplace.[14]

As a result, a new call has been made for further legislative action to close the remaining loopholes,[15] but, as this Note argues,

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6 Banait, *supra* note 2, at 4.

7 *Id.*

8 *Generic Drugs: The Stalling Game*, CONSUMER REP., July 2001.

9 *See* Banait, *supra* note 2.

10 *Id.*

11 *Id.*

12 *See Medicare Improvement Act of 2003 – Much More than Just A Prescription Plan*, THE PIPER RUDNICK IP REPORT, Spring 2004, http://www.envoynews.com/piperrudnick/e_article000252447.cfm; *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

13 Banait, *supra* note 2, at 4.

14 *Id.*

15 A. Maureen Rouhi, *Beyond Hatch-Waxman: Legislative Action Seeks to Close Loopholes in U.S. Law that Delay Entry of Generics into the Market*, 80 CHEMICAL & ENGINEERING NEWS 38,

Congressional intervention may be unnecessary because generic drug manufacturers have found at least one way to fight back on their own: by entering into agreements with brand name drug makers that hinge on credible threats of "at-risk" introductions of generics into the market.[16] Part II of this Note lays out the history and purpose behind the enactment of the Hatch-Waxman Act. Part III of this Note delineates the remaining perceived loopholes of the Act; specifically, this section discusses the Hatch-Waxman Act's thirty-month stay provision and the practices of using authorized generics, citizen petitions, and reverse payment agreements in order to delay, or prevent altogether, market entry by a generic. Part IV provides an overview of litigation arising out of reverse payment agreements, which are a controversial method of delaying or denying generic entry into the market and have been at the epicenter of most current Hatch-Waxman Act litigation. There has been little consensus regarding the legality of these agreements among the circuit courts, and Part IV of this Note outlines the emerging trends. Importantly, this section of the Note demonstrates how reverse payment agreements actually provide the springboard for the "at-risk" launch strategy that generic manufacturers have been using to fight back and thus essentially patches up this particular Hatch-Waxman Act loophole. Finally, Part V tracks the recent litigation initiated by Bristol-Myers Squibb and Sanofi-Synthelabo against the generic drug-maker Apotex and indicates how the "at-risk" launch strategy used by Apotex may eliminate the need for Congressional involvement in closing at least one of the perceived Hatch-Waxman Act gaps, that of the reverse payment agreements.

II. THE HATCH-WAXMAN ACT

A. *Enactment History and Purpose*

In 1984, the United States Court of Appeals for the Federal Circuit declared in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*,[17] that "taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug"[18] is "a violation of the patent laws in the guise of 'scientific inquiry,' when that

53 (2002), *available at* http://pubs.acs.org/cen/coverstory/8038/8038biogenerics2.html.

[16] John Carreyrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense Of $4 Billion Drug*, WALL ST. J., Sep. 2, 2006, at A1.

[17] 733 F.2d 858 (Fed. Cir. 1984).

[18] *Id.* at 860.

inquiry has definite, cognizable, and not insubstantial commercial purposes."[19] Under this rule, manufacturers of generic drugs were obligated to wait until the date of a branded drug's patent expiry in order to take actions necessary to obtain FDA approval.[20] The *Roche* court's holding delayed manufacturers of generic drugs from entering the market for a significant period of time, even after patent expiry, because it took three to four years for a generic manufacturer to conduct all the tests required for New Drug Application ("NDA") filing and to obtain FDA approval.[21] The patent holder was thus able to enjoy gratuitous extended patent protection.[22]

In response to *Roche*,[23] and in an effort to bring less costly generic versions of brand name drugs to market, Congress adopted the Hatch-Waxman Amendments (generally known as the Hatch-Waxman Act)[24] and codified them under the FDCA in 1984[25] and the United States Patent Act in 1994.[26] Collectively, the amendments had the effect of allowing generic drug manufacturers to submit an ANDA, a filing that must show bioequivalence of the generic drug to its brand name counterpart, thus eliminating the need to conduct costly and time-consuming clinical trials that the FDA requires for submission of an NDA.[27] By taking this step, the federal government effectively gave freedom to generic drug manufacturers to "piggy-back on the pioneer drug's human clinical trials and labeling"[28] and reduced the delay following the date of patent expiry for market entry of a generic from an average of three to four years to under three months.[29]

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19 *Id.* at 863.

20 CONG. BUDGET OFFICE, 100TH CONG., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 43 (1998) [hereinafter INCREASED COMPETITION], *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf; *see also* Banait, *supra* note 2, at 2.

21 *See Roche*, 733 F.2d at 860.

22 Banait, *supra* note 2, at 2.

23 *Id.*

24 Paul Burgess & John Lucas, *Which Generic Drug Would You Want to Use? The Federal Circuit's Interpretation of "Active Ingredient," "Active Moiety" and "Approved Product,"* 87 J. PAT. & TRADEMARK OFF. SOC'Y 11 (2005).

25 21 U.S.C. § 355 (2006). In relevant part, amendments included the addition of section (j).

26 35 U.S.C. § 271 (2006). In relevant part, amendments included the addition of section (e).

27 Ann K. Wooster, Annotation, *Construction and Application of Hatch-Waxman* Act, 180 A.L.R. FED. 487 (2005).

28 *Id.* at 2a.

29 *See* INCREASED COMPETITION, *supra* note 20, at 43.

B. *One Hundred and Eighty Day Provision for Market Exclusivity Granted to First-in-Time Successful ANDA Filer*

Approved Drug Products with Therapeutic Equivalence Evaluations, the FDA publication commonly known as the *Orange Book*, lists all FDA-approved brand name pharmaceuticals along with their corresponding patents.[30] The relevant patents listed in the *Orange Book* are provided by the pioneer manufacturer that files the original NDA.[31] Under the Hatch-Waxman Act, an ANDA filed by a generic manufacturer must certify, with respect to the applicable patent listed in the *Orange Book*, one of the following four reasons for the filing: (1) a patent was never filed (and is not listed in the *Orange Book*); (2) the patent has expired; (3) the ANDA will take effect after the patent has expired; or (4) the patent is "invalid or will not be infringed by the manufacture, use, or sale of the . . . drug for which the [ANDA] application is submitted."[32] Because the Hatch-Waxman Act endows the first-in-time successful ANDA filer with 180 days of market exclusivity,[33] to the exclusion of any other generic manufacturers looking to enter the market,[34] it gives generic manufacturers a substantial incentive to challenge existing patents.[35]

Six months of market exclusivity rewards the generic manufacturer "for taking the risk of an infringement suit."[36] Because the generic drug company has the chance to be the sole offeror of a lower-priced alternative to the brand name pharmaceutical for 180 days, it is able to "establish itself with a larger customer base[,] thereby[, due to customer loyalty,] retaining a greater market share after the [period of] exclusivity ends."[37] By virtue of being the sole generic market participant, the generic drug company is essentially allowed to "develop [its own]

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30 21 U.S.C. § 355(j)(7)(A)(iii) (2006).

31 Anik Banerjee & Mark E. Nagle, *180 Days of Exclusive Marketing: A Right, an Incentive, or a Property Interest?*, SHEPPARD MULLIN ANTITRUST LAW BLOG, June 7, 2005, http://www.antitrustlawblog.com/article-180-days-of-exclusive-marketing-a-right-an-incentive-or-a-property-interest.html.

32 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2006).

33 The 180 days of exclusivity begins at the earlier occurrence of either of the two instances: (1) when the first successful ANDA applicant initiates commercial marketing of its generic drug; or (2) after a court issues a ruling (in the infringement lawsuit filed by the patent-holder in response to ANDA filing) that the patent is invalid or not infringed. *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 901 (6th Cir. 2003).

34 *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006) (providing that the 180-day exclusivity period is measured with respect to other generic manufacturers; however, authorized generics (discussed *infra* in this note) are exempt from this provision and are allowed market entry during the 180 days. Banait, *supra* note 2, at 1.

35 *See* Banait, *supra* note 2, at 4.

36 *Id.*

37 *Id.*

brand, enhance [its] reputation in the industry, and increase customer good will."[38] However, while the 180 days of exclusivity are a period of significant profit-generating activity for the generic drug maker,[39] under the current version of the Hatch-Waxman Act, the period may sometimes have to be shared among two or more generic market entrants, as when "more than one applicant files a 'substantially complete' ANDA for a previously unchallenged drug on the same day,"[40] or when authorized generics, discussed in greater detail *infra*, encroach on the six months of the first successful ANDA filer's exclusivity period.[41]

III. PERCEIVED LOOPHOLES IN THE HATCH-WAXMAN ACT AND CALL FOR LEGISLATIVE ACTION

A. *Pioneer Pharmaceutical Companies Have Found Several Ways to Circumvent the Hatch-Waxman Act's Provisions That Still Prove To Be Effective*

It is undeniable that as a result of the Hatch-Waxman Act the pharmaceutical market has seen a significant influx of low-priced generic drugs;[42] the Act is said to have "created today's generic drug industry."[43] A mere decade after the enactment of the law, the average market share of generic drugs rose to sixty four percent.[44] With generics replacing brand name products after patent expiration, the profit margins of pioneer pharmaceutical companies have declined noticeably.[45] To minimize the damage brought about by competition from generics, brand name drug manufacturers have sought out several loopholes in the Hatch-Waxman provisions that impede — and in some cases preclude altogether — a generic from appearing on the market.[46]

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38 *Id.*

39 *Id.*

40 *Id.*

41 *See* Banait, *supra* note 2, at 1.

42 Anne Field, *Doctoring the Hatch-Waxman Act, in* STANFORD GRADUATE SCH. OF BUS. RESEARCH PAPER SERIES (2003), *available at* http://www.gsb.stanford.edu/news/research/pubpolicy_bulow_hatchwaxman_act.shtml.

43 Robert D. Bajefsky & Gregory Chopskie, *Biting the Hand That Feeds?: Generic Drugs and Abuse of the Hatch-Waxman Law,* 17 WASHINGTON LEGAL FOUNDATION, 1, 1 (2002), *available at* http://www.wlf.org/upload/120602LBBajefsky.pdf.

44 CONG. BUDGET OFFICE, 109TH CONG., RESEARCH AND DEVELOPMENT IN THE PHARACEUTICAL INDUSTRY 16 (2006) [hereinafter Research and Development], *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

45 *See* INCREASED COMPETITION, *supra* note 20, at 45.

46 *See* Banait, *supra* note 2, at 2-3.

1. Thirty-Month Stay Period

One loophole in the Hatch-Waxman Act is triggered when a generic drug manufacturer certifies its ANDA under "Paragraph IV,"[47] the section of the FDCA that protects ANDA applicants from claims of patent infringement if the underlying patent is, as alleged, invalid.[48] When a brand name manufacturer disagrees with the ANDA's Paragraph IV certification, or its allegation of a void patent, and within forty five days of the filing initiates an infringement lawsuit, this lawsuit triggers an automatic "30-month stay" period.[49] Consequently, the generic drug manufacturer is prohibited from entering the market during that period, unless one of the following three scenarios occurs prior to the end of the thirty months: (1) the underlying patent expires; (2) the court finds that there is no infringement; or (3) the court pronounces the patent invalid.[50] A fourth possibility is that the generic manufacturer uses the at-risk launch strategy, discussed in detail *infra.*

Before the passage of the Medicare Act of 2003, brand name drug manufacturers were able to bar generics from virtually ever receiving FDA approval of their ANDAs by perpetuating consecutive thirty-month stays.[51] Patent-holding pharmaceutical companies achieved this result by adding new patents to those *Orange Book* NDA listings that were being challenged by generic manufacturers.[52] Such new patent entries included "intermediates," "product by process patents," and "double patents."[53] Prior to the amendments enacted under the Medicare Act of 2003, each new patent entry attached to a specific brand name drug required a separate notice of Paragraph IV certification, and each time such notice was issued to the brand name drug manufacturer, a new infringement lawsuit was initiated and a new thirty-month stay period was triggered.[54] Creative patent holders had the capability of weaving an infinite chain of multiple thirty-month stays, until the Medicare Act of 2003 put an

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47 *Id.*

48 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

49 Banait, *supra* note 2, at 3; *see also* 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

50 Banait, *supra* note 2, at 3.

51 *Id.*; *see also* 108 P.L. 173 (2003).

52 *See Medicare Improvement Act of 2003 — Much More than Just a Prescription Plan, supra* note 12.

53 Devesh Srivastava, *The Food and Drug Administration and Patent Law at a Crossroads: The Listing of Polymorph Patents as a Barrier to Generic Drug Entry*, 59 FOOD & DRUG L.J. 339, 345 (2004).

54 *See Medicare Improvement Act of 2003 — Much More than Just a Prescription Plan, supra* note 12.

end to the practice by requiring Paragraph IV certifications to cover only those patents that are listed in the *Orange Book* at the time of the initial ANDA filing,[55] and also by limiting the number of thirty-month stays that may be granted to just one.[56]

2. Authorized Generics

Production of authorized generics, a practice employed by pioneer pharmaceutical companies to bring their own "generics" to market, currently escapes coverage under the Hatch-Waxman Act and gives brand name drug manufacturers the opportunity to encroach on the Act's 180-day exclusivity provision.[57] The pioneer pharmaceutical company usually either re-labels its brand name product and promotes it as a generic, or licenses the marketing rights for that product to another company.[58] In either case, the brand name pharmaceutical manufacturer reaps the profits from providing its own "lower cost . . . alternative[] to [its own] brand name product."[59] Patent-holding companies have not launched authorized generics solely as a means to preempt entry of or share the market with a "real" generic; rather, other reasons for such launches include to "settle patent litigation with a generic company by partnering with it . . . or to maintain manufacturing capacity for the drug substance or the drug product."[60] Whatever the reason for their presence on the market, the fact remains that competition from authorized generics substantially cuts into the share of profits that could otherwise be realized by the generic that was granted, under the Hatch-Waxman Act, 180 days of presumed market exclusivity.[61]

Providing a case in point, Narinder Banait, a patent litigation associate at Fenwick & West LLP, briefly discussed the case of nitrofurantonin, a treatment for urinary tract infections, in his update on authorized generics.[62] Just when Mylan Pharmaceuticals was ready to market its generic version of the drug, Proctor & Gamble, the original patent holder, licensed the right to market its authorized generic to Watson

55 Banait, *supra* note 2, at 3.
56 Melissa Ganz, *The Medicare Prescription Drug, Improvement, & Modernization Act Of 2003: Are We Playing The Lottery With Healthcare Reform?*, 11 DUKE L. & TECH. REV. (2004).
57 Banait, *supra* note 2, at 1.
58 *Id.*
59 *Id.*
60 *Id.*
61 *Id.* at 4.
62 *Id.*

Pharmaceuticals.[63] As a result, Mylan is thought to have lost a projected $30 million of the revenue it was set to realize under its 180-day exclusivity grant from the FDA.[64] In general, "[t]he entry of a second generic reduces the revenues of a first generic company by about 80%" and poses a significant financial detriment to first generic manufacturer, leaving it without a clear prospect of recouping the loss.[65]

Besides interfering with the Hatch-Waxman Act's exclusivity scheme, authorized generics also raise antitrust concerns.[66] The court in *Mylan Pharmaceuticals Inc. v. Food and Drug Administration*, for example, pointed out that since introduction of authorized generics substantially lessens the financial incentive for a generic drug manufacturer to file an ANDA petition challenging a brand company's patent, authorized generics thus act to suppress competition.[67] A possible predatory pricing issue may also be attributed to the practice of authorized generics: when the pioneer pharmaceutical company prices the authorized generic lower in an "unfair manner," it places a restraint on competition.[68] The burden of proof, however, rests on the generic ANDA filer, who "must prove that the prices complained of are below an appropriate measure of the brand's costs and that the brand had a reasonable prospect of recouping its investments in below cost prices."[69]

An opinion promulgated by the FDA, however, states that, contrary to raising antitrust concerns, authorized generics "promote rather than impede competition."[70] The Fourth Circuit Court of Appeals, in agreement with the FDA, held in *Mylan Pharmaceuticals* that authorized generics should be allowed to enter the market concurrently with the successful generic ANDA applicant that received the Hatch-Waxman Act's 180 days of exclusivity.[71]

3. Citizen Petitions

Another Hatch-Waxman Act loophole utilized by the pioneer pharmaceutical companies to delay the arrival of a generic on the

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63 *Id.* at 5.
64 *Id.*
65 *Id.* at 4.
66 *Id.* at 4-5.
67 *Id.*
68 *Id.* at 5.
69 *Id.*
70 *Id.* at 4.
71 Mylan Pharm., Inc. v. FDA, 454 F.3d 270 (4th Cir. 2006).

market is the citizen petition mechanism.[72] Citizen petitions may be filed under an FDA regulation that is intended to allow the general public to voice its opinions regarding the agency's decisions.[73] Any "interested person" (a term that includes brand name drug manufacturers), by way of such a petition may ask the FDA "Commissioner to issue, amend, or revoke a regulation . . . [or] an order . . . [or] to take or refrain from taking any other form of . . . action."[74] This request must be supported by a certified "statement of grounds."[75] Whether the FDA approves, denies, or provides a tentative response to the petition, the filing results in a hold placed on the generic drug manufacturer's ANDA application, as the Commissioner is allowed to take up to ninety days to investigate the filer's request.[76] Pioneer pharmaceutical companies have been known to file groundless citizen petitions and effectively delay the FDA's approval of the pending ANDA.[77]

4. Reverse Payment Agreements

More recently, brand name drug manufacturers have begun entering into reverse payment agreements with generic drug makers, under which the brand company pays a substantial amount of money to the generic company to either not file an ANDA application or, if it has already filed the application, to stay out of the market for some period of time.[78] In one such case, Schering-Plough paid a generic drug manufacturer $60 million, allegedly as consideration for the generic company's product licenses.[79] The generic company, in addition, promised not to market its version of Schering-Plough's patented drug before a certain date (the date chosen was before the patent was set to expire).[80] An administrative law judge found this agreement legal, reasoning that "Schering's patent was presumed both valid and

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72 *See The Stalling Game, supra* note 8.

73 *Id.*

74 21 C.F.R. § 10.30 (b) (2007).

75 *Id.*

76 *Id.* § 10.30 (e)(4); *see also Generic Drugs: The Stalling Game, supra* note 8, at 39.

77 *See Generic Drugs: The Stalling Game, supra* note 8, at 39.

78 *See* Field, *supra* note 42; *see also* Thomas B. Leary, Commissioner, Federal Trade Commission, Address Before the American Bar Association's Antitrust Healthcare Program: Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II (May 17, 2001), *available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm.

79 *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, *in* STANFORD GRADUATE SCH. OF BUS. RESEARCH PAPER SERIES, *supra* note 42, at 14, *available at* https://faculty-gsb.stanford.edu/bulow/articles/6.27.1036%20Pharmaceutical.pdf.

80 *Id.*

infringed[,] and anticompetitive effects could not therefore be presumed . . . . Further, . . . Schering's $60 million payments . . . were in consideration for licenses . . . and not in return for [the generic company's] agreeing to stay off the market."[81] Had the *Schering-Plough* court found that the payoff to the generic drug manufacturer was instead made for its promise to stay out of the market, such restraint on trade could have arguably amounted to a violation of antitrust laws.[82]

While the Federal Trade Commission maintains that reverse payments made by patent-holders are *per se* illegal, the issue, however, is still up for debate in federal courts.[83] In 2003, the Sixth Circuit held in *In re Cardizem CD Antitrust Litigation* that a similar agreement "was, at its core, a horizontal agreement to eliminate competition . . . a classic example of a *per se* illegal restraint of trade."[84] But in 2005, the Second and the Eleventh Circuits both found no *per se* illegality in reverse payments and held that such agreements were legitimate,[85] subject to a finding that "the challenged agreements restrict competition beyond the exclusionary effects of the [patent] . . . ."[86]

B. *Call for Legislative Action*

In the past, as pioneer pharmaceutical companies developed strategies and tactics to delay or prevent generic market entry, Congress acted to close these Hatch-Waxman Act loopholes by amending the Act in 2003.[87] Congress was successful in closing some loopholes, such as the ability of a brand company to perpetuate an unlimited number of thirty-month stays,[88] but, as this Note has thus far indicated, brand name drug manufacturers have been able to find novel ways of circumventing the Act's provisions.[89] Calls for additional legislative action have been made to close the current loopholes and allow the generic

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81 *Id.* at 15.

82 *See* Wooster, *supra* note 27, at 487.

83 Saami Zain, *Suppression of Innovation or Collaborative Efficiencies?: An Antitrust Analysis of a Research & Development Collaboration That Led to the Shelving of a Promising Drug*, 5 J. MARSHALL REV. INTELL. PROP. L. 347, 365 (2006); *see also* EARL W. KINTNER ET AL., 1 FEDERAL ANTITRUST LAW § 11.34 (Supp. 2005).

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

85 *See In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005); *see also* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

86 *Schering-Plough Corp.*, 402 F.3d at 1068; *see also* Federal Bar Council Panel: *Antitrust Issues In Patent Litigation Settlements: the Divergent Views of Federal Courts and Agencies* (Nov. 9, 2006).

87 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

88 Banait, *supra* note 2, at 3.

89 *See supra* Part III.B.

manufacturers to take full advantage of the incentives provided by the Hatch-Waxman Act.[90] But is further legislative action truly necessary? Recent legal struggles between pioneer and generic drug manufacturers suggest that the generic drug makers have found at least one way to strike back and regain their footing in the competitive field without Congressional intervention: by relying on the "at risk" launch method.

IV. OVERVIEW AND OUTCOMES OF REVERSE PAYMENT AGREEMENT LITIGATION

A. Lack of Consensus Among the United States Federal Circuit Courts on the Subject of Legality

Reverse payment agreements are currently the focus of debate among the federal circuit courts: to date, no consensus has been reached regarding the legality of such agreements.[91] While some circuits have branded reverse payments as illegal restraints on trade and violations of antitrust provisions, other circuits have upheld their legality as long as they do not "restrict competition beyond the exclusionary effects of the [patent] . . . ."[92] The following cases will illustrate the positions that the Sixth, Eleventh, and Second Circuits have taken in the recent past on the subject of reverse payment settlement agreements entered into between brand name pharmaceutical companies and generic drug manufacturers.

B. Application of Reverse Payment Agreements: Some Notable Cases

1. In re Cardizem CD Antitrust Litigation (Sixth Circuit)[93]

The defendant parties to this case, Andrx Pharmaceuticals, Inc. ("Andrx") and Hoescht Marion Roussel, Inc. ("Hoescht"), entered into a reverse payment agreement.[94] The agreement specified that Hoescht, the manufacturer of Cardizem CD, a brand-name prescription drug used to treat angina and hypertension, would make payments of $40 million per year to

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90 Brian Porter, Note, *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 (2005).

91 *Compare In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005) *and Schering-Plough Corp.*, 402 F.3d 1056, *with In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

92 Federal Bar Council Panel, *supra* note 86.

93 *In re Cardizem*, 332 F.3d 896.

94 *Id.* at 902.

Andrx, manufacturer of the generic version of the same drug, in return for Andrx abstaining from marketing the generic, even if given the green light by the FDA.[95] The plaintiffs, direct and indirect buyers of Cardizem CD, initiated an action in district court, claiming that the agreement between Hoescht and Andrx violated federal and state antitrust laws.[96] The district court proclaimed that the agreement was a horizontal restraint on trade and thus *per se* illegal, and the court granted the plaintiffs partial summary judgment.[97]

Hoescht's patent for the active ingredient in Cardizem CD expired in November 1992, and in September 1995, Andrx was the first generic manufacturer to file an ANDA with the FDA, asking for approval to manufacture and sell a generic version of the brand name drug.[98] In December 1995, Andrx certified under Paragraph IV that the generic it was planning to manufacture would not infringe any patents listed in the *Orange Book*.[99] In November 1995, however, Hoescht received a new patent for its time-release version of Cardizem CD, and in January 1996, Hoescht, in its infringement suit against Andrx, claimed that Andrx's generic would infringe the new patent.[100] This filing automatically triggered the thirty-month stay period. Andrx then counterclaimed with allegations of antitrust and unfair competition by Hoescht.[101]

In September 1997, Andrx received the FDA's tentative approval for its ANDA (the ANDA was to receive final approval either when the thirty-month stay period expired or if the pending patent infringement suit was resolved by the court in Andrx's favor).[102] Nine days later, Hoescht and Andrx entered into the agreement at issue in this case.[103] Specifically, the agreement required Andrx not to market its generic version of Cardizem CD until either: (1) the patent infringement case was finally resolved in Andrx's favor; (2) Hoescht and Andrx entered into a licensing agreement; or (3) Hoescht entered into a licensing agreement with a third party. Under the agreement, Andrx agreed to dismiss its counterclaims and to not trigger or disclaim its 180-day period of exclusivity.[104] In consideration, in addition to making other

95 *Id.* at 902-03.
96 *Id.* at 903-04.
97 *Id.* at 905.
98 *Id.* at 902.
99 *Id.*
100 *Id.*
101 *Id.*
102 *Id.*
103 *Id.*
104 *Id.* FDA regulations permit ANDA filers to relinquish or transfer the 180-day period

payments, Hoescht was to pay Andrx $40 million per year, in quarterly installments, starting on the date of Andrx's receipt of final FDA approval.[105]

The Sixth Circuit Court of Appeals upheld the district court's decision and declared that:

> [t]here is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.[106]

The court found that Andrx, Hoescht's only potential competitor in the market for Cardizem CD, was paid $40 million per year to abstain from marketing its generic version of the drug even after being legally cleared and authorized to do so by the FDA.[107] Hoescht would thus retain "exclusive access to the market for Cardizem CD throughout the United States until the occurrence of one of the end dates contemplated by the Agreement."[108] The Sixth Circuit further ruled that by asking Andrx to promise neither to trigger nor disclaim its 180-day exclusivity period, Hoescht effectively prevented other generic competitors from entering the market.[109] The court was unable to "fairly characterize [the agreement] as merely an attempt to enforce patent rights or an interim settlement of the patent litigation"; there is a distinction, it said, between "tak[ing] advantage of a monopoly that naturally arises from a patent" and effecting an artificial extension of the patent by "inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[110] The anticompetitive nature of the agreement was also reflected in the fact that, under the agreement, Andrx was to refrain from marketing other versions of Cardizem CD, versions that were not covered by the litigation.[111] This led the court to the conclusion that "'the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem [CD].'"[112] Based on

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of exclusivity to other ANDA filers in exchange for consideration. Federal Bar Council Panel, *supra* note 86.

105 *In re Cardizem*, 332 F.3d at 896.

106 *Id.* at 908.

107 *Id.*

108 *Id.* at 907.

109 *Id.*

110 *Id.* at 908.

111 *Id.* at 909, n.13.

112 *Id.* (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188,

these findings, the Sixth Circuit held that the agreement between Andrx and Hoescht was presumptively (or *per se*) illegal because the reverse payments constituted a horizontal agreement designed to restrict competition in violation of antitrust provisions.[113]

2. Schering-Plough Corp. v. FTC (Eleventh Circuit)[114]

K-Dur 20 is a supplement taken alongside other medicines for the treatment of high blood pressure.[115] Although its active ingredient is unpatentable, Schering-Plough ("Schering"), the manufacturer of this supplement, held a patent (that expired in September 2006) for the extended-release coating used by K-Dur 20.[116] In 1995, Upsher-Smith Laboratories ("Upsher") filed an ANDA and a Paragraph IV certification with the FDA, seeking approval to market a generic version of K-Dur 20.[117] Upsher's filing gave rise to a patent infringement suit, brought by Schering, which in turn triggered the Hatch-Waxman Act thirty-month stay provision.[118] In June 1997, the day before the trial began, Schering and Upsher entered into a settlement agreement.[119] During the settlement discussion process, Schering refused to pay Upsher to "'stay off the market'" and instead negotiated with Upsher an exclusive licensing agreement to globally market Niacor, one of Upsher's products.[120] Under the agreement, Schering would pay Upsher: (1) initial royalties of $60 million; (2) milestone royalty payments of $10 million; and (3) sales royalties amounting to 10% or 15%.[121] In return, Upsher promised not to market its generic version of K-Dur 20.[122]

In December 1995, another pharmaceutical manufacturer, ESI Lederle, Inc. ("ESI"), a subsidiary of American Home Products, Inc. ("AHP"), filed an ANDA and a Paragraph IV certification with the FDA asking for permission to make its own generic version of K-Dur 20.[123] In response, Schering sued ESI, triggering the thirty-month stay provision.[124] Following an

242 (E.D.N.Y. 2003)).

113 *In re Cardizem*, 332 F.3d at 896.

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

115 *Id.* at 1058.

116 *Id.*

117 *Id.*

118 *Id.* at 1058 n.2, 1059.

119 *Id.* at 1060.

120 *Id.*

121 *Id.*

122 *Id.*

123 *Id.*

124 *Id.*

unsuccessful judicial mediation process, in December 1997, Schering entered into a settlement agreement with ESI.[125] ESI agreed to postpone its generic version of K-Dur 20 from entering the market until January 1, 2004.[126] In return, ESI would receive up to $10 million in payments from Schering, but only if the FDA approved ESI's ANDA by a given date.[127] The settlement received approval from the judge that presided over the failed mediation process.[128] A side agreement allowed Schering to exclusively license two of ESI's generic products in exchange for a payment of $15 million.[129]

In March 2001, the FTC filed a complaint against Schering, Upsher, and AHP, alleging that the two settlement agreements, one between Schering and Upsher, and the other between Schering and ESI, were illegal because they placed a restraint on trade and violated the antitrust laws.[130] In December 2003, the FTC issued a Final Order, holding that "[a] payment for delayed generic entry under a Hatch-Waxman framework is no less anticompetitive than a similar payment under the 'traditional' regime."[131] Thus ruling that the agreements at issue were anticompetitive, the FTC pointed to the absence of evidence that "payments by pioneers to generics are a 'natural by-product of the Hatch-Waxman process' or that Congress intended to immunize payments of this kind."[132]

The Eleventh Circuit Court of Appeals reversed the FTC's finding that the agreements were anticompetitive and decided that because of the existing presumption that the patent relating to K-Dur 20 is a valid one, Schering may act to exclude anyone who infringes on its product.[133] Withholding any examination of the patent claims, the court held in light of Schering's allegations of patent infringement that it was legal for the company to make payments to generic manufacturers in return for their promises not to market competing products.[134] According to the Eleventh Circuit, the issue in this case turns on whether "the challenged agreements restrict competition beyond the exclusionary effects of the [patent.]"[135] Here they do not because both agreements

125 *Id.*
126 *Id.*
127 *Id.*
128 *Id.*
129 *Id.*
130 *Id.*
131 *In re* Schering-Plough Corp., No. 9297, 2003 FTC LEXIS 187, at *66 (FTC Dec, 8, 2003).
132 *Id.*
133 Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).
134 *Id.*
135 *Id.* at 1068.

stayed within the scope of the patent temporally as well as with respect to the subject matter covered by the patent.[136] The court concluded 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," and agreements such as those concluded between Schering and Upsher and Schering and ESI are, therefore, not *per se* illegal.[137]

3. In re Tamoxifen Citrate Antitrust Litigation (Second Circuit) [138]

In 2001, a number of consumer groups brought a class action lawsuit against AstraZeneca and Barr Laboratories ("Barr"), charging the defendants with conspiring in their 1993 settlement agreement to restrain generic competition, to "monopolize the market for tamoxifen [citrate]" ("tamoxifen"), a drug that is widely prescribed for breast cancer treatment, and to keep the prices for this drug "artificially high."[139] The United States Court of Appeals for the Second Circuit ultimately heard and decided this case.

Barr's 1987 Chapter IV ANDA application, filed two years after AstraZeneca's predecessor, Imperial Chemical Industries, PLC ("ICI"), had obtained a patent for its branded tamoxifen, Nolvadex, triggered an immediate infringement lawsuit.[140] The District Court for the Southern District of New York declared ICI's patent invalid, and ICI appealed the decision.[141] While the appeal was pending, Barr and AstraZeneca, who by this time inherited ICI's tamoxifen patent, entered into a $21 million settlement agreement, which incited over two dozen consumer groups to initiate a class action lawsuit.[142] The agreement stated that, in return for the reverse payment of $21 million and a license under which AstraZeneca would supply Barr with AstraZeneca-manufactured tamoxifen, which Barr would then sell under its own label (in effect, Barr would be selling an authorized generic), Barr would refrain from marketing its own generic version of the

136 *Id.* The court ruled that the exclusionary effects of the patent were respected by both agreements because they affected only the generic versions of K-Dur 20 with respect to the patented time-release mechanism and the restrictions placed on generic market entries did not exceed the date of patent expiry (in fact, both agreements expired well before K-Dur 20's date of patent expiry). *Id.*

137 *Id.* at 1076.

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

139 *Id.* at 374, 380.

140 *Id.* at 377.

141 *Id.*

142 *Id.*

drug.[143] Under the agreement, Barr sold the unbranded tamoxifen to distributors at a fifteen percent discount, as compared to Nolvadex, but when the drug reached consumers, its cost, as reported in 2001, was equivalent to that of Novadex.[144] Additionally, the agreement depended on having the courts vacate the previous judgment that declared the tamoxifen patent invalid.[145] The agreement was to be in place until either AstraZeneca's patent expired in 2002 or until another generic drug maker won an unappealable judgment against AstraZeneca that, as in Barr's case, declared the tamoxifen patent invalid.[146]

The Second Circuit vacated the district court's judgment invalidating its tamoxifen patent.[147] In 1998, Barr brought a claim for and was granted a 180-day period of exclusivity as the first successful ANDA filer.[148] Other generic manufacturers were prevented from marketing their own versions of tamoxifen until the six months granted to Barr expired.[149] Barr, however, as holder of the license to market AstraZeneca's tamoxifen under its own label, had no intent to manufacture its own generic version and did not trigger the 180-day exclusivity period until the settlement agreement expired in 2002, when AstraZeneca's patent finally ran out.[150]

In their class action lawsuit, the plaintiff consumer groups argued not only that the defendants violated antitrust laws by restraining trade, but also that the settlement agreement "effectively . . . circumvent[ed] the district court's invalidation of [Astra]Zeneca's tamoxifen patent."[151] If AstraZeneca continued with its appeal and the patent's invalidity was held up by the circuit court on appeal, the 180-day exclusivity period would have been triggered when Barr began marketing its own generic version of tamoxifen.[152] At the end of six months of exclusivity, other generic manufacturers would have entered the market, competing and effectively lowering the price of generic tamoxifen.[153]

The District Court for the Southern District of New York found for the defendants and dismissed the consumer groups'

143 *Id.*
144 *See Generic Drugs: The Stalling Game*, *supra* note 8, at 39.
145 *In re Tamoxifen*, 429 F.3d at 370.
146 *Id.*
147 *Id.*
148 *Id.*
149 *Id.*
150 *Id.*
151 *Id.* at 381.
152 *Id.*
153 *Id.*

lawsuit for failure to state a claim upon which relief could be granted.[154] The district court concluded that the settlement agreement did not restrain trade in violation of antitrust laws, as long as the agreement did not extend the monopoly beyond the scope of AstraZeneca's patent.[155]

The consumer groups appealed, but the Second Circuit, in November 2005, upheld the district court's decision.[156] In its holding, the Second Circuit observed that, at first glance, it may "seem 'suspicious'" for a patent holder to settle with a generic drug manufacturer for a greater sum than the manufacturer would have earned by marketing its generic, had he been victorious in the suit.[157] But, "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."[158] Such settlement agreements, therefore, do not violate any antitrust rules as long as they conform to the scope of the patent.[159] In light of the vacatur of the decision that invalidated AstraZeneca's tamoxifen patent (and subsequent infringement lawsuits, brought by other generic manufacturers against AstraZeneca, being resolved in AstraZeneca's favor — i.e., upholding the patent's validity), the Second Circuit also held that while an excessive reverse payment may hint at the patent holder's belief that its patent is weak, it does not provide sufficient grounds for holding that patent invalid.[160] Barr's postponement of triggering its 180-day period of exclusivity until AstraZeneca's patent ran out was not an antitrust violation, according to the Second Circuit, and can be "easily explained by Barr's own interest in protecting itself from competition through a petition to the FDA for a statutorily prescribed benefit."[161] The court thus rejected the plaintiffs' contention that Barr's actions with respect to the exclusivity period were implicit in the Settlement Agreement and taken in concert with AstraZeneca's attempts to restrict competition.[162]

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154 *Id.*
155 *Id.*
156 *Id.*
157 *Id.* at 392.
158 *Id.*
159 *Id.*
160 *Id.*
161 *Id.* at 402.
162 *Id.*

C. *Reverse Payment Settlement Agreements Summary and Main Theme*

Although the Sixth Circuit ruled that reverse payment settlement agreements place illegal restraints on trade in violation of antirust laws and are therefore *per se* illegal, it is important to note that there is at least one main difference between the case decided by the Sixth Circuit, *In re Cardizem CD Antitrust Litigation*, and the two cases decided by the Eleventh and the Second Circuits (*Schering-Plough Corp. v. FTC* and *In re Tamoxifen Citrate Antitrust Litigation*), which likely caused the circuits' decisions to differ. The Sixth Circuit was faced with a settlement agreement where the brand name drug manufacturer paid the generic drug maker to refrain from marketing its generic version of the branded drug – and any other generic versions of it not covered by the lawsuit – that may or may not have infringed on the patent. Additionally, in that case, Andrx and Hoescht entered into the agreement *after* the district court rendered a judgment in favor of the generic manufacturer, perhaps making it easier for the court to discern a restraint on competition.

The main theme among the three cases, however, is that for the courts to be able to find the reverse payment agreement legal, the agreement must stay within the scope of the underlying patent. Yet another factor that differentiated the Sixth Circuit case from the Eleventh and the Second Circuit cases is that the reverse payments made by the brand name drug manufacturer (Hoescht) to the generic drug maker (Andrx), under the termination options as provided for in the agreement, had the possibility of extending well after the natural life of the patent. As illuminated by the three cases discussed above, circuit courts view such an unnatural extension of monopoly as a clear restraint on trade in violation of antitrust laws. In sum, as long as the reverse payment agreement does not spill over the scope of the patent, there is a chance it will be upheld by the courts.

The courts are already restricting reverse payment settlement agreements to the life of the corresponding patents, and thus tightening the perceived loophole in the Hatch-Waxman Act that these agreements have been said to cause.[163] Legislative action may still be the only method of eliminating such agreements altogether. If reverse payments were outlawed, more infringement cases are likely to be litigated to judgment and, every time a patent is found to be invalid, at least one generic drug manufacturer (or

[163] The loophole caused by reverse payment agreements arises from the fact that the Hatch-Waxman Act does not expressly prohibit such arrangements. *See* 21 U.S.C. § 355 (2006); 35 U.S.C. § 271 (2006).

more than one if no 180-day exclusivity period applies) would be able to enter the market without having to wait for patent expiry, break up the brand name drug maker's monopoly, and potentially lower that drug's price as a result of competition.

V. GENERIC DRUG MANUFACTURERS HAVE ALREADY FOUND A WAY TO FIGHT THE HATCH-WAXMAN ACT LOOPHOLES ON THEIR OWN WITHOUT THE HELP OF LEGISLATIVE ACTION

A. *Use of the Credible Threat and At-Risk Launch Strategies: Sanofi-Synthelabo and Bristol-Myers Squibb v. Apotex*

Clopidogrel bisulfate, the active ingredient in the blockbuster blood thinner drug Plavix, which resulted from a partnership among Sanofi-Aventis, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership ("Sanofi"), was patented by Sanofi in 1989 (the '265 patent) and is set to expire in November 2011.[164] In November 2001, Apotex, Inc. and Apotex Corporation ("Apotex") filed a Paragraph IV ANDA with the FDA, asking for permission to manufacture and market clopidogrel bisulfate.[165] In its application, Apotex claimed that Sanofi's '265 patent was invalid.[166] Apotex was the first in time filer of an ANDA challenging the '265 patent and as such was entitled to the 180-day period of exclusivity under the Hatch-Waxman Act.[167] Sanofi, in response, sued Apotex for patent infringement, triggering the thirty-month stay period on the FDA's approval of Apotex's application.[168] Apotex brought a counterclaim, stating that the subject matter of the '265 patent would have been obvious to a person of ordinary skill because the '265 patent was anticipated by one of Sanofi's already expired patents.[169] Apotex further counterclaimed that "the '265 patent is unenforceable on the basis of Sanofi's alleged inequitable conduct before the U.S. Patent and Trademark Office . . . ."[170] Both parties agreed that Apotex's ANDA filing was an act of infringement on Sanofi's 265 patent, meaning that the Paragraph IV certification applied.[171]

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164 Sanofi-Synthelabo v. Apotex, 488 F. Supp. 2d 317 (S.D.N.Y. 2006).
165 *Id.*
166 *Id.*
167 *Id.*
168 *Id.*
169 *See* Carreyrou & Lublin, *supra* note 16, at A1.
170 *Sanofi-Synthelabo*, 488 F. Supp. 2d at 323.
171 *Id.*

In January 2006, eight months after the thirty-month stay expired, the FDA approved Apotex's ANDA.[172] But, in October 2005, three months before the FDA authorized Apotex's ANDA, Apotex, using the at-risk launch strategy,[173] informed Sanofi in a letter that it would launch the generic product as soon as possible upon final approval of its application — that is, before resolution of the pending litigation as to the validity of Sanofi's '265 patent.[174] The threat of Apotex's generic drug launch was credible because Apotex had previously carried out an at-risk launch.[175] Apotex also had the necessary quantities of the drug manufactured and ready to be marketed.[176]

Likely pressured by the credibility of Apotex's threat of an at-risk launch, and discounting the fact that its patent has already been declared valid by the courts of two other countries, a few days before the FDA granted the anticipated ANDA approval, Sanofi entered into settlement negotiations with Apotex.[177] The resulting settlement agreement provided that "Apotex would not launch its generic and Sanofi would not move for . . . [a preliminary] injunction during settlement negotiations."[178] A second agreement, executed in February 2006, memorialized Sanofi's consent to postpone the trial date in order to accommodate the schedule of Apotex's counsel, and reiterated the agreement that neither Sanofi nor Apotex would launch a generic and that Sanofi would not move for any injunctions or restraining orders during the postponement.[179] The parties reached a settlement agreement three months before the trial, but due to an order resulting from a previous Bristol-Myers Squibb action, the agreement had to be approved by the FTC and a group of the attorneys general.[180] Under the agreement, Sanofi would pay Apotex $40 million to delay the launch of its generic until the '265 patent expired in 2011, and Sanofi in turn would not market an authorized generic.[181] Sanofi and Bristol-Myers Squibb additionally agreed to pay Apotex a $60 million break-up fee if the deal was ultimately rejected by the regulatory authorities.[182]

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172 *Id.*

173 *See* Carreyrou & Lublin, *supra* note 16, at A1 (explaining that the launch is "at-risk," because if the generic drug manufacturer loses the patent case, it can be liable for triple the damages incurred by the brand-name company).

174 See *id.*; *see also Sanofi-Synthelabo*, 488 F. Supp. 2d at 323.

175 *See* Carreyrou & Lublin, *supra* note 16, at A1.

176 *Id.*

177 *Id.*

178 *Sanofi-Synthelabo*, 488 F. Supp. 2d at 324.

179 *Id.*

180 *Id.*

181 *See* Carreyrou & Lublin, *supra* note 16, at A1.

182 *Id.*

The first settlement agreement was rejected, and the parties negotiated a second, revised, version of the agreement.[183] That version, however, was also rejected.[184] A clause in the second agreement stated that if the FTC and the attorneys general failed to approve a settlement agreement by July 31, 2006, either party could declare "regulatory denial," which Apotex did declare on that date.[185] In case of such a denial, the agreement provided for a number of provisions to take effect.[186] First, the parties would return to litigating the issues, and, if the '265 patent was found to be valid and enforceable, Sanofi's infringement damages would be categorically limited to 50% of Apotex's net sales of the generic.[187] The 50%-damage-capping clause reduced Apotex's potential liability from triple to double the damages and thus considerably mitigated the risk borne by Apotex of launching its generic before the outcome of the trial.[188] Additionally, for five business days following the declaration of regulatory denial, Apotex agreed not to launch its generic and Sanofi agreed not to launch an authorized generic or to move for a restraining order or a preliminary injunction.[189] Sanofi further agreed to refrain from launching its own authorized generic or from seeking an injunction or a restraining order for five additional business days after Apotex has launched its generic product.[190] This part of the agreement "would give Apotex enough time to flood U.S. pharmacies with its product."[191] With these conditions in place, a second regulatory rejection of the agreement was highly advantageous for Apotex.[192]

As soon as Apotex declared regulatory denial, Sanofi moved for a temporary restraining order in an attempt to bar Apotex from marketing its generic.[193] Sanofi's motion was denied on the grounds that it would be a breach of the agreement provisions, and eight days later Apotex launched its generic version of clopidogrel bisulfate.[194] Sanofi then notified Apotex and moved for a preliminary injunction five business days after Apotex's launch, asking the court to prevent Apotex from further distributing its generic product and to force the generic drug

183 *Sanofi-Synthelabo*, 488 F. Supp. 2d at 324.
184 *Id.*
185 *Id.*
186 *Id.*
187 *Id.* at 325.
188 *See* Carreyrou & Lublin, *supra* note 16, at A1.
189 *Sanofi-Synthelabo*, 488 F. Supp. 2d at 325.
190 *Id.*
191 *See* Carreyrou & Lublin, *supra* note 16, at A1.
192 *See id.*
193 *Sanofi-Synthelabo*, 488 F. Supp. 2d at 325.
194 *Id.*

maker to recall the quantities that it had already distributed.[195]

B. Legal Outcome of the Credible Threat and At-Risk Launch Strategies

Three weeks after Apotex's launch of its generic clopidogrel bisulfate product, the District Court for the Southern District of New York handed down its decision on Sanofi's preliminary injunction suit on August 31, 2006.[196] In its opinion, the district court stated that Sanofi not only showed that it is likely to prevail over Apotex's claims of the '265 patent's invalidity, but that the brand-name drug manufacturer will also "suffer irreparable harm" if Apotex were to continue distributing its infringing generic version of clopidogrel bisulfate until a decision in the patent validity litigation is reached.[197] The court declared that there was a likelihood that Sanofi was going to win the patent case on the merits because Apotex failed to raise substantial issues that could lead to the invalidation of the patent.[198] After finding that Sanofi would be likely to prevail on the merits of the patent case, Judge Sidney H. Stein granted the brand name manufacturer "the benefit of a presumption of irreparable harm."[199] In addition to being assigned this presumption, Sanofi also presented evidence that "it will suffer irreversible price erosion, loss of good will, and will be forced to lay off personnel and discontinue research devoted to developing other medical uses for Plavix."[200] At the time of Apotex's product's launch, Sanofi did, in fact, suffer price erosion; to stay competitive with the newly-launched generic, Sanofi was forced to provide rebates and discounts to third party payers in order to keep them from moving Plavix to a less favorable pricing tier on their drug formularies.[201]

The district court moreover found that the balance of incurred hardships tipped in Sanofi's favor.[202] If the injunction were granted to Sanofi, Apotex would lose at least some of the 180-day exclusivity period and the profits associated with it.[203] It would also lose a great portion of the market share (40-45%) that generic manufacturers usually gain during the exclusivity period.[204] Apotex, however, would suffer these difficulties as a

195 *Id.*
196 *Id.* at 350.
197 *Id.* at 344.
198 *Id.* at 341.
199 *Id.* at 342.
200 *Id.*
201 *Id.*
202 *Id.* at 345.
203 *Id.* at 344.
204 *Id.*

result of its own calculated risk-taking, while Sanofi, whose patent, the court found, is likely to be found valid once the pending patent case is decided on the merits, would be subject to "irreparable harm" as a result of Apotex's risk-taking strategy.[205] Finally, the court found that the competing public interests in this case (cheaper version of the drug being available to the consumer as a result of generic competition versus protecting the inventor's patented invention in order to encourage investment in new uses of the drug as well as other new compounds) balance slightly in favor of Sanofi when both parties' agreement with respect to infringement on the '265 patent is taken into consideration.[206] Based on these and a handful of other factors, the district court granted Sanofi's motion in part and denied it in part; it enjoined Apotex from marketing its generic product any further, but it denied Sanofi's request to recall the product that Apotex has already placed on the market during the three weeks of its activity prior to this partial injunction.[207]

C. Discussion and Aftermath of Sanofi-Synthelabo v. Apotex

According to a Wall Street Journal article,[208] Apotex's strategy was to entice Bristol-Myers Squibb and Sanofi-Synthelabo into negotiating an agreement that Apotex projected would be ultimately rejected by the regulatory authorities. Apotex counted on the regulatory rejection so that it could subsequently execute an at-risk launch of its generic and flood the U.S. pharmacies' shelves with its product before the district court was able to issue an injunction.[209] Apotex negotiated the second agreement so that the provisions triggered by regulatory denial would work entirely to Apotex's advantage.[210] Because Sanofi agreed to wait for five business days to move for a preliminary injunction, Apotex had sufficient time to launch its ready supply of the generic product upon the market. Furthermore, since the generic drug maker negotiated a 50% cap on reimbursing Sanofi for sustained damages if the '265 patent were found to be valid and enforceable, Apotex may still be able to profit from its at-risk launch even if it loses the patent litigation.[211]

Although Sanofi received the preliminary injunction that it

205 *Id.* at 345.
206 *Id.* at 346.
207 *Id.* at 348-49.
208 *See* Carreyrou & Lublin, *supra* note 16, at A1.
209 *Id.*
210 *Id.*
211 *Id.*

requested, Apotex was excused from recalling the generic product that it had already distributed, which means that however much it was able to put on the pharmacies' shelves, will remain there for the consumer.[212] Apotex's careful planning for its generic launch in early August ensured that enough generic product had been sold to wholesalers to last into 2007.[213] Due to Apotex's at-risk strategy, "[i]n the [first] three weeks since its launch, generic Plavix has conquered nearly 75% of the U.S. market for the drug,"[214] and Apotex was, in fact, able to keep its market lead for a period of five months while U.S. sales of Sanofi's brand name drug plummeted.[215] On January 11, 2007, AFX Financial News reported that U.S. sales of Plavix have finally rebounded to levels that exceed the sales of Apotex's generic product.[216] Plavix's recovery was brought about by the August 31, 2006 injunction that caused the market supply of the generic to dwindle in January 2007.[217] Damage caused to Bristol-Myers Squibb and Sanofi-Synthelabo by Apotex supplying the market with its generic version of Plavix for a mere three weeks could be measured in "hundreds of millions of dollars in revenue."[218]

VI. CONCLUSION: LEGISLATIVE ACTION IS UNNECESSARY TO CLOSE THE PERCEIVED HATCH-WAXMAN ACT LOOPHOLES

While calls for legislative reform to close the Hatch-Waxman Act's perceived loopholes have been made, it is the contention of this Note that such reform is not necessary. For one, generic drug manufacturers have been finding effective ways to fight back against the brand-name drug makers, looked upon by some as Hatch-Waxman Act abusers. Generic drug makers have adapted reverse payment agreement strategies to their own economic advantage and, as in the case of Apotex, discussed *supra*, have successfully used at-risk launches in the same manner. It is important to note that, under some reverse payment agreements, the generic manufacturer is allowed to sell a cheaper version of the brand name drug even during the period that the agreement is in effect.[219]

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212 *Id.*

213 *Id.*

214 *Id.*

215 *Sales of Sanofi-Aventis Blockbuster Drug Plavix Rebound in US*, AFX FINANCIAL NEWS, Jan. 11, 2007, http://abcmoney.co.uk/news/1120074333.htm.

216 *Id.*

217 *Id.*

218 *See* Carreyrou & Lublin, *supra* note 16, at A1.

219 *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005). *But see Generic Drugs: The Stalling Game*, *supra* note 8, at 40 (explaining that even though Barr sold

Legislative action aimed at negating the legality of reverse payment agreements is unlikely to help the generic manufacturer that is barred from entering the market by a reverse payment agreement. In fact, the generic manufacturer may be economically harmed, rather than helped, by such legislation. As demonstrated by the agreement between AstraZeneca and Barr in *In re Tamoxifen Citrate Antitrust Litigation*, generic manufacturers that enter into reverse payment settlement agreements can be paid more by the brand name pharmaceutical company than they would make if they were to market their generic versions of the branded product.

Apotex's at-risk strategy is evidence that generic drug manufacturers are responding to brand-name pharmaceutical companies' gaming of the Hatch-Waxman Act; today, generic manufacturers are successfully gaming the brand name drug makers. Unfair play, it seems, is no longer confined to the toolbox of brand name pharmaceutical giants. Generic manufacturers are devising effective strategies, such as at-risk launches, in an attempt to enter the pharmaceutical market. They are not merely helping themselves by reaping the financial rewards of entering the pharmaceutical market before scheduled patents expire, but they are also engendering competition and are thus in the position to bring down drug prices for the consumer.[220]

But even with the presence of generics on the market, is the consumer necessarily better off? Attempting to close these loopholes through legislative action may benefit the generic drug company, but benefits to the consumer are likely to be elusive at best. While judicial courts, consumer groups, and regulatory authorities do not generally favor settlement agreements, generic and brand name drug manufacturers have been entering into them and receiving approval from the courts.[221] It is argued that eliminating reverse payment agreements — and other Hatch-Waxman Act loopholes, such as the thirty-month stay period, the authorized generic practice, and citizen petitions — through legislative action may give the consumers access to cheaper generic versions of brand-name drugs sooner. However, as it is commonly acknowledged, for Congress to pass a new law or to

Astra Zeneca's AG to distributors at a fifteen percent discount, by the time the medicine reached the consumer, it cost as much as the branded drug).

220 By negotiating a settlement deal with Sanofi that it knew the regulators were likely to reject, Apotex essentially saved the consumers "at least $1billion a year," according to a former FTC antitrust enforcer David Balto. John Carreyrou, *States Reject Deal on Plavix, in Blow to Bristol-Myers*, WALL ST. J., July 29, 2006, at A2.

221 *See, e.g. In re Tamoxifen*, 429 F.3d at 370; Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

amend an existing one, it would require not only a great deal of time, but also an expenditure of consumers' dollars. The consumers and generic manufacturers will still be left to contend with lengthy infringement trials. In addition, as is sometimes the case with new legislation (the Hatch-Waxman Act being a prime example), new loopholes may arise. Furthermore, even though generics usually cost significantly less than brand-name medications, most pharmacies are reluctant to pass the savings on to the consumer and thereby decrease their own sales margins.[222] Finally, it is likely that only years of research studies or sophisticated financial analysis could reveal whether the cost of taking legislative action to close the Act's loopholes would outweigh the resulting benefit to the consumer.

*Yana Pechersky**

222 Sarah Rubenstein, *Why Generic Doesn't Always Mean Cheap:* Zocor *Case Shows Drugstores May Offer Only Small Savings Over Brand-Name Drug Prices*, WALL ST. J., Mar. 13, 2007, at D1.

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