University of Baltimore Law Review

Volume 41
Issue 3 *Spring 2012*

Article 7

2012

Comments: Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements

Alyssa L. Brown
University of Baltimore School of Law

MODEST PROPOSALS FOR A COMPLEX PROBLEM: PATENT MISUSE AND INCREMENTAL CHANGES TO THE HATCH-WAXMAN ACT AS SOLUTIONS TO THE PROBLEM OF REVERSE PAYMENT SETTLEMENTS.

I. INTRODUCTION

As the country struggles with myriad economic problems, the escalating cost of health care in the United States has attracted much attention.[1] The high cost of brand-name medications is one issue in the spotlight.[2] In 2008, Americans spent $2,339 billion on health care, accounting for 16.2% of the country's gross domestic product.[3] Of that, $234.1 billion was spent on prescription medications.[4] The Kaiser Family Foundation reports that prescription drugs account for approximately 10% of health care spending in the United States annually.[5] Further, the Department of Health and Human Services projects that prescription drug spending will increase from $234.1 billion in 2008 to $457.8 billion in 2019, almost doubling over the 11-year period.[6]

The introduction of generic medications can reduce the cost of medications to consumers.[7] However, the entry of generic

1. *See, e.g.*, Robert Pear, *Economy Led Americans to Limit Use of Routine Health Services, Study Says*, N.Y. TIMES, Aug. 17, 2010, at A14.
2. *See, e.g.*, Editorial, *The High Cost of Health Care*, N.Y. TIMES (Nov. 25, 2007), http://www.nytimes.com/2007/11/25/opinion/25sun1.html?pagewanted= all.
3. CMS Office of the Actuary, *Health Spending Climbs to 16.2% of GDP*, HEALTHCARE ECONOMIST (Jan. 25, 2010), http://healthcare-economist.com/2010/01/25/health-spending-climbs-to-16-2-of-gdp/; *U.S. Total Real National Health Expenditures Using Alternative Price Deflators: 1929 to 2019*, AMERICAN, www.google.com (search "Google" for "U.S. Total Real National Health Expenditures Using Alternative Price Deflators: 1929 to 2019"; click on the link titled, "Table 1.1 The American") (last visited May 30, 2012).
4. KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS 1 (2010), *available at* http://www.kff.org/rxdrugs/upload/3057-08.pdf.
5. *Id.*
6. *Id.* at 8.
7. *Abbreviated New Drug Application (ANDA): Generics*, FDA, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/default.htm (last visited May 30, 2012) ("A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristicsand intended use.").

medications to the market prior to the expiration of a brand-name medication's patent is anything but simple, and the brand-name manufacturer often files suit against the generic challenger for patent infringement.[8]

Due to these suits between brand-name drug manufacturers and generic drug manufacturers, so-called "reverse payment settlements" are on the rise.[9] The agreements earned their name because unlike a typical settlement, the patent holder who brought the suit pays or otherwise compensates the alleged infringer, the generic manufacturer.[10] Some critics label these agreements as "pay to delay" agreements because generic drug manufacturers often receive substantial payments or other incentives in exchange for delaying or not marketing the sale of their generic competitors.[11] As a result, the Federal Trade Commission (FTC), the Department of Justice, and private parties, such as consumers, have challenged these agreements as violations of antitrust law.[12] A split between the Sixth, Second, Eleventh, and Federal circuits has emerged.[13] Congress has also proposed solutions through legislation such as the Preserve Access to Affordable Generics Act.[14]

This comment considers first the process by which generic medications enter the market and the statutory incentives in place to encourage generic manufacturers to enter the market prior to the expiration of a brand-name medication's patent.[15] Second, different approaches adopted by the courts and proposed by Congress with respect to reverse payment settlements will be addressed.[16] Finally,

---

8. *See infra* Part II.
9. FTC, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, AN FTC STAFF STUDY 1, 8 (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (noting that manufacturers entered three such agreements in 2005, fourteen in 2006, fourteen in 2007, sixteen in 2008, and nineteen in 2009).
10. Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 205 (2d Cir. 2005) (quoting David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000)) ("Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as "reverse" payments because, by contrast, '[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder.'").
11. *See, e.g.*, Editorial, *Faint Progress on Drug Payoffs*, N.Y. TIMES, Aug. 10, 2010, at A24.
12. *See infra* Part IV.B.
13. *See infra* Part IV.B.
14. Preserve Access to Affordable Generics Act, S.27, 112th Cong. (2011); *see infra* Part IV.C.
15. *See infra* Parts II–III.
16. *See infra* Part IV.

alternative solutions will be addressed including whether an ample solution to the perceived problem of reverse payment settlements already exists under the doctrine of patent misuse or if an incremental change to the Hatch-Waxman Act, tweaking the incentives available to the first generic manufacturer to enter the market, offers the best solution.[17]

II. BACKGROUND

A. The Hatch-Waxman Act

In response to escalating drug costs, Congress changed the way the Food and Drug Administration (FDA) approves new drugs for marketing and sale in the United States in 1984 when it passed the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).[18] The legislation sought to lower the average price paid by consumers for prescription pharmaceuticals.[19] To achieve this goal, the Act established an abbreviated new drug application (ANDA) to bring generic drugs to the market faster.[20] The Act also included provisions to encourage generic manufacturers to challenge the patents of brand-name pharmaceutical companies.[21]

1. Abbreviated New Drug Applications: Getting Generics to Market Faster

Prior to the change in the law, manufacturers seeking to market a generic version of an existing drug faced the same rigorous standards as new drug applications (NDA).[22] Today, a generic manufacturer of a previously patented medication can circumvent many of the restrictions on the original manufacturer.[23] Generic manufacturers

17. *See infra* Part V.
18. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1538 (codified as amended in scattered sections of 21 & 35 U.S.C.).
19. Schering-Plough Corp. v. FTC, 402 F.3d 1056, n.2 (11th Cir. 2005). The legislation also served a goal somewhat at odds with reducing consumer prices, "preserv[ing] the technologies pioneered by the brand-name pharmaceutical companies" and continuing to encourage research and development. *See id.*
20. *Id.*
21. *See infra* Part II.A.1–2.
22. *See* 21 U.S.C. § 355(a)-(b) (2006); 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); Fiona M. Scott Morton, *Entry Decisions in the Generic Pharmaceutical Industry*, 30 RAND J. ECON. 421, 422 (1999).
23. 21 U.S.C. § 355(j) (2006).

filing an ANDA avoid the lengthy and costly process of independently demonstrating the safety and efficacy of their products because they need only to "demonstrate the 'bioequivalence' [of the generic medication] to an already-approved innovator drug."[24] Generic manufacturers can also file an application for approval through the FDA prior to the expiration of the brand-name patent.[25]

Since 1984, the number of generic pharmaceuticals entering the market has risen dramatically.[26] Prior to the enactment of the Hatch-Waxman Act, generic medications for top-selling drugs could take more than three years to enter the market following the expiration of the brand-name drug's patent.[27] Today, introduction of a generic often occurs in less than three months after a brand-name drug's patent expires.[28]

2. Additional Incentives for Generics to Enter the Market Sooner

Streamlining the application process for generic manufacturers is only one mechanism built into the Hatch-Waxman Act to bring less expensive generic medications to consumers faster. The Hatch-Waxman Act also contains a provision that encourages generic pharmaceutical manufacturers to challenge the validity of the patents of brand-name pharmaceutical manufacturers prior to their expiration.[29]

---

24. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at xii (1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf. "Bioequivalence means that the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the innovator drug." *Id.*

25. 21 U.S.C. § 355(j); *see also infra* Part II.A.2.

26. CONG. BUDGET OFFICE, *supra* note 24, at 27.

> Since the [Hatch-Waxman Act] became law in 1984, the market share of generic drugs has indeed been rising steadily—although not all of that increase stems from the act. For drugs that come in easily countable units, such as tablets and capsules, the share of generic units sold more than doubled between 1984 and 1996—from 18.6 percent of all drug units sold to 42.6 percent.

Id. A greater desire by consumers to purchase generic medications as well as changes to state laws making it easier for pharmacists to prescribe generic substitutes are two other sources for the change. *Id.* at xiv.

27. *Id.* at ix.

28. *Id.*

29. Op-Ed., *The "Pay for Delay" Rap: The Drug Industry, the FTC and Overzealous Antitrust*, WALL ST. J., Oct. 5, 2010, at A22.

a. Paragraph IV certifications

During the application process, an ANDA filer must submit one of four types of certifications.[30] The most common of these certifications are so-called "Paragraph III" and "Paragraph IV" certifications. In a Paragraph III certification, the ANDA applicant indicates that the FDA should certify its application upon the expiration of the brand-name pharmaceutical's patent.[31] By filing a so-called "Paragraph IV certification," the applicant certifies that the relevant patent(s) on the brand-name drug are either "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[32]

Once the FDA receives an ANDA filing, it has 180 days to accept it.[33] After the FDA accepts an application containing a Paragraph IV certification, the ANDA filer has twenty days to notify the brand-name patent holder of its application.[34] Specifically, the ANDA applicant must inform the brand-name patent holder of the reasons the applicant believes the patent is either not infringed or is invalid.[35] The patent owner then has forty-five days to respond.[36] If the patent owner sues for infringement within this period, the FDA institutes an automatic thirty-month stay on the generic manufacturer's ANDA approval.[37] This stay remains effective until the end of thirty months

30. 21 U.S.C. 355(j)(2)(A)(vii).

> [A] certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section-
> (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 drug for which the application is submitted.

Id.

31. *Id.* § 355(j)(2)(A)(vii)(III).
32. *Id.* § 355(j)(2)(A)(vii)(IV).
33. *Id.* § 355(j)(5)(A).
34. 21 U.S.C.A. § 355(b)(3)(B)(i) (2010).
35. 21 U.S.C. § 355(j)(2)(B) (2006).
36. *Id.* § 355(j)(5)(B)(iii).
37. *Id.*

or until a court decision is reached regarding the infringement suit, whichever is earlier.[38]

b. 180-day exclusivity period granted to first ANDA filer

The first ANDA filer to make a Paragraph IV certification and gain FDA approval is rewarded with a 180-day market exclusivity during which no subsequent ANDA filers can commence marketing of their own generic version of the drug.[39] As discussed in Part IV.A, when this exclusivity period commences depends on the circumstances.[40] As a result of this exclusivity period, more generic filers are seeking to enter the market sooner and Paragraph IV filings have substantially increased.[41]

III. RISE OF "REVERSE PAYMENT SETTLEMENT" AGREEMENTS

The lure of a 180-day exclusivity period to generic pharmaceutical manufacturers as well as the high stakes at play for brand-name manufacturers facing Paragraph IV challenges has had a significant impact on the way such suits are litigated and settled.[42] As a result, reverse payment settlement agreements between brand-name and generic medication manufacturers are on the rise.[43] These

38. *Id.* Notably, launching a generic pharmaceutical at the end of the thirty-month stay but before a court decision regarding the Paragraph IV certification is not without risks. Generic companies whose products are found to infringe *after* such a launch may be liable for treble damages. RBC CAPITAL MKTS. CORP., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 3–4 (2010), *available at* http://amlawdaily.typepad.com/pharmareport.pdf.

39. 21 U.S.C. § 355(j)(5)(B)(iv).

40. *See infra* Part IV.A.

41. RBC CAPITAL MKTS. CORP., *supra* note 38, at 3 (indicating the following trend for first-to-file lawsuits since 2003: thirteen (2003), fifteen (2004), twenty-four (2005), twenty-seven (2006), forty-three (2007), fifty-one (2008), and sixty-five (2009)).

42. Loss or expiration of patent protection of a brand-name pharmaceutical has significant implications for its manufacturer. For example, Pfizer's anticipated yearly revenue loss due to the expiration of its Lipitor patent was $10 billion. Duff Wilson, *Drug Firms Face Billions in Losses in '11 as Patents End*, N.Y. TIMES, March 7, 2011, at A1, *available at* http://www.nytimes.com/2011/03/07/business/07drug.html?page wanted=2&sq=Drug Firms Face Billions in Losses in '11 as Patents End&st=cse&scp=1. When its patent for Claritin expired in 2003, Schering Plough saw its stocks' value drop 20% while annual sales for the drug plummeted from $2 billion in 2002 to less than $200 million in the first half of 2003. Amy Tsao, *Schering-Plough: Drugmaker, Heal Thyself*, BUSINESSWEEK ONLINE, June 11, 2003, http://www.businessweek.com/technology/content/jun2003/tc20030611_0956_tc055.htm.

43. FTC, *supra* note 9, at 1.

agreements earned their name because they travel in the opposite direction of a typical settlement—the patent holder who brought the suit originally makes a settlement payment to the alleged infringer, the generic manufacturer.[44]

Reverse payment settlements take a variety of forms. They can vary from a cash payment from the brand-name to the generic manufacturer to an agreement by the generic manufacturer to stay out of the market for a set period of time ("with or without royalty payments to the brand-name manufacturer").[45] Agreements can also include provisions for "ancillary business transactions such as cross-licensing or supply agreements" or provide that the brand-name manufacturer will not market or license an authorized generic for a set time after the generic manufacturer launches its product.[46] It is not uncommon for agreements to include a combination of these provisions.[47]

A. Impact of Reverse Payment Settlements on Consumers

The introduction of generic versions of brand-name medications has the potential to significantly lower the cost of pharmaceuticals to consumers over time. As such, reverse payment settlements are criticized in part due to their potential to slow consumers' access to generic medications and keep medication prices higher for longer.[48] In 2008, on average, brand-name prescription medications cost four times more than generic medications ($137.90 compared to $35.22).[49] In that same year, generic medications accounted for 22% of the total drug sales in the United States and 72% of the total prescriptions dispensed.[50]

While the exact impact of the introduction of generic pharmaceuticals on consumer prices is subject to some debate,[51] it is

---

44. *See supra* note 10.
45. Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 374 (2010).
46. *Id.* An authorized generic is a drug that has been approved by the Food and Drug Administration as a brand-name medication, which the brand-name manufacturer decides to market simultaneously with the brand-name version of its medication, but under different trade dress and at a generic price. FTC, AUTHORIZED GENERICS: AN INTERIM REPORT 1 (2009), *available at* http://www.ftc.gov/os/2009/06/P062105 authorizedgenericsreport.pdf.
47. *See infra* Part IV.B.
48. *Faint Progress on Drug Payoffs*, *supra* note 11.
49. KAISER FAMILY FOUND., *supra* note 4, at 3.
50. *Id.* at 4.
51. *See* CONG. BUDGET OFFICE, *supra* note 24, at 29.

clear that increased competition reduces prices.[52] Studies by the FDA indicate the first generic competitor typically enters the marketplace at a price point only slightly lower than its brand-name counterpart, resulting in only small savings to a consumer.[53] However, the entrance of a second generic manufacturer to the market can decrease the cost of a generic version of a medication to half that of its brand-name counterpart.[54] Further, the entry of a significant number of generic manufacturers into the marketplace can result in a price point for the generic medications at a rate 20% or lower than the cost of the brand-name drug.[55]

A Congressional Budget Office (CBO) report suggests a slightly different impact on prices as the result of the introduction of generic pharmaceuticals than the FDA's estimates.[56] The CBO report indicates that the first generic competitor to enter the market typically enters at a price point 25% lower than the brand-name pharmaceutical.[57] The introduction of additional generic medications can lower the market price by as much as 60% of the brand-name price.[58]

The FTC estimates that reverse payment settlements cost American consumers anywhere between $0.6 billion and $7.5 billion each year, or $3.5 billion each year on average.[59] As such, the FTC asserts that banning these agreements outright has the potential to save consumers $35 billion over the course of a decade.[60]

---

52. FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at ii–iii, 63, 118 (2011), *available at* http://www.ftc.gov/os/2011/08/2011generic drugreport.pdf; *Generic Competition and Drug Prices*, FDA, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

53. *Generic Competition and Drug Prices*, *supra* note 52.

54. *Id.*

55. *Id.*; *see also* CONG. BUDGET OFFICE, *supra* note 24, at xiii ("[W]hen one to 10 firms are manufacturing and distributing generic forms of a particular drug, the generic retail price of that drug averages about 60 percent of the brand-name price. When more than 10 manufacturers have entered the market, the average generic prescription price falls to less than half of the brand-name price.").
Paradoxically, the Congressional Budget Office study also suggested that brand-name pharmaceutical prices actually increase after the introduction of a generic competitor. *Id.* at 29. One study found a one percent increase in the brand-name price as a result of each new generic competitor that entered the marketplace. *Id.*

56. CONG. BUDGET OFFICE, *supra* note 24, at xiii.

57. *Id.*

58. *Id.*

59. FTC, *supra* note 9, at 8, 10.

60. *Id.* (calculating the ten-year average on the basis of the $3.5 billion per year average).

B. *180-day Exclusivity Period and Its Impact on Reverse Payment Settlements*

Eligibility for the 180-day exclusivity period is a significant incentive to generic manufacturers to be the first ANDA filer since they are guaranteed a window of time where they are competing only with the brand-name manufacturer.[61] Further, even if the first ANDA filer enters the market at a price point as much as 25% below the brand-name price, it still enjoys a greater profit margin than subsequent generic manufacturers who might drive generic prices down to less than 50% of the market price of the brand-name drug.[62]

The exclusivity period also bestows upon the first ANDA filer a unique bargaining power, which fuels the reverse payment settlement system.[63] In some situations, a generic manufacturer has strong incentives to settle an infringement suit rather than proceed to trial. For example, the potential profits the generic manufacturer stands to gain on entry into the market may be outweighed by the potential loss in profits faced by the brand-name manufacturer when it must compete with a generic medication.[64] The uncertainties of the litigation process can also influence generic and brand-name manufacturers, with the generic manufacturer settling to avoid the "risk of losing the case and being unable to market during the life of the patent" and the brand-name settling in order to avoid the risk of "losing the case and revenues from the patent exclusivity altogether" if the court finds its patent invalid.[65]

---

61. *See supra* Part II.A.2.b.

62. *See* CONG. BUDGET OFFICE, *supra* note 24, at xiii; *see also* text accompanying notes 57–58.

63. Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 90, 91 n.201, 92–93 (2010).

64. *Id.* at 93.

> [If] the ANDA filer has a ten percent chance of victory at trial, the generic stands to earn $10 million if it wins and enters the market, and the patent holder stands to lose $200 million if it loses its monopoly. The ANDA filer's expected value is $1 million ($10 million multiplied by a ten percent chance of victory). The patent holder's expected loss is $20 million ($200 million multiplied by a ten percent chance of loss at trial). These different expected values establish a bargaining range of $1 million to $20 million.

Id. at 94.

65. Gerard Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 52 (2010).

Importantly, due to more recent changes in the law, the first ANDA filer retains its 180-day exclusivity period despite entering a settlement.[66] As a result, some agreements offer a compromise between the two extremes, with a first ANDA filer agreeing to delay marketing of its generic for a specified period, but still being able to commence sales prior to the expiration of the brand-name drug's patent.[67] Given these considerations, both the brand-name manufacturer and the first ANDA filer stand to benefit greatly in some circumstances by settling their lawsuit and preventing or delaying the generic medication's entry into the market.

IV. APPROACHES TO THE REVERSE PAYMENT PROBLEM

Although no such agreements were entered into in 2004, a recent study indicates that reverse payment settlements have been rising steadily over the last few years.[68] The increased prevalence of these agreements has led to myriad proposed solutions with some courts and critics considering them to be illegal restraints of trade that should be subject to antitrust law.[69]

A. An Early Effort: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), represents one attempt to deal with the continued rise of prescription drug prices and the advent of reverse payment settlements following the implementation of the Hatch-Waxman Act.[70] The MMA effectively changed the playing field by altering the events that trigger an ANDA filer's 180-day exclusivity period and implementing six provisions whereby the first ANDA filer forfeits the exclusivity period.

Prior to MMA, the earlier of one of two events could trigger the 180-day exclusivity period: (1) a final court decision holding the brand-name patent invalid, unenforceable, or uninfringed, or (2) the commencement of commercial sales by the first ANDA applicant.[71]

---

66. *See infra* Part IV.A.
67. *See infra* Part IV.B.2.b.
68. FTC, *supra* note 9, at 1 (noting that manufacturers entered three such agreements in 2005, fourteen in 2006, fourteen in 2007, sixteen in 2008, and nineteen in 2009).
69. *See infra* Part IV.B.
70. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.).
71. La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 901 (6th Cir. 2003) (citing Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003)).

As a result, if a brand-name and generic manufacturer entered a reverse payment settlement, subsequent ANDA filers were effectively blocked from entering the market until the expiration of the brand-name patent because the first ANDA filer's 180-day exclusivity period was never triggered.[72] Under the MMA, the 180-day exclusivity period can now be triggered only by the commencement of commercial sales by the first ANDA filer.[73] Additionally, the 180-day exclusivity period is limited in that it does not extend beyond the life of the patent of the innovator drug.[74]

The MMA also added six provisions whereby the first ANDA filer would forfeit its 180-day exclusivity period.[75] If all first ANDA filers forfeit their 180-day exclusivity, subsequent ANDA applicants are ineligible for the 180-day exclusivity period, but can still attempt to enter the market prior to the expiration of the brand-name patent.[76]

First, forfeiture can result from the withdrawal of the ANDA filer's application[77] or second, by amendment of the Paragraph IV certification after filing.[78] Third, failure of the ANDA filer to obtain approval of its application from the FDA within thirty months of filing also triggers forfeiture of the exclusivity period.[79] Fourth, the expiration of the relevant innovator patents can trigger forfeiture of the exclusivity period.[80] Fifth, if the first ANDA filer enters an

72. 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003).
73. 21 U.S.C. § 355(j)(5)(D) (2006).
74. *Id.* § 355(j)(2)(A)(vii)(II). Following the expiration of the innovator patent, the ANDA filer's Paragraph IV certification is reclassified under Paragraph II, which certifies that the brand-name patent has expired. *See id.* § 355(j)(2)(A)(vii)(II), (IV).
75. *Id.* § 355(j)(5)(D)(I)-(VI). Use of these forfeiture provisions is relatively rare. *See* Kurt R. Karst, *Taking Stock of FDA's 180-Day Exclusivity Forfeiture Decisions—A Forfeiture Scorecard*, FDA L. BLOG (Jan. 26, 2010, 3:46 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/01/taking-stock-of-180day-exclusivity-forfeiture-a-forfeiture-scorecard-.html. Between their enactment in 2003 and 2009, only thirteen ANDA applicants forfeited their exclusivity period with the majority (ten) losing the marketing right due to failure to obtain tentative approval within a thirty-month period. *Id.*
76. 21 U.S.C. § 355(j)(5)(D)(iii). The "term 'first applicant' means an applicant that . . . submits a substantially complete application" according to the requirements of the statute. *Id.* § 355(j)(5)(B)(iii)(IV)(iv)(II)(bb). Theoretically, more than one generic manufacturer can qualify as a first filer, and, thus, two or more companies could share the 180-day exclusivity period in cases where more than one "substantially complete" ANDA application is filed on the same day.
77. *Id.* § 355(j)(5)(D)(i)(II).
78. *Id.* § 355(j)(5)(D)(i)(III).
79. *Id.* § 355(j)(5)(D)(i)(IV).
80. *Id.* § 355(j)(5)(D)(i)(VI).

agreement with another applicant, the marketing exclusivity period is forfeited.[81]

Finally, the most problematic of the six provisions provides that the first ANDA filer can forfeit exclusivity by failing to market the product.[82] This forfeiture event is contingent upon the occurrence of two triggering events.[83] Specifically, the statute defines a failure to market a drug as the later of one of two dates.[84] First, under 21 USC 355(j)(5)(D)(i)(I)(aa) ("(aa)"), the earlier of either 75 days after the approval of the first ANDA filer's application or 30 months after the date of submission of the first ANDA filer's application.[85] Second, under 21 USC 355(j)(5)(D)(i)(I)(bb) ("(bb)"), 75 days after one of the following: (1) a final court decision ("other than on petition to the Supreme Court for a writ of certiorari") that all of the brand-name patents challenged by the first ANDA filer's Paragraph IV certification are invalid or not infringed; (2) a settlement in an infringement action in which the court enters a final judgment that includes a judicial finding that the brand-name patents challenged by the first ANDA filer's Paragraph IV certification are invalid or not infringed; or (3) the brand-name manufacturer withdraws the patents subject to the challenge of the first ANDA filer's Paragraph IV certification.[86] However, these provisions still do not obviate the

---

81. *Id.*

82. *Id.* § 355(j)(5)(D)(i)(I).

83. *Id.*

84. *Id.*

85. *Id.* § 355(j)(5)(D)(i)(I)(aa).

> The first applicant fails to market the drug by the later of-
>
> (aa) the earlier of the date that is-
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; . . . .

Id.

86. *Id.* § 355(j)(5)(D)(i)(I)(bb).

> [W]ith respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:
>
> (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the

need for a final court decision regarding the validity of the brand-name manufacturer's patent to trigger the forfeiture of the 180-day exclusivity period because both an (aa) and a (bb) event must occur in order for the forfeiture provision to kick in.[87]

Given these six provisions, while there are now more ways that the 180-day exclusivity period can be triggered or forfeited, reverse payment settlements can still limit or bar the ability of subsequent ANDA filers to enter the market prior to the expiration of the brand-name patent. Further, absent the incentive of the exclusivity period, some generic manufacturers may be reticent to seek to enter the market ahead of the brand-name patent's expiration given the potential to be sued by the brand-name manufacturer for infringement.[88]

B. Reaction of the Courts: Reverse Payment Settlements and Antitrust Law

The courts have differed when addressing the question of whether reverse payment settlements violate the antitrust provisions of the Sherman Act. Specifically, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States."[89] "[M]onopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or commerce among the several States" are also forbidden.[90] In order to establish an antitrust cause of action, a plaintiff must prove (1) injury in fact;

> Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
>
> (CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

Id.

87. *See* Teva North America, FDA Decision Letter: ANDA 77-165: Granisetron Hydrochloride Injection, 1mg/mL, Docket No. 2007N-0389 (Jan. 17, 2008), *available at* http://www.fda.gov/ohrms/dockets/DOCKETS/07n0389/07n-0389-let0003.pdf (finding that in absence of both an (aa) and (bb) date, the exclusivity period is not forfeited).

88. *See supra* Part II.A.2.a.

89. 15 U.S.C. § 1 (2006).

90. *Id.* § 2.

(2) proximate cause; and (3) antitrust injury—(a) the type of injury intended to be prevented by antitrust law and (b) an injury that "flows from that which makes the defendant's actions unlawful."[91]

Cases involving reverse payment settlements have created a split between the circuits. The Sixth Circuit has held them to be unlawful per se.[92] The Second Circuit and Federal Circuit have both found that reverse payment settlements are presumptively legal and within the scope of the brand-name manufacturer's patent rights.[93] The Eleventh Circuit applied a three-prong analysis accounting for "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[94] Thus far the Supreme Court has denied certiorari on cases dealing with reverse payment settlements.[95]

1. Sixth Circuit Holds Reverse Payment Settlements Per Se Illegal

In *In re Cardizem*, a group of consumers of the heart medication diltiazem hydrochloride filed suit against the drug's brand-name manufacturer, Hoechst Marion Roussel, Inc. (HMR), and a generic manufacturer, Andrx Pharmaceuticals, Inc. (Andrx) of a less expensive version.[96] The plaintiffs alleged that the drug manufacturers violated the Sherman Act and state antitrust laws by entering into a settlement whereby Andrx agreed to refrain from marketing its generic version of the medication, even after FDA approval of its ANDA, in exchange for quarterly payments of $10 million.[97]

The Sixth Circuit considered the use of the rule of reason, but ultimately adopted the rule that pay for delay agreements are unlawful per se and found the agreement constituted a classic case of

---

91. *See* Brunswick Corp. v. Pueblo Bowl-O-Mat, 429 U.S. 477, 488–89 (1977).

92. *See, e.g.*, La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 900, 907–08 (6th Cir. 2003).

93. *See, e.g.*, Ark. Carpenters' Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104–07 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606, 1606 (2011); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciproflaxin Hydrochloride Antitrust Litig.), 544 F.3d 1323, 1332, 1336–37 (Fed. Cir. 2008); Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 212–13 (2d Cir. 2006).

94. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)); *see also Valley Drug Co.*, 344 F.3d 1294.

95. *See, e.g.*, *Ark. Carpenters' Health & Welfare Fund*, 604 F.3d at 104–07, *cert. denied*, 131 S. Ct. at 1606.

96. *In re* Cardizem CD Antitrust Litig., 332 F.3d at 899–902. The drug sold under the brand-name Cardizem CD. *Id.*

97. *Id.* at 899–900.

horizontal restraint of trade in violation of the Sherman Act.[98] Some types of restraints, the court reasoned, are unlawful per se when "they 'have such predictable and pernicious anticompetitive effect, and such limited potential for pro-competitive benefit.'"[99] Under this approach, the parties' intent, the potential for a pro-competitive effect, or the lack of any actual impact on competition are irrelevant.[100]

2. The Second, Eleventh, and Federal Circuits Allow Reverse Payment Settlements

In cases involving reverse payment settlements, the Second, Eleventh, and Federal Circuits have all rejected the reasoning applied by the Sixth Circuit and held that reverse payment settlements are not presumptively unlawful under a variety of different approaches.

a. Second Circuit case law favors settlements

In *In re Tamoxifen*, a group of consumers, medical benefits providers, and consumer advocacy groups filed suit against the brand-name patent holder and the first ANDA filer for a cancer drug, tamoxifen, alleging that the reverse payment settlement between the two pharmaceutical companies created a monopoly in violation of the Sherman Act. [101] Under the terms of the settlement agreement, which included a $21 million dollar payment to the generic manufacturer to not sell its generic version of tamoxifen, subsequent ANDA filers were prevented from obtaining approval to sell their generic versions of the drug because the generic manufacturer's 180-day exclusivity period was never triggered.[102]

The Second Circuit Court of Appeals determined that reverse payment settlements are presumptively legal.[103] The court reasoned that reverse payment settlements fall within the scope of a brand-

98. *Id.* at 906–08. To apply a rule of reason analysis, the "finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* at 906 (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)).

99. *Id.*

100. *Id.* at 906–907 (citing NCAA v. Bd. of Regents, 468 U.S. 85, 100 (1984)).

101. Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 190 (2d Cir. 2006).

102. *Id.* at 193–94.

103. *Id.* at 206.

name manufacturer's patent even if they limit competition because "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."[104] Further, such settlements make sense due to the high degree of risk borne by the brand-name manufacturer in the litigation compared to the relatively low risk faced by the ANDA filer.[105] Finally, even if a brand-name manufacturer's patent is weak and a reverse payment settlement helps extend it artificially, "[i]t is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it."[106]

The court also questioned whether the plaintiffs suffered an injury sufficient to support an antitrust claim, noting that "[t]he injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation."[107] Additionally, the court stated that even if the plaintiffs were assumed to have stated an antitrust violation and alleged a sufficient injury:

> any injury that the plaintiffs suffered . . . resulted from [the brand-name manufacturer's] valid patent and from the inability of other generic manufacturers to establish that the patent was either invalid or not infringed-and not from any agreement between [the generic manufacturer and the brand-name manufacturer that the former] should employ its exclusivity powers to exclude competition.[108]

b. Federal Circuit favors presumptive legality of reverse payment settlements

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit Court of Appeals considered a settlement between the brand-name patent holder, Bayer, and generic manufacturer, Barr, which had been challenged on antitrust grounds by a group of

104. *Id.* at 208–09.

105. *Id.* at 207.

106. *Id.* at 212 (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005), *aff'd in part*, Ark. Carpenters Health & Welfare Fund v. Bayer AG, 544 F.3d 1323 (Fed. Cir. 2008), *aff'd*, 604 F.3d 98 (2d Cir. 2010)).

107. *Joblove*, 466 F.3d at 219 (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)).

108. *Id.*

consumers and advocacy groups.[109] Bayer agreed to pay Barr $49.1 million to delay marketing its generic version of Cipro until six months before Bayer's brand-name patent expired.[110] The settlement also required Bayer to make quarterly payments to Barr for a seven-year period totaling $349 million or to supply Barr with Cipro for resale.[111]

Similar to the reasoning of the Second Circuit, the court determined that "the essence of the Agreements was to exclude the defendants from profiting from the patented invention," which was "well within Bayer's rights as the patentee."[112] The court also emphasized the long-standing public policy in favor of settlement agreements in infringement litigation, particularly in Hatch-Waxman litigation where the relative risks for the brand-name manufacturer are high.[113]

c. *Eleventh Circuit develops a three-part analysis to determine the legality of reverse payment settlements*

In *Schering-Plough Corp. v. Federal Trade Commission*, pharmaceutical companies Schering-Plough, the brand-name patent holder, and Upsher-Smith Laboratories, the first ANDA filer, petitioned for a review of the FTC's determination that their patent infringement settlement agreement constituted an unreasonable restraint of trade in violation of the Sherman Act.[114] As part of a June 1997 settlement agreement in its suit against Upsher for patent infringement, Schering agreed to license the rights to several drugs owned by Upsher in exchange for the latter's agreement to delay marketing its generic version of Schering's drug, K-Dur 20 until at least September 2001.[115] In 1998, Schering entered into settlement with another generic manufacturer, ESI, whereby ESI agreed to license two drugs to Schering and postpone marketing its version of

109. *In re Ciprofloxacin*, 544 F.3d at 1328–30.
110. *Id.* at 1328–29.
111. *Id.* at 1329 & n.5.
112. *Id.* at 1333.
113. *Id.* at 1333 & n.11 (citing Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001)); *see also* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005); Foster v. Hallco Mfg. Co., 947 F.2d 469, 477 (Fed. Cir. 1991).
114. *Schering-Plough Corp.*, 402 F.3d at 1058. The Eleventh Circuit also addressed the question of reverse payment settlements in an earlier case, *Valley Drug Co. v Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).
115. *Schering-Plough Corp.*, 402 F.3d at 1058–59. The final terms of the licensing deal "called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales." *Id.* at 1060.

K-Dur 20 until January 2004 in exchange for $5 million to cover legal fees and $15 million apiece for the two drug licenses.[116]

In 2001, the FTC filed an administrative complaint against Schering, Upsher, and ESI alleging that the settlement agreements violated 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.[117] Specifically, the FTC had determined that the multimillion-dollar payments to Upsher and ESI did not represent "legitimate consideration" for the two agreements.[118] The FTC also claimed that "Schering monopolized and conspired to monopolize the potassium supplement market."[119] In reaching its decision, the FTC "prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities."[120]

The court determined neither a per se or rule of reason approach was appropriate to analyze the settlements at issue.[121] The court recognized that Schering, by obtaining its initial patent for K-Dur 20, "obtained the legal right to exclude Upsher and ESI from the market until they proved either that [Schering's patent] was invalid or that their [generic] products . . . did not infringe Schering's patent."[122] As such, the burden is on the plaintiff to demonstrate the anti-competitive effects of the settlement agreement, after which the defendant must prove its pro-competitive objectives. Specifically, the Court stated that "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[123]

---

116. *Id.* at 1060–61 n.8. Specifically, the agreement included "$5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. 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." *Id.*

117. *Id.* at 1061. While the legality of ESI's agreement with Schering remained an issue at the trial, the complaint against it was withdrawn before the trial so it was not a party to any of the proceedings. *Id.* at 1061 n.9.

118. *Id.* at 1062.

119. *Id.* at 1061.

120. *Id.* at 1062. The only exception under the FTC's standard was for payments to a generic manufacturer for up to $2 million in litigation fees so long as the Commission was notified of the settlement.

121. *Id.* at 1065.

122. *Id.* at 1066–67.

123. *Id.* at 1066 (citing Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)).

C. *One Congressional Solution: The Preserving Access to Affordable Generics Act*

The split between the federal circuit courts has led congressional members to propose resolutions of the conflict through the introduction of legislation, such as the "Preserve Access to Affordable Generics Act" (S. 27).[124] First introduced during the 109th Congress in 2006 as S. 3582, this legislation has lead to significant debate amongst congressional members.[125] During the 111th Congress, the bill's potential to pass in both chambers of Congress looked promising.[126] The House passed a companion version of the bill (H.R. 1706) as part of a supplemental appropriations bill; however, efforts to pass the bill in the Senate ultimately failed.[127]

---

124. Preserve Access to Affordable Generics Act, S.27, 112th Cong. (2011). Introduced by Sen. Herb Kohl (D-WI) with original co-sponsors Sens. Sherrod Brown (D-OH), Susan Collins (R-ME), Richard Durbin (D-IL), Al Franken (D-MN), Sen. Chuck Grassley (R-IA), Amy Klobuchar (D-MN), and Bernard Sanders (D-VT). In addition to costing consumers a significant amount of money, the federal government also carries a substantial portion of the cost of prescription drugs. *Id.* at § 2(a)(5) ("Federal dollars currently account for an estimated 30 percent of the $235,000,000,000 spent on prescription drugs in 2008, and this share is expected to rise to 40 percent by 2018.").

125. *See, e.g.*, Preserve Access to Affordable Generics Act, S.3582, 109th Cong. (2006); Donald Zuhn, *Pay-For-Delay Provision Added to Senate Appropriations Bill*, PATENT DOCS BLOG (Aug. 5, 2010), http://www.patentdocs.org/2010/08/payfordelay-provision-back-in-appropriations-bill.html.

126. *See S. 369: Preserve Access to Affordable Generics Act*, GOVTRACK.US, http://www.govtrack.us/congress/bill.xpd?bill=s111-369 (last visited May 30, 2012). During the 111th Congress, the Committee on the Judiciary filed a written report (Report No. 111-123) on S. 369 and minority views were filed; however, the proposed bill did not proceed to a Senate and House vote. *Id.*

127. *See* Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009). During the 111th Congress, the Senate version of the bill, Preserve Access to Affordable Generics Act, S.369, 111th Cong. (2009), was attached to the Financial Services and General Government Appropriations Act, 2011, S. 3677, 111th Cong. (2010) (enacted), in a hotly debated vote that came down largely along party lines. *GPhA Comments on 15-15 Senate Appropriations Committee Vote on Patent Settlements*, GENERIC PHARM. ASS'N (July 30, 2010), http://www.gphaonline.org/media/press-releases/2010/gpha-comments-15-15-senate-appropriations-committee-vote-patent-settlement. However, the addition was ultimately removed before the Act passed. Financial Services and General Government Appropriations Act, 2011, S. 3677, 111th Cong. (2010) (enacted).

1. Provisions of the Preserving Access to Affordable Generics Act

Contrary to the holdings of the Second, Eleventh, and Federal Circuits, under the Preserve Access to Affordable Generics Act and more in line with the approach favored by the FTC, nearly all agreements would be considered per se unlawful subject to a rebuttable presumption.[128] The proposed law permits the FTC to "initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim in connection with the sale of a drug product."[129] Specifically, any agreement where "an ANDA filer receives anything of value, and the ANDA filer agrees to limit or forego research, development, manufacturing, or sales of the ANDA product for any period of time" is presumptively anti-competitive and unlawful.[130] This provision essentially removes all of the burden of proof from the FTC and makes reverse payment agreements per se illegal, with few exceptions.[131]

To defeat the presumption of unlawfulness, the parties to an agreement must "demonstrate by clear and convincing evidence that the pro-competitive benefits of the agreement outweigh [its] anti-competitive effects."[132] To determine whether an agreement is not anti-competitive, the court would need to account for the following factors:

> (1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;
>
> (2) the value to consumers of the competition from the ANDA product allowed under the agreement;
>
> (3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;
>
> (4) the revenue the ANDA filer would have received by winning the patent litigation;
>
> (5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

128. *See supra* Part IV.B.2.
129. S. 27, § 28(a)(1).
130. *Id.* § 28(a)(2).
131. *See id.*
132. *Id.* § 28(a)(2)(B).

> 6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and
>
> (7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.[133]

2. Concerns with the Preserve Access to Affordable Generics Act

If passed, the Preserve Access to Affordable Generics Act has the potential to weed out some problematic reverse payment settlements; however, it also has the potential to interfere with agreements that can benefit consumers. Based on the information available, it is anything but clear as to whether every reverse payment settlement is anti-competitive by nature.[134]

Critics of an outright ban posit that it 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 anti-competitive."[135] Further, other opponents suggest that some reverse settlements can actually be positive and result in generic drugs entering the market faster than they would have had litigation been pursued and before the expiration of the patent in question.[136] An independent 2010 report from RBC Capital Markets concluded that of the thirty-seven new generic drug launches expected in 2010 and 2011, twenty-four of them would launch prior to patent expiration because of settlements.[137]

Implementing a per se presumption against all agreements where the ANDA filer receives "anything of value" overcompensates for the problem posed by reverse payment settlements. Not all such agreements have an anticompetitive effect. Requiring the parties to prove the pro-competitive nature of their agreement has the potential to discourage valid settlements.[138] The additional costs and time

---

133. *Id.* § 28(b).
134. *See id.* § 28(a)(2).
135. Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 989 (N.D. Ill. 2003), *dismissed*, 104 F. App'x. 178 (Fed. Cir. 2004).
136. *The "Pay for Delay" Rap*, *supra* note 29.
137. RBC CAPITAL MKTS. CORP., *supra* note 38, at app. A.
138. Yuki Onoe, *"Pay-for-Delay" Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone*, 9 J. MARSHALL REV. INTELL. PROP. L. 527, 545–46 (2009); *see also The "Pay for Delay" Rap*, *supra* note 29. "If the only choice is an expensive litigation death match that lasts for years, fewer

involved in litigating the various stipulations of the bill also has the potential to defeat the benefits of settling and to further hamper the efficiency of the legal system.[139]

V. ALTERNATIVE SOLUTIONS: PATENT MISUSE AND INCREMENTAL CHANGES TO THE HATCH-WAXMAN ACT

A significant problem with reverse payment settlements is their impact on both the ability and interest of subsequent ANDA filers to enter the market prior to the expiration of a brand-name manufacturer's patent.[140]

A. Patent Misuse: A Potential Solution to the Problem of Reverse Payment Settlements Without the Need for Legislative Action by Congress

An alternative means of triggering the forfeiture of the first ANDA filer's 180-day exclusivity period would be for subsequent ANDA filers to invoke the defense of patent misuse in response to infringement charges by the brand-name manufacturer. With a lower threshold of proof than that required for a successful antitrust inquiry, a successful patent misuse defense to an infringement suit would result in the invalidation of the brand-name manufacturer's patent, thus opening the door to increased competition by other generic manufacturers and lower prices for consumers.[141]

1. The Advantages of Patent Misuse as a Solution

Patent misuse has its origins in the equitable doctrine of unclean hands, "whereby a court of equity will not lend its support to enforcement of a patent that has been misused."[142] It is an affirmative

---

generic companies will sue under the probability that they will themselves face patent infringement suits." *Id.*

139. *See* Butler & Jarosch, *supra* note 63, at 109–10 (discussing Prof. Daniel Crane's proposition that requiring non-trial determinations as to the potential validity of an infringement suit as being akin to a "mini-trial" that would "swallow the benefits of settlement that parties seek").

140. *See supra* Part III.

141. Marshall Leaffer, *Patent Misuse and Innovation*, 10 J. HIGH TECH L. 142, 147 (2010) (citing Eugene R. Quinn, Jr., *Abusing Intellectual Property Rights in Cyberspace: Patent Misuse Revisited*, 28 WM. MITCHELL L. REV. 955, 988–89 (2002)).

142. B. Braun Med., Inc. v. Abbot Labs., 124 F.3d 1419, 1427 (Fed. Cir. 1997). Patent misuse originated as a court-made remedy rather than a legislative one. The Supreme Court first applied the doctrine in 1917 in *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917). Section 271(d) of Title 35 of the U.S. Code

defense that can be invoked by a party charged with patent infringement or breach of a license agreement.[143] The Court of Appeals for the Federal Circuit has stated, "[t]he key inquiry under this fact-intensive doctrine is whether, by imposing the condition, the patentee has 'impermissibly broadened the "physical or temporal scope" of the patent grant with anticompetitive effect.'"[144] The doctrine of misuse is meant "to restrain practices that [do] not in themselves violate any law, but that [draw] anticompetitive strength from the patent right, and thus [are] deemed to be contrary to public policy."[145] When a court finds a party guilty of patent misuse, the judgment renders the patent in question unenforceable.[146]

Although some critics argue that the importance of patent misuse has waned thanks to the continued development of antitrust law, others argue that due to the fundamental differences between the two, patent misuse retains its validity in the modern age.[147] Most critically, a patent owner's conduct need not rise to the level of an

---

addresses patent misuse briefly in the negative by defining some of the actions by a patent holder that do *not* constitute misuse, although the provision is not exhaustive. It states:

> (d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

35 U.S.C. § 271(d)(2006).

143. Leaffer, *supra* note 141, at 153.
144. *B. Braun Med., Inc.*, 124 F.3d at 1426 (quoting Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1001–02 (Fed. Cir. 1986)).
145. Mallinkrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992).
146. Leaffer, *supra* note 141, at 147 (citing Quinn, Jr., *supra* note 141, at 988–89).
147. *Id.* at 152–60.

antitrust violation in order for the defense of patent misuse to be raised by another party.[148]

Because defendants claiming patent misuse need not demonstrate that they have been harmed by the alleged misuse, the doctrine presents a novel solution to the impact of reverse payment settlements on subsequent ANDA filers.[149] An affirmative defense, patent misuse could be used by subsequent ANDA filers seeking to challenge the 180-day exclusivity period of first ANDA filers. Under this approach, a subsequent ANDA filer being sued by the innovator patent owner for infringement can respond with the defense that the brand-name manufacturer misused its patent.[150] If successful, the innovator patent is invalidated, and the first ANDA filer would thus effectively forfeit its 180-day exclusivity period.[151]

When faced with the possibility of having both the brand-name patent and the generic patent declared invalid due to a reverse payment agreement frustrating "the public good," both parties might be less likely to enter such an agreement in the first place. Although the subsequent ANDA filer would no longer have the incentive of the 180-day exclusivity period, it would still stand to gain much more by effectively opening up the marketplace to generic manufacturers. Still, the lack of 180-day exclusivity might be enough to discourage many takers from this option given the expense involved in pursuing litigation and the uncertainty of the outcome.[152]

2. Potential Problems with the Patent Misuse Defense: Disclosure of Settlement Agreements

Typically, when two parties settle, the settlement agreement is done outside the court system entirely. If the two parties stipulate to a judgment, it is considered more as a contract between the parties

148. *Id.* at 153–54. In order to establish an antitrust cause of action, a plaintiff must prove (1) injury in fact, (2) proximate cause, (3) antitrust injury—(a) the type of injury intended to be prevented by antitrust law and (b) an injury that "flows from that which makes defendant's acts unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488–89 (1977). "Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met." 6 R. CARL MOY, MOY'S WALKER ON PATENTS § 18:1 n.10 (4th ed. 2011) (quoting C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1988)).

149. Note, *Is the Patent Misuse Doctrine Obsolete?*, 110 HARV. L. REV. 1922, 1924 (1997); *see also supra* Part IV.B.2.a–b (discussing the Second Circuit and Federal Circuit's approaches to reverse settlements).

150. *See* B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1426 (Fed. Cir. 1997).

151. Leaffer, *supra* note 141, at 147.

152. *See* Sobel, *supra* note 65, at 51–52; *supra* note 138 and accompanying text.

than as a final judgment by the court. However, under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), certain types of settlement agreements between brand-name manufacturers and generic manufacturers must be disclosed to the FTC within ten days of their execution.[153] Interestingly, the information disclosed to the FTC regarding the specifics of these agreements is kept secret from disclosure "except as may be relevant to any administrative or judicial action or proceeding."[154]

The inability to obtain information regarding the agreements a brand-name manufacturer has entered into with the first ANDA filer and other subsequent ANDA filers can pose a significant hurdle for subsequent ANDA filers seeking to enter the market prior to the expiration of the brand-name patent or invoke a patent misuse defense. In *Pfizer Inc. et al. v. Apotex Inc. et al.*, Apotex, a subsequent ANDA filer, filed suit against Pfizer, the brand-name patent holder, seeking to trigger the 180-day marketing exclusivity period of Ranbaxy, the first ANDA filer, regarding Lipitor.[155] As part of its discovery requests, Apotex sought to obtain the settlement agreements and documents related to them between Pfizer and Ranbaxy.[156] Pfizer attempted to block the discovery on the grounds that revealing the agreements and related documents and sought a protective order covering the documents on the grounds that they were confidential and would provide Apotex with an "immense competitive advantage."[157] In deciding to grant Apotex access to the settlement agreements, the court recognized the value of such information to Apotex's suit on several grounds, including its relation to the considerations directly relevant to the patent at issue such as obviousness and commercial success.[158] The court also noted that Apotex might also be able to cultivate a defense of patent misuse against Pfizer if the evidence suggested that Pfizer induced Ranbaxy

153. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, § 1112(a)(2) (codified as amended in scattered sections of 21 & 42 U.S.C.) (providing that agreements relating to "(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved; (B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or (C) the 180-day [exclusivity] period" must be disclosed).

154. *Id.* § 1114, 117 Stat. at 2463. The information is also used by the FTC to create reports aggregating general data on the prevalence of these agreements. *See* FTC, *supra* note 46, at 1.

155. Pfizer Inc. v. Apotex Inc., 744 F. Supp. 2d 758 (N.D. Ill. 2010).

156. *Id.* at 761.

157. *Id.* at 767.

158. *Id.* at 762.

to settle by threatening an infringement claim based on the reissuing of the patent at issue.[159]

The secrecy of the reverse payment agreements has also recently been challenged by Cephalon who is seeking information from the FTC with regard to the specific agreements on which its reports are based due to the FTC's reliance on figures from these reports during the course of litigation.[160] The move has met with significant resistance by Pfizer and 35 other pharmaceutical companies, who assert that "[d]isclosure of these settlement agreements and related documents in this matter would seriously damage the third parties' business and legal interests."[161]

B. A Simpler Alternative: Opening the 180-day Exclusivity Period to Subsequent Filers

By its nature, law develops incrementally over time and is not as prone to changes as drastic as those that Congress implements. Intellectual property law is no different.[162] An incremental approach to change is particularly beneficial in altering a very complex system, such as that employed in pharmaceutical patenting, where the outcome of changes cannot be predicted with confidence.[163]

Given the complexity of reverse payment settlements, the great variation in their terms, and the difficulty in efficiently and inexpensively determining whether they are pro- or anti-competitive in nature, an incremental change to the Hatch-Waxman Act may be a more appropriate solution than a piece of legislation as complicated as the Preserve Access to Affordable Generics Act. Indeed, making an adjustment to the system currently in place presents a simple solution with the potential to diffuse the problem of reverse payment settlements over time.

1. The Patent System Provides an Incentive for Innovation

At the core of the U.S. patent system is the idea that innovation can be encouraged by granting inventors the exclusive right to

159. *Id.* (citing Pfizer Inc. v. Apotex Inc., 731 F.Supp.2d 754, 760 (N.D. Ill. 2010)).

160. Peter Loftus, *Pfizer, 36 Other Drug Companies Want Patent Documents Kept Secret*, WALL ST. J. (Jan. 20, 2011), http://online.wsj.com/article/BT-CO-20110120-712765.html.

161. *Id.*

162. Shyamkrishna Balganesh, *The Pragmatic Incrementalism of Common Law Intellectual Property*, 63 VAND. L. REV. 1543, 1544–46 (2010).

163. Daniel R. Cahoy, *An Incrementalist Approach to Patent Reform Policy*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 587, 632 (2006).

manufacture, sell, and license their inventions for a period of time.[164] Ultimately, a patent grants its owner the power to exclude others.[165] Therefore, by granting the patent holder an effective monopoly, the courts have recognized that the patent system by its nature is at odds with an antitrust analysis.[166]

2. Absence of the 180-day Exclusivity Period to Subsequent ANDA Filers Reduces Incentive to Enter the Market Prior to the Expiration of the Brand-name Manufacturer's Patent

The problem presented by reverse payment settlements has its origins in the incentive to generic manufacturers to gain the 180-day exclusivity period.[167] Previous changes to the Hatch-Waxman Act circumvented part of the problem by preventing an initial ANDA filer from retaining hold of the 180-day exclusivity period indefinitely; however, loopholes still exist in the law.[168] Further amending the law to extend the grant of a 180-day exclusivity period to subsequent filers after a first filer forfeited the period under one of the provisions of 21 USC § 355 (j)(5)(D)(iii) represents a potentially small change that could bear significant results. Additionally, the need for further court involvement or consideration of the pro- or anti-competitive effects of an agreement would be obviated by granting subsequent ANDA filers the ability to obtain the 180-day exclusivity period. Two solutions of this variety, one proposed by Henry N. Butler and Jeffrey Paul Jarosch and another under consideration by Congress, merit closer scrutiny.[169]

164. Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), *in* 5 THE WRITINGS OF THOMAS JEFFERSON 74, 76 (H.A. Washington ed. 1853) (noting that "ingenuity should receive a liberal encouragement").
165. Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).
166. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066–67 (2003).
167. *See supra* Part III.
168. *See supra* Part IV.A.
169. Butler & Jarosch, *supra* note 63, at 123–24.

3. Two Alternative Solutions Related to the 180-day Exclusivity Period

a. Any ANDA filer entering a reverse payment settlement relinquishes 180-day exclusivity and benefit passes to subsequent filer

Perhaps the simplest solution to the problem of reverse payment settlements would be to amend the law so that any ANDA filer who accepts a reverse payment settlement would forfeit its right to the 180-day exclusivity period and to allow a subsequent ANDA filer to be eligible for the exclusivity right.[170] One fundamental problem with the current system is the lack of incentive to subsequent ANDA filers to pursue the patenting of a generic version of a drug because there is less reward to do so once the 180-day exclusivity period is not available.[171] Subsequent ANDA filers are not guaranteed the duopoly granted to the first ANDA filer, but they still face the specter of potentially costly litigation if challenged with infringement by the innovator company who holds the brand-name patent.

The benefits of such an approach are three-fold. First, such an amendment would be less controversial than the proposed Preserve Access to Affordable Generics Act, which has been before Congress for four sessions without success due to vehement opposition by conservative congressional members.[172] Second, by allowing subsequent filers to be eligible for the 180-day exclusivity period, such a change would not discourage valid settlements, yet it would still reduce the benefit to a brand-name manufacturer to enter into a sham agreement.[173] When faced with the possibility of having to settle with multiple generic manufacturer litigants all vying for the 180-day exclusivity period, brand-name manufacturers would be less likely to settle those cases likely to be decided in their favor as a means of obstructing the entry of generic competitors into the marketplace.[174] Finally, by making an incremental change, Congress could avoid adding to the problems already facing the country with respect to health care costs by not enacting legislation that overcorrects and overcompensates for the weaknesses currently present in the system.[175]

170. *Id.* at 124.
171. *See supra* Part II.A.2.
172. *See supra* Part IV.C.
173. *See supra* note 106 and accompanying text.
174. *See supra* note 106 and accompanying text.
175. *See supra* Part IV.C.

b. Drug Price Competition Act: Broadening eligibility for the 180-day exclusivity period

The Drug Price Competition Act is a variation on this approach.[176] Rather than the "wait in line" style approach considered above, the Act would permit multiple generic manufacturers to jointly share the 180-day exclusivity period, thus widening the group of applicants eligible for the incentive.[177] Under this proposal, in order for subsequent filers to qualify for the exclusivity period after the initial filer, they would need to meet two conditions. First, the subsequent filer would have to file its ANDA prior to the first ANDA filer commencing marketing of the drug.[178] Second, the subsequent filer would need to either survive an infringement challenge by the brand-name manufacturer brought within forty-five days of filing or not be subject to such a challenge at all.[179]

Under this approach, ANDA filers would continue to have significant incentive to enter the market ahead of a brand-name manufacturer's patent, thus having the potential to lower prices to consumers.[180] Brand-name manufacturers would also still have the possibility of settling litigation, but the lure of entering a reverse payment settlement to slow the entry of generic competitors would be reduced given the costs of making payments to multiple ANDA filers in exchange for their agreement to stay off the market.[181]

VI. CONCLUSION

Reverse payment settlements present a unique problem given their potential to both help and harm consumers faced with high prescription drug prices.[182] Given the varied nature of these settlements and the lack of information publicly available about them,

176. Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009); Drug Price Competition Act of 2009, H.R. 3777, 111th Cong. (daily ed. June 22, 2009). At the time of this writing, the bill has been not reintroduced during the 112th Congress. *Bill Summary & Status, 111th Congress (2009 2010) S.1315 All information*, THOMAS (The Library of Congress), http://thomas.loc.gov/cgi-bin/bdquery/z?d111:SN01315:@@@L&summ2=m& (last visited May 30, 2012). Interestingly, the Act did not garner much support during the 111th Congress and between the House and Senate it collected only 3 supporters. 155 Cong. Rec. S6887 (2009); 156 Cong. Rec. H472 (2010).

177. S. 1315.

178. *Id.*

179. *Id.*

180. *See supra* Part III.

181. *See supra* note 106 and accompanying text.

182. *See supra* Part III.A.

as well as, the cost and time needed for the courts to determine whether agreements are anticompetitive or procompetitive under antitrust law, alternative solutions to the problem must be considered.[183] For these reasons, patent misuse represents one possible defense available to subsequent ANDA filers under the current system.[184] A better, and simpler, solution would be a small alteration to the Hatch-Waxman Act broadening the availability 180-day exclusivity period so as to provide additional incentive to subsequent ANDA filers to enter the market and to reduce the incentive to brand-name manufacturers to enter into reverse payment settlements in the first place.[185]

Alyssa L. Brown†

183. *See supra* Parts IV.B, V.A.

184. *See supra* Part V.A.

185. *See supra* Part V.B.

† I would like to express my appreciation to Prof. William Hubbard for his time and guidance as I prepared this comment. I also thank the editors and student-writers of the *University of Baltimore Law Review*, for publishing and editing this comment; and finally, my family and friends for their support.

ERRATA

The *University of Baltimore Law Review* regrets the following error occurring in Beryl Blaustone, *Improving Clinical Judgment in Lawyering with Multidisciplinary Knowledge About Brain Function and Human Behavior: What Should Law Students Learn About Human Behavior for Effective Lawyering?*, 40 U. BALT. L. REV. 607 (2011). We offer this correction and apologize for any inconvenience.

In footnote 128, the second sentence should read:

Professor Margaret A. Berger, renowned evidence law professor and legal scholar, conducted studies among her law students at Brooklyn Law School to demonstrate for them that their inaccurate recall of external facts was substantial and that their conviction of belief reinforced those inaccuracies.