

# IF HATCH WINS, MAKE WAXMAN PAY: ONE-WAY FEE SHIFTING AS A SUBSTITUTE INCENTIVE TO RESOLVE ABUSE OF THE HATCH-WAXMAN ACT

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## I. INTRODUCTION

There has been a rising societal concern in recent years with high drug prices. Many individuals with health concerns, especially senior citizens, are forced into tight financial situations from having to purchase the drugs that they need to survive.<sup>1</sup> Marilyn Taylor, a senior citizen from Manchester, Maine, decided to deny herself much needed medication including prescription drugs for asthma, arthritis, depression, and high blood pressure to cut her drug costs.<sup>2</sup> While low income uninsured individuals who are forced to pay the bills from their own pocket are feeling the cost of high drug prices, many moderate income seniors are feeling the high drug prices as well.<sup>3</sup> Policymakers have realized “that you don’t have to be destitute to be hobbled by high drug costs.”<sup>4</sup>

Consumers receive benefits from generic drugs because they are less expensive, granting those consumers without a large income and limited insurance coverage a better quality of life.<sup>5</sup> Generic drugs often come on the market at a price 35–40% less than that of the brand name drugs.<sup>6</sup> While generic drugs are not always available, another barrier to their widespread use is the common misconception among consumers that you get what you pay for, that generic drugs are not as effective as the brand name drugs.<sup>7</sup> As many have found out, this is not the case.<sup>8</sup> With the amount of prescription drug takers and the demand for drugs by consumers ever increasing, the price of proprietary drugs and the availability of generic drugs has become a fierce topic of public debate.

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1. Wayne J. Guglielmo, *Prescription Drugs At Bargain Prices*, NEWSWEEK, Apr. 23, 2001, at 62.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.* For example, as of 2001, the brand-name Vasotec cost \$180 for a one month supply of the drug used to treat hypertension and congestive heart failure while its generic equivalent only cost \$55. *Id.* Additionally, for a 90 day supply of Tagamet, an ulcer medication, it cost \$135 while the generic equivalent Cimetidine only cost \$20. *Id.*

6. *Bill Addresses Foot-Dragging on Generic Drugs*, NEW YORK TEACHER, Nov. 7, 2001, available at <http://nysut.org/newyorkteacher/2001-2002/011107health2.html>.

7. Guglielmo, *supra* note 1 at 62.

8. *Id.*

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, was enacted as a compromise between legislators seeking to balance the interests of maintaining incentives for research-based pharmaceutical companies to innovate, with society's interest in the availability to consumers of lower-priced generic drugs.<sup>9</sup> The dual purposes of the Hatch-Waxman Act are to reimburse pharmaceutical patent holders for time lost due to the long review period needed to achieve FDA approval, and to encourage generic drugs to enter the market by enacting procedures that expedite and incentivize their introduction.<sup>10</sup> However, several provisions have been abused which impedes the designed effect of higher availability of generic drugs.<sup>11</sup>

In Part II, this Note provides background on the Hatch-Waxman Act and its amendments. In Part III, this Note first analyzes the results of Hatch-Waxman litigation and the incentives in place for generic drug manufacturers to challenge invalid patents or design around them. In Part III.B explores the possible effects of recent amendments to the Hatch-Waxman Act. This Note in Part III.C will then analyze the effects of providing the additional incentive to generic drug companies of one-way fee shifting. Finally, Part III.D discusses the antitrust policy choice in regard to settlements where the brand-name plaintiff pays the alleged infringer. In Part IV, this Note recommends the legislative imposition of a one-way fee shifting regime applied to Hatch-Waxman litigation. In Part IV, this Note also recommends that payments from a patent holder to a Hatch-Waxman defendant challenging the patent be considered a per se antitrust violation.

## II. BACKGROUND

The Hatch-Waxman Act was enacted in 1984 with the dual purposes of reimbursing pharmaceutical patent holders for time lost on the effective life of the patent due to the FDA approval process while also encouraging generic drug manufacturers to get to market, including providing incentives to challenge invalid patents or develop non-infringing drugs.<sup>12</sup> The Hatch-Waxman Act has been an overall success, responsible for creating a generic drug industry.<sup>13</sup> Before the Hatch-Waxman Act, only 35% of brand name drugs met generic competitors upon the expiration of the drug's patent, but now nearly every patented drug has a generic competitor upon expiration of

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9. *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 37 (2002) [hereinafter *Muris Statement*] (statement of Timothy J. Muris, Chairman, FTC), available at <http://www.ftc.gov/os/2002/10/genericestimony021009.pdf>.

10. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)); *Muris Statement*, *supra* note 9, at 4.

11. See *Muris Statement*, *supra* note 9, at 2.

12. See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873-01, at 42,873-75 (Aug. 6, 1999) (to be codified at 21 C.F.R. pt. 314). The Act is simultaneously designed to give consumers the benefit of lower priced generic drugs while maintaining incentives for pharmaceutical companies to invest in innovative efforts. *Id.* at 42,873.

13. 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 53, 54 (Sept. 23, 2003).

the drug's patent.<sup>14</sup> Furthermore, generic drugs comprised more than 47% of prescriptions filled in July 2002 whereas generic drugs comprised only 19% of prescriptions filled in 1984 when the Hatch-Waxman Act was enacted.<sup>15</sup>

#### A. Hatch-Waxman Act

The Hatch-Waxman Act amends the Food, Drug, and Cosmetic Act (FDCA).<sup>16</sup> The FDCA requires drug companies to obtain FDA approval prior to the marketing of any new drug, whereby the brand name drug manufacturer must file a New Drug Application (NDA).<sup>17</sup> Along with the application, the applicant must submit any patent information relevant to the drug product.<sup>18</sup> The FDA publishes the patent information in an agency publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book."<sup>19</sup> Prior to the Hatch-Waxman Act, generic manufacturers had to go through the same costly and time-consuming regulatory process as "innovator" (brand name) drugs, discouraging and delaying generics from coming to market.<sup>20</sup>

In order to implement the Hatch-Waxman Act goal of encouraging generic drugs to enter the market upon the expiration of a brand name drug's patent, a system was put in place whereby a generic drug manufacturer can submit an Abbreviated New Drug Application (ANDA) with the FDA.<sup>21</sup> The ANDA process reduces the time and cost to the generic manufacturer by allowing reference to the data of the already approved brand name drug in regards to safety and efficacy.<sup>22</sup> The ANDA applicant must submit data showing that the generic drug is the bioequivalent of the innovator drug.<sup>23</sup>

An additional requirement for approval of an ANDA is a certification regarding each patent listed in the Orange Book from the innovator's New Drug Application.<sup>24</sup> For each patent, the ANDA applicant has to certify one of the following:

- (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.<sup>25</sup>

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14. *Id.*

15. FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, (2002) [hereinafter FTC STUDY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

16. Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)); *Muris Statement*, *supra* note 9, at 1–2.

17. 21 U.S.C. § 355(a) (2000); *Muris Statement*, *supra* note 9, at 4–5.

18. 21 U.S.C. § 355(b)(1); *Muris Statement*, *supra* note 9, at 4–5.

19. 21 U.S.C. § 355(j)(7)(A); *Muris Statement*, *supra* note 9, at 5.

20. *Muris Statement*, *supra* note 9, at 5.

21. 21 U.S.C. § 355(j)(1); *Muris Statement*, *supra* note 9, at 5.

22. 21 U.S.C. § 355(j)(2)(A)(i), (ii), (iii); *Muris Statement*, *supra* note 9, at 5.

23. 21 U.S.C. at 355(j)(2)(A)(iv); *Muris Statement*, *supra* note 9, at 5.

24. 21 U.S.C. at 355(j)(2)(A)(vii) (2005); *Muris Statement*, *supra* note 9, at 5.

25. 21 U.S.C. at 355(j)(2)(A)(vii) (2005); Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. &

A paragraph IV certification is an act of infringement and gives rise to a case or controversy under 35 U.S.C. § 271.<sup>26</sup> As a result, an ANDA containing a paragraph IV certification often results in patent infringement litigation.<sup>27</sup> The paragraph IV certification gives rise to several important provisions of the Hatch-Waxman Act that gives generic manufacturers incentive to challenge invalid patents and develop noninfringing alternatives that may subject them to litigation while also being fair to innovator patent holders.<sup>28</sup>

If an ANDA applicant files a paragraph IV certification, the applicant must send notice to the brand-name drug patent holder with a detailed factual and legal basis of their belief of invalidity or noninfringement within twenty days from the date of postmark of notification that the FDA confirms the ANDA application has been filed.<sup>29</sup> The patent holder then has forty-five days from receiving the notice of the paragraph IV certification to file an infringement action against the applicant.<sup>30</sup> If no suit is filed, the ANDA applicant may begin marketing the generic version of the drug subject to FDA approval.<sup>31</sup> If the patent holder files suit within this statutory period, approval of the ANDA must be stayed until the earliest of a court decision finding invalidity or noninfringement of the patent, the expiration of the patent term, or thirty months from the patent holder's notice of the paragraph IV certification.<sup>32</sup> The 30-month stay provision is designed to approximate the time it takes to litigate the validity or infringement of the patent, therefore allowing the patent holder the benefit of its patent during that time period.<sup>33</sup> If the litigation has not concluded by thirty months from the receipt of paragraph IV certification by the patent holder, the generic manufacturer may begin marketing the generic version of the drug upon FDA approval.<sup>34</sup>

A paragraph IV certification also gives rise to a 180-day period of exclusivity in marketing to the first generic drug producer to file an ANDA containing a paragraph IV certification asserting that the brand name producer's patent is invalid or not infringed.<sup>35</sup> This provision precludes FDA approval of any subsequent ANDA applicants for the brand-name drug product in dispute until the conclusion of the 180-day period of exclusivity for the first ANDA applicant.<sup>36</sup> The promise of 180 days of exclusivity therefore provides incentive to be the first ANDA applicant and compensates the generic drug applicant for subjecting themselves to the cost of infringement litigation.<sup>37</sup>

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TRADEMARK OFF. SOC'Y 602, 613 (2005).

26. 35 U.S.C. § 271 (e)(2) (2003); Karki, *supra* note 25, at 614.

27. Karki, *supra* note 25, at 614.

28. Karki, *supra* note 25, at 615. "As a result of the Act, generic drug manufacturers can avoid huge costs associated with developing a new drug." *Id.*

29. 21 U.S.C. § 355(j)(2)(B)(ii).

30. 21 U.S.C. § 355(j)(5)(B)(iii); *see also* FTC STUDY, *supra* note 15, at 7, 8 fig.1-2.

31. 21 U.S.C. § 355(j)(5)(B)(iii); FTC STUDY, *supra* note 15, at 7, 8 fig.1-2.

32. 21 U.S.C. § 355(j)(5)(B)(iii); *see also* FTC STUDY, *supra* note 15, at 7-8.

33. Doug Bandow, *Demonizing Drugmakers: The Political Assault on the Pharmaceutical Industry*, 475 POL'Y ANALYSIS 1, at 19 (2003), available at <http://www.cato.org/pubs/pas/pa475.pdf>.

34. FTC STUDY, *supra* note 15, at 8 fig.1-2.

35. 21 U.S.C. 355(j)(5)(B)(iv); FTC STUDY, *supra* note 15, at 7.

36. 21 U.S.C. 355(j)(5)(B)(iv); FTC STUDY, *supra* note 15, at 7.

37. FTC STUDY, *supra* note 15, at 7; *see* Granutec, Inc. v. Shalala, 139 F.3d 889, 891 (4th Cir. 1998).

The original Hatch-Waxman amendments provided that the 180-day period would begin to run at the earlier of either the first commercial marketing of the generic drug or the date of a court decision finding the patent invalid or not infringed.<sup>38</sup> After the 180-day exclusivity period expires, subsequent ANDA applicants may receive FDA approval and enter the market.<sup>39</sup>

### *B. Anti-competitive abuse of 30-month stay and 180-day exclusivity*

However, the two provisions relevant to paragraph IV certification, the 30-month stay and 180-day period of exclusivity, have been allegedly abused by allowing both brand name and generic drug producers to engage in anti-competitive conduct, using the provisions to improperly extend the monopoly given by the patent thereby frustrating the Hatch-Waxman Act's purpose of making generic drugs more available.<sup>40</sup> This has led to recent amendments to the Hatch-Waxman Act in 2003 in Title XI—Access to Affordable Pharmaceuticals—of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the “MMA Act”).<sup>41</sup> The abuses and recent amendments to curb such abuses are explained further in the following sections.

#### *1. 30-month stay*

The 30-month stay provision had been abused by brand name patent holders thereby receiving FTC scrutiny.<sup>42</sup> The temptation for abuse arose out of a provision allowing later issued patents on the same drug to be listed in the Orange Book, and consequently a new paragraph IV certification was required from the ANDA applicant for these additional patents.<sup>43</sup> Subjected to the same process for paragraph IV certifications, if the patent holder brought suit within forty-five days, a new 30-month stay provision was triggered from the receipt of this additional paragraph IV certification.<sup>44</sup> In response to receiving an initial paragraph IV certification, this allowed an opportunity for a patent holder to file for a new patent on the drug, requiring another paragraph IV certification by the ANDA applicant for this new patent, and the patent holder then obtaining an additional thirty months from that point, further delaying the generic drug's entry into the market.<sup>45</sup> This opportunity has been accentuated by the lack of any review mechanisms for patents listed in the Orange Book and the inability of ANDA applicants to have patents removed from the

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38. Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j)(5)(B)(iv) (1984). This provision was later amended in 2003 in Title XI of the Medicare Prescription Drug Improvement and Modernization Act so that the 180-day exclusivity began running only upon first commercial marketing subject to forfeiture events. Medicare Prescription Drug Improvement and Modernization Act, Pub. L. No. 108-173, § 1101, 117 Stat. 2066, 2448 (2003).

39. FTC STUDY, *supra* note 15, at 7, 8 fig.1-2.

40. *Muris Statement*, *supra* note 9, at 40.

41. Pub. L. No. 108-173, §§ 1101, 1102, 117 Stat. 2448, 2457 (2003).

42. See FTC STUDY, *supra* note 15, at 48–52.

43. *Id.* at 43–44.

44. *Id.* at 44.

45. *Id.*

Orange Book.<sup>46</sup> Studies have indicated that this has provided incentives for drug manufacturers to file frivolous patents to trigger multiple 30-month stays.<sup>47</sup> However, this loophole has been amended in the MMA Act by allowing only one 30-month stay and allowing generic ANDA applicants to file counter-claims to require the patent holder to make changes to the Orange Book.<sup>48</sup>

## 2. 180-day exclusivity

The other provision that has been abused is the 180-day period of market exclusivity that is granted to the first generic drug company to file an ANDA.<sup>49</sup> Settlements in patent litigation are generally pro-competitive and beneficial to consumers by reducing costs to all parties, reducing uncertainty by clarifying intellectual property rights, and potentially resulting in licensing.<sup>50</sup> However, many settlements reached in Hatch-Waxman litigation have either put aside or reserved for later use (“parked”) or had the potential to park the 180-day marketing exclusivity period, therefore delaying generic drug entry into the market.<sup>51</sup> This happens when the first ANDA applicant enters into an agreement not to enter the market for a given time, delaying the tolling of the 180 days of exclusivity until after they enter the market.<sup>52</sup> Since the FDA is precluded from approving subsequent ANDA applicants until the 180 day exclusivity period for the first applicant has run, the brand name manufacturer simply refrains from suing these subsequent applicants for infringement to avoid adverse court decisions and maintains their patent monopoly.<sup>53</sup> In other words, since these subsequent ANDA applicant generic drug companies are precluded from entering the market until the settled term plus the 180 days of exclusivity for the first ANDA applicant have run, there is no reason for a brand name patent holder to sue after settling with first ANDA applicant.<sup>54</sup>

In addition, many of these agreements involve a payment, or “brand payment,” from the brand name manufacturer to the alleged infringing generic

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46. *Id.* at 44; *see* *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1377–78 (Fed. Cir. 2002); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001).

47. *See* FTC STUDY, *supra* note 15, at 50. Patents have been issued for drugs more than one year after NDA approval of the drug where the patent is invalid due to the on-sale bar. *Id.*

48. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(b)(2)(b), (b)(2)(d), 117 Stat. 2066, 2453–55 (2003) (to be codified as amended at 21 U.S.C. § 355(c)(3)(C)); Wendy H. Schacht & John R. Thomas, The Library of Congress Congressional Research Service, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents* 7 (2004); Michelle Meadows, *Greater Access to Generic Drugs: New FDA Initiatives to Improve Drug Reviews and Reduce Legal Loopholes*, FDA CONSUMER, September-October 2003, available at [http://www.fda.gov/fdac/features/2003/503\\_drug.html](http://www.fda.gov/fdac/features/2003/503_drug.html).

49. *See* FTC STUDY, *supra* note 15, at 26.

50. *Id.* at 25.

51. *Id.* at 25–26. In an FTC study, fourteen of a sample of twenty final settlements possibly could park the triggering of the 180-day exclusivity of marketing period, thereby precluding FDA approval of subsequent ANDA applicants until that 180 day period expires. *Id.* at 26.

52. Paul T. Meiklejohn, *The Developing Law of Pharmaceutical Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 921, 924 (2005).

53. *Id.*

54. *Id.* “The patentee avoids intervening court decisions by not bringing infringement suits against subsequently filed ANDAs. Due to this indefinite delay of the 180-day exclusivity period, subsequently filed ANDAs cannot be approved by the FDA. *Id.*”

filing the ANDA.<sup>55</sup> The FTC has explained these possibly anti-competitive settlements as resulting from the fact that the entrance of generic drugs into the market substantially erodes the prices that brand name manufacturers can charge and the potential gain in profits for the generic manufacturer are often much less than the loss to the brand name manufacturer.<sup>56</sup> The FTC has already scrutinized several of these agreements.<sup>57</sup>

One such case involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. involving the brand name drug Hytrin.<sup>58</sup> In exchange for \$4.5 million a month, the agreement required Geneva not to market any generic version of Hytrin – infringing or noninfringing – until a final resolution of the patent litigation on the Hytrin tablets or the entrance of another generic into the market.<sup>59</sup> Geneva also agreed not to transfer or abandon their 180-day market exclusivity period.<sup>60</sup> These provisions ensured Geneva would not enter the market and that no other generic would enter the market, since Geneva’s 180-day exclusivity period would not begin to run, thereby precluding the FDA from approving other applicants.<sup>61</sup> Another case involving Hoechst Marion Roussel, Inc. and Andrx Corp. in relation to Hoechst’s drug Cardizem CD also involved an \$80 million pay-off to Andrx, the generic manufacturer, to delay entry of generics to the market using the 180-day exclusivity to shield away other ANDA applicants.<sup>62</sup> The FTC resolved these two agreements by consent order prohibiting the respondent companies from engaging in any agreements where the generic cannot bring noninfringing alternatives to market and any agreements that restrict the transfer of the 180-day marketing exclusivity period.<sup>63</sup> The consent orders also required that any settlement resulting in a “brand payment” be disclosed to the FTC before the possibility of being approved by a court so the FTC could express its views to the court.<sup>64</sup>

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55. FTC STUDY, *supra* note 15, at 26. 9 of the 14 settlements parking or potentially parking the 180-day exclusivity period in the FTC study had a “brand payment.” *Id.* at 25.

56. *Muris Statement*, *supra* note 9, at 40; Meiklejohn, *supra* note 52, at 925. For example, presume a pioneer drug is sold for \$10 per prescription and nets \$10 million in sales a year. Meiklejohn, *supra* note 52, at 925. If a generic can enter the market at \$6 a prescription and acquires 40% of the market, in one year, the generic’s profit will be \$2.4 million but the pioneer’s loss will be \$4 million. *Id.* However, this would save consumers a total of \$1.6 million in that year. *See id.*

57. *Muris Statement*, *supra* note 9, at 40–41.

58. *Id.* at 7.

59. *In re Abbott Labs.*, No. C-3945 (F.T.C. May 22, 2000) (complaint) [hereinafter Abbott Complaint], <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *In re Abbott Labs.*, No. C-3946 (F.T.C. May 22, 2000) (complaint) [hereinafter Geneva Complaint], <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; *see also Muris Statement*, *supra* note 15, at 40–41.

60. Abbott Complaint, *supra* note 59, at ¶ 2; Geneva Complaint, *supra* note 59, at ¶ 2; *see also Muris Statement*, *supra* note 15, at 40–41.

61. FTC STUDY, *supra* note 15, at 35 Box 3-1.

62. *In re Hoechst Marion Roussel, Inc.*, No. 9293 (F.T.C. May 8, 2001) (complaint) [hereinafter Hoechst Complaint], <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>; *see also Muris Statement*, *supra* note 9, at 8.

63. *In re Abbott Labs.*, No. C-3945 (F.T.C. May 26, 2000) (decision and order), <http://www.ftc.gov/os/2000/03/abbott.do.htm>; *In re Abbott Labs.*, No. C-3946 (F.T.C. May 26, 2000) (decision and order), <http://www.ftc.gov/os/2000/05/c3946.do.htm>; *In re Hoechst Marion Russell, Inc.*, No. 9293 (F.T.C. May 8, 2001) (decision and order), <http://www.ftc.gov/os/2001/05/hoechstdo.htm>; *Muris Statement*, *supra* note 9, at 40–41.

64. *Muris Statement*, *supra* note 9, at 40–41.

The FTC's actions in these cases evidences the agency's distrust for agreements that delay generic drug entry, thereby leading to less competition and higher prices for consumers.<sup>65</sup> The FTC has been particularly distrustful of provisions that involve brand payments, restrictions on noninfringing generics, and restrictions on the transfer of the 180 day marketing exclusivity period.<sup>66</sup>

### C. Recent Amendments to Hatch-Waxman Act

The antitrust concerns resulting from procedural aspects of the Hatch-Waxman Act's provision of 180-day exclusivity have resulted in recent amendments, via the MMA Act.<sup>67</sup> First, the amendments attempted to curb the parking of the 180-day exclusivity period as applied to subsequent ANDA applicants by allowing for a declaratory action for subsequent ANDA applicants if they are not sued for patent infringement within the 45-day period after they file.<sup>68</sup> The amendments also changed the trigger for the 180-day period to run exclusively at the time of the first ANDA applicant's marketing of the drug and eliminated the court decision trigger.<sup>69</sup> To prevent these agreements from parking the running of the 180 days of exclusivity and to ensure that generic drug companies will market generic drugs as soon as they become eligible, the amendments provide for forfeiture of the period of marketing exclusivity for the first generic ANDA applicant.<sup>70</sup> First, it is a forfeiture event for the ANDA applicant to fail to market within seventy-five days of the later of either: (a) final approval of its ANDA, which will not exceed thirty months; or (b) an appeals court decision on the patent(s).<sup>71</sup> Additional forfeiture events include withdrawing an ANDA or amending paragraph IV certifications, failing to obtain tentative FDA approval, entering into an agreement violating antitrust law, and expiration of the patents that gave rise to the eligibility for 180 day exclusivity.<sup>72</sup> Additionally, agreements reached between brand-name and generic ANDA applicants must be submitted to the FTC within 10 days from the agreement's execution to be scrutinized for

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65. *Id.* at 41.

66. *Id.*

67. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101, 1102, 1103, 117 Stat. 2066, 2448, 2457, 2460 (2003) (to be codified as amended at 21 U.S.C. § 355).

68. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(b)(2)(D), 117 Stat. 2066, 2454-55 (2003) (to be codified as amended at 35 U.S.C. § 271(e)(5)); Meiklejohn *supra* note 52, at 925-26.

69. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2457 (2003) (to be codified as amended at 21 U.S.C. 355(j)(5)(B)); *Prepared Statement of The Federal Trade Commission Before the S. Comm. on the Judiciary*, 107th Cong. 36, 46-47 (2003) [hereinafter *Judiciary Statement*] (statement of Timothy J. Muris, Chairman, Federal Trade Commission), available at <http://www.ftc.gov/os/2003/08/030801pharmtest.htm>.

70. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2), 117 Stat. 2066, 2457, 2458-59 (2003) (to be codified as amended at 21 U.S.C. 355(j)(5)(B)).

71. *Id.*; *Judiciary Statement*, *supra* note 69, at 47.

72. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(2), 117 Stat. 2066, 2457, 2458-59 (2003) (to be codified as amended at 21 U.S.C. § 355); Edward R. Ergenzinger Jr. & Jeffrey L. Williams, *Patents and Health Care at Cross Purposes: Reconciling Innovation, Economy and Equity*, INNOVATION ONLINE, <http://www.ncsu.edu/iei/innovationonline/comphealth.htm> (last visited Oct. 24, 2007).

antitrust implications.<sup>73</sup>

### III. ANALYSIS

This Part will first analyze the results of Hatch-Waxman litigation to illuminate the incentives provided by the Act to both patent holders and ANDA applicants. Second, this Part will analyze the effects of the recent amendments of 2003. Third, this Part will hypothesize the effects on Hatch-Waxman litigation of the addition on a fee shifting regime. Finally, this Part will explore the antitrust implications of settlement payments from brand name pharmaceutical companies to potential generic competitors.

#### A. *FTC Study of Results of Hatch-Waxman Litigation*

The FTC conducted a study prior to the amendments in 2003.<sup>74</sup> Analysis of the FTC study of the results of Hatch-Waxman litigation can shed light upon the incentives put in place by the Act to both brand-name manufacturers and the generic competitors.<sup>75</sup> While the sample information was taken prior to the amendments in 2003, the study can still effectively provide valuable information regarding the incentives for both parties.<sup>76</sup>

The FTC studied a sample of 104 ANDAs filed with a paragraph IV certification.<sup>77</sup> Of the fifty-three cases that were resolved, twenty settled, thirty involved a final decision of a court on the merits, in two cases the patent expired, and in one case the patent was withdrawn.<sup>78</sup> Of the thirty cases where the court decided on the merits, the court found in twenty-two of the cases either invalidity of the patent or noninfringement.<sup>79</sup> Therefore, the ANDA applicant won on the merits 73% of the time,<sup>80</sup> which indicates that ANDA applicants file a paragraph IV certification only when they are very certain they have a meritorious case for invalidity or non-infringement. This seems to indicate that the incentives for generic drug companies to file paragraph IV certifications and subject themselves to the costs of litigation are only there for the strongest of cases. The first ANDA applicant can expect that they will be sued for patent infringement within forty-five days of filing a paragraph IV certification.<sup>81</sup> Additionally, the patent holder's motivation to protect monopoly profits for the extent of the 30-month stay period irrespective of the merits of his patent claim ensures that the ANDA applicant will most likely be in for a long and expensive battle since the gains from monopoly profits can

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73. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112(a), 117 Stat. 2066, 2461-62 (2003) (to be codified as amended at 21 U.S.C. § 355(j)(5)(D)(i)(v)).

74. FTC STUDY, *supra* note 15.

75. *Id.* at 15 fig.2-1.

76. *See id.* at 16 (summarizing patent infringement litigation activity as of June 1, 2002).

77. *Id.* at 15 fig.2-1.

78. *Id.*

79. *Id.*

80. *Id.* at 16. Compare this statistic to another study in patent law that found overall only 46% of final decisions involving patent validity find the patent invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998).

81. *See* FTC STUDY, *supra* note 15, at 13. Nearly 75% of the generic applicants filing a paragraph IV certification were sued for patent infringement. *Id.*

often outweigh the costs of patent litigation.<sup>82</sup> Other prospective ANDA applicants with meritorious claims of patent invalidity or non-infringement may be scared away by the costs of litigation, especially when the drug product at issue has a smaller market value.<sup>83</sup> The consuming public then loses the benefit of lower prices when possibly meritorious ANDA applicants are scared away and while the substantive bounds of pharmaceutical patents are not adequately policed.<sup>84</sup>

Of the twenty settlements, nine involved “brand payments” from the brand name company to the generic first ANDA applicant.<sup>85</sup> The concern regarding brand payments are that the brand name companies have more to lose than the ANDA applicant has to gain and therefore will pay to maintain their monopoly, imposing these extra costs on consumers.<sup>86</sup> Additionally, the FDA is precluded from approving any subsequent ANDA applicants until 180 days from the first ANDA applicant’s entrance, keeping any other potential competitors out of the market as well.<sup>87</sup>

Under the recent amendments, the generic manufacturer will forfeit the 180 days of exclusivity if the generic fails to market seventy-five days after the later of FDA approval after thirty months, or a final decision of patent invalidity or non-infringement by an appeals court.<sup>88</sup> This does not adequately address agreements that park the first ANDA applicant’s first marketing of the generic, as well as the 180-day exclusivity period. The only provision protecting against such agreements is the forfeiture event as a result of FTC action against the parties to the agreements upon a finding of violation of the antitrust laws.<sup>89</sup> The limited number of settlements immediately following the amendments showed the pharmaceutical industry’s fear of being held in violation of the antitrust laws due to settlements involving “brand payments” that restrict generic entry.<sup>90</sup> However, a more recent study of the settlements

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82. The patent holder can foreclose the market for the 30 month stay period, allowing the patent holder “to keep its price elevated above the competitive level and restrict market output.” See James Gould and James Langenfeld, *Antitrust and Intellectual Property: Landing on Patent Avenue in the Game of Monopoly*, 37 IDEA 449, 455 (1997). The FTC study indicates that 33 of 53 resolved cases were not settled but extended to a final decision. FTC STUDY, *supra* note 15, at 15 fig.2-1. In fact, fourteen district court decisions of invalidity or non-infringement were appealed to the Federal Circuit where only one was partially reversed. *Id.* at 21. This indicates the strong incentive for patent holders to extend the litigation to take full advantage of the 30-month stay provision.

83. See Robert Steyer, *FTC Member Seeks Study of Generic Competition*, THE STREET, May 12, 2005, <http://www.thestreet.com/stocks/robertsteyer/10223207.html> (indicating that the “pot of gold” is larger for higher grossing drugs but that there may not be adequate incentives in many cases for generic companies to file ANDA applications).

84. *Id.*

85. FTC STUDY, *supra* note 15, at 31. “Brand payments” occur in a settlement agreement when the plaintiff in patent infringement litigation agrees to pay the accused generic infringer to maintain the exclusive rights associated with their patent. *Id.*

86. *Muris Statement*, *supra* note 9, at 40; Meiklejohn, *supra* note 52, at 925.

87. Meiklejohn, *supra* note 52, at 924–25.

88. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1102(a)(2), 117 Stat. 2066, 2457, 2458 (2003) (to be codified at 21 U.S.C. § 355(j)(5)(B)(iv)(D)).

89. *Id.*

90. See FEDERAL TRADE COMMISSION BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004 4–5 (2005) [hereinafter COMPETITION STUDY FY 2004], available at <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>. The number of settlements in the 2004 fiscal year increased over the pace it had prior to 2000 and since receiving

in the 2005 fiscal year show that final settlements in Hatch-Waxman litigation are beginning to test the waters of anti-competitive conduct with settlements involving both compensation to the generic manufacturer and restrictions upon generic entry.<sup>91</sup> In the long run, this puts a substantial burden on the FTC and may result in future generic drugs being kept off the market as agreements are made which restrict generic entry by parking the 180-day period of exclusivity without violating antitrust law. Additionally, the FTC has shown its reluctance in the past to attach antitrust sanctions to these settlement agreements.<sup>92</sup>

The settlements in Hatch-Waxman litigation show many situations where the 180-day exclusivity period may not provide adequate incentives to generic ANDA applicants to challenge the validity of brand-name drug patents through expensive litigation, or to design non-infringing alternatives. Allowing the brand name drug manufacturer to compete with the ANDA applicant as an “authorized generic” during the 180-day exclusivity period further weakens any incentives to applicants.<sup>93</sup> While this is pro-consumer, giving them the benefit of competitive drug prices, it does hamper the incentive of 180 days of exclusivity provided to generic ANDA applicants by filing a paragraph IV certification.<sup>94</sup> The ramification may be fewer challenges to pharmaceutical patents that could harm the policing of overly broad patents and thereby be harmful to competition in the pharmaceutical market.

Of the twenty settlements in the FTC study of 2002, seven involved licensing agreements.<sup>95</sup> License agreements are generally pro-consumer because they can introduce competition, resulting in lower prices for consumers.<sup>96</sup> However, these licensing agreements also have shown the ability to delay generic drug entry onto the market.<sup>97</sup> Four of the seven licensing agreements involved a waiting period for the generic drug to come onto the

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FTC scrutiny, none of the settlements had both the potential to park the 180 day exclusivity period and also involved a brand payment. *Id.*

91. See Federal Trade Commission Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 3-4 (2006) [hereinafter Competition Study FY 2005], available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>. Three of the eleven final settlements in the 2005 fiscal year involved “both compensation to the generic and a restriction on the generic’s ability to market the product.” *Id.* at 4.

92. In two cases, the FTC negotiated a consent decree but did not impose any financial penalties. Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 322, 326 (2002).

93. Martin Sipkoff, *Big Pharma Uses Effective Strategies to Battle Generic Competitors*, DRUG TOPICS, Aug. 8, 2004, <http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=121720>. “An authorized generic is like any other generic in that it is deemed equivalent to a brand-name drug . . . [b]ut rather than being made by an independent generic drug manufacturer pursuant to an Abbreviated New Drug Application, it is either made by or under a license from the New Drug Application holder itself.” *Id.* (quoting Robert Reznick, chair of the Pharmaceutical and Healthcare Practice Group at the law firm of Hughes Hubbard & Reed).

94. *Id.*

95. FTC STUDY, *supra* note 15, at 17.

96. See EUROPEAN FED’N OF PHARM. INDUS. AND ASS’NS, EFPIA’S COMMENTS ON THE DRAFT TRANSFER OF TECHNOLOGY BLOCK EXEMPTION REGULATION (TTBER) 1 (2003) [http://ec.europa.eu/comm/competition/antitrust/technology\\_transfer\\_2/23\\_efpia\\_en.pdf](http://ec.europa.eu/comm/competition/antitrust/technology_transfer_2/23_efpia_en.pdf). Settlement agreements may “result in faster market entry of the generic, and thereby promote competition.” Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 56 (2005).

97. See FTC STUDY, *supra* note 15, at 28, 29 tbl.3.2.

market.<sup>98</sup> Subsequent ANDA applicants were then precluded from getting FDA approval until the first ANDA applicant's 180-day exclusivity period had run,<sup>99</sup> while missing out on the 180-day exclusivity incentive for challenging patent validity or non-infringement themselves. A possible policy to prevent parking of generic drug competition would be to make settlements that have a waiting period for marketing generic drugs along with a payment from the patentee to the alleged infringer per se illegal.<sup>100</sup> Although studies following recent antitrust scrutiny have found pharmaceutical companies on their best behavior,<sup>101</sup> formalizing this as illegal under antitrust law will prevent abuse that already appears to be resurfacing.<sup>102</sup> However, imposition of per se antitrust illegality may discourage settlements that involve licensing agreements in Hatch-Waxman litigation by reducing opportunities for the parties to settle based on their evaluation of the merits of their case.<sup>103</sup>

The FTC's study of Hatch-Waxman litigation seems to indicate that there is a possibility that the incentives provided may not be enough to effectively serve the purpose of the Act in encouraging generic manufacturers to file ANDA applications with a paragraph IV certification for patents that they believe are invalid or can be designed around. This may be particularly prevalent for drugs with lower revenues. The existing incentive, 180 days of exclusivity, has suffered from anti-competitive abuses.<sup>104</sup> The end result is less competition, allowing patent rights to be effectively extended beyond their actual scope. If we want to encourage generic drug companies to challenge invalid patents and design noninfringing alternatives in order to increase drug price competition, we may need to offer additional or other forms of incentives for generics to do so.

### B. Effect of recent amendments

The recent amendments calculated to eliminate loopholes in the Hatch-Waxman Act are likely to be effective in furthering a purpose of the Act, getting generic pharmaceuticals to the market faster.<sup>105</sup> The amendments are

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98. *Id.* Of the four agreements, the average delay for the generic to be allowed to come onto the market after the agreement was thirteen months, while the longest delay of the four agreements was seventeen months. *See id.* at 29 tbl.3.2.

99. Meiklejohn, *supra* note 52, at 924.

100. RICHARD A. FEINSTEIN, PER SE ANTITRUST RISKS IN HATCH-WAXMAN AGREEMENTS, FEDERAL TRADE COMMISSION AND DEPARTMENT OF JUSTICE HEARINGS ON THE IMPLICATIONS OF COMPETITION AND PATENT LAW AND POLICY 9-10 (2002), <http://www.ftc.gov/opp/intellect/020502feinstein.pdf>.

101. *See* COMPETITION STUDY FY 2004, *supra* note 90, at 4. No settlements in the 2004 fiscal year combined a brand payment with a potential parking of the 180 day exclusivity period. *Id.*

102. *See generally* COMPETITION STUDY FY 2005, *supra* note 91, at 4 (providing a background on recent settlements in which the brand received a royalty in exchange for granting the generic a license to the patent at issue in litigation).

103. *See generally* Williams, *supra* note 96, at 18 (claiming that some courts view the goals of the antitrust and patent laws as complimentary, rather than clashing). Some courts have found that these settlements may "very well relate to questions of validity of the patent or risks and profits at stake." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1310 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004); Williams, *supra* note 96, at 18.

104. *See supra* Part II.B.2.

105. *Statement Of Daniel E. Troy, Chief Counsel, U.S. Food And Drug Administration, Before the S. Committee on the Judiciary, 107th Cong. 1 (2003)* [hereinafter *Troy Statement*] (statement of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration), available at

likely to further competition and ensure that consumers realize the benefits of lower prescription drug prices.<sup>106</sup> Nonetheless, generic drugs may still be blocked from entering the market, requiring further reforms to advance the goal of the Hatch-Waxman Act in encouraging generic competition.

### 1. 30 month stay provision

The MMA Act ensures that patent holders only receive one 30-month stay for a drug product,<sup>107</sup> therefore eliminating the incentives of patent holders to file for patents that they know will likely be held invalid in order to trigger a new 30 month stay. The MMA Act provides further reform by allowing the ANDA applicant to file a counterclaim requiring changes to patent information in the Orange Book when sued for infringement.<sup>108</sup> These changes ensure that the first ANDA applicant will always receive FDA approval within thirty months of filing for an ANDA in accordance with the intent of the Hatch-Waxman Act regardless of the presence of later-issued patents.<sup>109</sup>

### 2. 180 day market exclusivity

The MMA Act does not go far enough to discourage anti-competitive agreements between brand-name drug manufacturers and generic manufacturers when the agreement delays the triggering of the 180 day exclusivity period. While the forfeiture events do ensure that generic drug manufacturers market their drug within seventy-five days upon finding the brand name manufacturer's patent invalid or not infringed or after receiving FDA approval,<sup>110</sup> they do not adequately address settlements that park the 180-day exclusivity period. In other words, there is no defined forfeiture event of the 180-day exclusivity period subsequent to a settlement.<sup>111</sup> These agreements are only addressed by requiring settlements to be disclosed with the FTC and forfeiture of the 180 days of exclusivity only upon an FTC finding that the settlement is in violation of the antitrust laws.<sup>112</sup> While these agreements have not been much of a problem since the amendments, the pharmaceutical companies are beginning to test the limits of the antitrust law.<sup>113</sup> This puts far too much pressure upon the FTC to prevent abuses of the 180 day exclusivity period.

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<http://www.fda.gov/ola/2003/genericdrugs0801.html>.

106. *Id.*

107. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1101(b)(2)(B), 117 Stat. 2066, 2448, 2453 (2003) (to be codified at 21 U.S.C. § 355(j)(5)(B)).

108. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1101(b)(2)(D), 117 Stat. 2066, 2454, 2456 (2003) (to be codified at 21 U.S.C. § 355(j)(5)(C)(ii)).

109. *See Troy Statement, supra* note 105, at 1.

110. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1102(a)(2), 117 Stat. 2066, 2458 (2003) (to be codified at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)).

111. *Id.* at 2458–60.

112. *Id.* at 2459; *see also* W. Edward Bailey et al., *Recent Hatch-Waxman reform: balancing innovation, competition and affordability*, IP VALUE 2005, [http://www.buildingipvalue.com/05\\_NA/107\\_110.htm](http://www.buildingipvalue.com/05_NA/107_110.htm).

113. *See supra* notes 90–91 and accompanying text.

### 3. Declaratory Judgment Provision

The only provision of the recent amendments helping to prevent parking of the 180-day exclusivity period is a portion amending 35 U.S.C. § 271(e)(5), providing ANDA applicants with a declaratory action if they are not sued for patent infringement within forty-five days.<sup>114</sup> Giving a declaratory judgment to ANDA applicants would help to mitigate the effects of any anti-competitive settlements because the brand name manufacturer will have to consider future litigation with subsequent ANDA applicants when contemplating whether to enter into anti-competitive settlement negotiations with the first applicant. However, the Federal Circuit has interpreted this provision to not allow subsequent ANDA applicants a declaratory action because it does not meet the constitutional “case or controversy” requirement.<sup>115</sup> This poses problems because subsequent ANDA applicants have no way of challenging the validity or non-infringement of pharmaceutical patents after the first ANDA applicant settles.<sup>116</sup> This is results from the fact that they cannot receive FDA approval until the expiration of the 180 days of exclusivity awarded to the first applicant which has been delayed because of the settlement.<sup>117</sup> Even though an ANDA application is an act of infringement,<sup>118</sup> the brand-name patent holder has no motivation for bringing suit because these subsequent ANDA filers will not enter the market until after the first applicant has profited from 180 days of exclusivity.<sup>119</sup>

In a patent infringement suit, the test for whether there is a case or controversy is a two part test formulated by the Federal Circuit.<sup>120</sup> In that test, there must be both:

(1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and

(2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.<sup>121</sup>

While the second prong is met by the filing of the ANDA application with a paragraph IV certification, the court found in *Teva* that the district court did not err in its application of the reasonable apprehension prong, finding that the patentee, Pfizer, “had not created a reasonable apprehension that it would bring suit against Teva for infringement.”<sup>122</sup> The court emphasized that listing

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114. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1101(b)(2)(D), 117 Stat. 2066, 2454–55 (2003) (to be codified at 21 U.S.C. § 271(e)(5)); *see also* Meiklejohn, *supra* note 52, at 926.

115. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1336 (Fed. Cir. 2005).

116. Meiklejohn, *supra* note 52, at 924. “The patentee avoids intervening court decisions by not bringing infringement suits against subsequently filed ANDAs,” while taking advantage of preclusion of FDA approval to these ANDAs until after the delayed 180 day exclusivity period expires. *Id.*

117. *Id.*

118. 35 U.S.C. § 271(e)(2) (2000).

119. Meiklejohn, *supra* note 52, at 924.

120. *Teva*, 395 F.3d at 1330.

121. *Id.*

122. *Id.* at 1332, 1334. The court held that there is not a reasonable apprehension in cases solely where: (1) the patent holder complies with the statutory requirement of submitting their patent in the Orange Book as

patents in the Orange Book is a statutory requirement, and that compliance with the requirement “should not be construed as a blanket threat to potential infringers as far as . . . patent enforcement intentions are concerned.”<sup>123</sup> The court held that more is required than the existence of an adversely held patent in the Orange Book in order to satisfy the reasonable apprehension prong.<sup>124</sup>

However, in *Teva*, Judge Mayer dissented stating that the two-part test including the requirement of a reasonable apprehension is useful in evaluating the justiciability of declaratory judgment actions, but not a constitutional requirement that must necessarily be applied.<sup>125</sup> Even under application of the two-part test, Judge Mayer states that the “reasonable apprehension” prong should be met as a result of listing a patent in the Orange Book, a representation of the patentee’s “future intent to enforce its patent rights.”<sup>126</sup> He also states that in determining the existence of an actual controversy, the totality of the circumstances must be analyzed; in this Hatch-Waxman scenario, the court must “take into account the injury that a generic drug manufacturer suffers.”<sup>127</sup> Judge Mayer would find that the delay to subsequent ANDA filers associated with parking of the 180-day period of exclusivity is a direct injury because subsequent ANDA applicants are “depriv[ed] . . . of the opportunity to enter the market.”<sup>128</sup> Denying a declaratory judgment action for subsequent ANDA applicants allows parking of the 180-day period of exclusivity<sup>129</sup> and runs counter to the purposes of making a paragraph IV certification an act of infringement, denying “*de facto* extension” of patent terms for pharmaceuticals and encouraging generic drugs to get to the market.<sup>130</sup> Nonetheless, the legislative history of the amendments indicates that the reasonable apprehension prong is still required to be met for a declaratory judgment action.<sup>131</sup> Judge Mayer posits that the fact that an ANDA applicant suffers a cognizable injury of not being allowed to get to the market until the running of the 180 days of exclusivity requires an other-than-traditional application of the reasonable apprehension prong to vindicate these applicants’ legal rights.<sup>132</sup> By denying subsequent applicants a declaratory judgment action, this only furthers the incentives for brand name manufacturers to negotiate with the first ANDA applicant to delay market

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part of their NDA; (2) the ANDA applicant files a paragraph IV certification on the patent; and (3) an infringement suit by the patentee is not brought against the ANDA applicant. *Id.* at 1332–33.

123. *Id.* at 1333.

124. *Id.*

125. *Id.* at 1339 (Mayer, J., dissenting). Judge Mayer disputes the necessity of satisfying the two-part test and finds that satisfaction of both elements “merely assure[s] that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the ‘actual controversy’ requirement.” *Id.* (quoting *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997)).

126. *Id.* at 1341.

127. *Id.*

128. *Id.* at 1342.

129. *Id.*

130. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

131. *Id.* at 1339 (citing H.R. CONF. REP. NO. 108–391, at 836 (2003)).

132. *Id.* at 1339.

entry with assurance that no other generic will be able to challenge their patent because they would not be able to get FDA approval.

### C. Fee-Shifting

This Section will first discuss the American and British fee regimes and explore the aspects of both that are best fitted for Hatch-Waxman litigation. This section will then explore one-way fee shifting in Hatch-Waxman litigation.

#### 1. Rationales of Various Fee-Shifting Regimes

The “American rule” with regards to litigation costs has traditionally been that each litigant bears his own costs.<sup>133</sup> The “British rule,” on the other hand, has been that the loser in the litigation pays the costs, a two way fee-shifting rule.<sup>134</sup> Some commentators claim that the American rule encourages wasteful litigation allowing less than meritorious lawsuits at a low cost to the plaintiff.<sup>135</sup> These same commentators claim that the British rule is preferential in discouraging frivolous lawsuits because of the disincentive of having to pay the other party’s legal fees, which forces parties to carefully consider the merits of a case before proceeding in any litigation.<sup>136</sup> This could also encourage settlement by giving the parties an incentive to evaluate the merits of their case.<sup>137</sup> While settlements reduce transaction costs and are economically preferred, some commentators hold a negative view towards settlements in the Hatch-Waxman context because they often tend to be anti-competitive, delaying a generic drug’s entry into the market.<sup>138</sup>

In the context of patent litigation, the results of the previously discussed FTC study suggest generic manufacturer ANDA applicants carefully consider the merits of their cases before filing paragraph IV certifications, as indicated by the high success rate in litigation.<sup>139</sup> Therefore, the rationale for imposing the British rule – that is, each party is more likely to settle because they are encouraged to carefully consider the merits of his position – has less application to the generic ANDA applicant in the Hatch-Waxman litigation context. This rationale is also minimized because the brand name patent

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133. Valner L. Johnson, *The Award of Attorney’s Fees to Prevailing Defendants Under the Washington Long Arm Statute*, 63 WASH. L. REV. 125, 126 (1988); Susan M. Olson, *How Much Access to Justice from State “Equal Access to Justice Acts” ?*, 71 CHI.-KENT L. REV. 547, 549 (1995).

134. Johnson, *supra* note 133, at 126 (referred to in the piece as the “English Rule”).

135. Jonathan Fischbach & Michael Fischbach, *Rethinking Optimality in Tort Litigation: The Promise of Reverse Cost-Shifting*, 19 BYU J. PUB. L. 317, 318, 326 (2005).

136. *Id.* at 318, 327 (citing Dan Quayle, *Agenda for Civil Justice Reform in America*, 60 U. CIN. L. REV. 979, 1003 (1992)).

137. Fischbach & Fischbach, *supra* note 135 at 331.

138. See Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 40 (2004) (suggesting that there should be a duty to litigate and ban on settlements in Hatch-Waxman litigation).

139. See *supra* Part.III.A.

holder has an incentive to draw out the litigation while the monopoly profits continue to come rolling in.<sup>140</sup> Upon first glance, the rationale of the British rule of encouraging settlement would seem to further the purposes of the Hatch-Waxman Act in getting more generic pharmaceuticals to market quicker by reducing the litigation period. However, the British rule generally encourages settlement as a result of each side's fear of footing the entire bill for litigation.<sup>141</sup> In Hatch-Waxman litigation, it is likely that the disincentive provided by fear of paying all the litigation costs differs between brand name and generic manufacturers. The alleged infringer is likely to be much more averse to the risk of footing the entire bill because they don't have the monopoly profits rolling in, which may affect their motivation in filing for paragraph IV certification.<sup>142</sup> This difference in risk preference between the brand name patent holder and generic ANDA applicant also may provide the patent holder the opportunity to pressure the paragraph IV applicant, giving the patent holder a better bargaining position and advantage through the course of the litigation. This imbalance in position may indicate that the nature of the solution requires a counterbalance to ensure there are proper incentives for generic manufacturers to challenge and design around pharmaceutical patents.

A criticism of the American rule is its tendency to deter small but meritorious claims.<sup>143</sup> This is evidently a result of the transaction costs involved.<sup>144</sup> On the other hand, under the British rule, a party knows the other side will pay its fees if it is successful, potentially allowing the most meritorious of patent claims, large or small, to be fully litigated.<sup>145</sup> Paragraph IV ANDA applicants in Hatch-Waxman litigation are more likely to have meritorious cases than other alleged infringers in patent litigation because they carefully consider their invalidity challenge or their attempt to design around the brand name pharmaceutical's patent.<sup>146</sup> This is also partially because the alleged infringer in Hatch-Waxman litigation essentially acts as the plaintiff by initiating the litigation with the paragraph IV certification.<sup>147</sup> Therefore, the party considers the merits of the case before litigation is initiated. The higher the probability of success on the merits for the alleged infringer, the more attractive becomes the incentive of having the other party in the litigation pay your fees.<sup>148</sup>

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140. Patent holders abused the 30 month stay provision in order to extend the litigation and delay a final decision of the case. *See, e.g.* FTC STUDY, *supra* note 15, at 50 Box 4-4 (summarizing the FTC's enforcement action involving the drug Tiazac).

141. Fischbach & Fischbach, *supra* note 135, at 331.

142. *Id.* ("[P]arties who are risk-averse or have shallow pockets may be hesitant to expose themselves to substantial fee-shifts at the close of litigation.").

143. *Id.* at 327.

144. *See id.* (stating that "[s]mall claims . . . are swallowed by attorneys' fees")

145. *See id.* at 331 ("Some laud the British Rule as a corrective mechanism for the American Rule's over-deterrence of small claims in which the operative legal rule substantially favors the potential plaintiff.").

146. *See supra* note 81 and accompanying text.

147. *See supra* notes 26, 27 and accompanying text.

148. *See* Fischbach & Fischbach, *supra* note 135, at 331 (noting that commentators support the British

On the other hand, if there is unpredictability, as there are in many areas of the law, the British rule can potentially scare away litigants who fear the worst.<sup>149</sup> Patent law is particularly susceptible to uncertainty in determining the metes and bounds of the patent right in the infringement and also in the validity context.<sup>150</sup> This has the potential to prejudice the patent holder if there is no way that he could have known that his patent would be invalid and then be forced to pay the fees of the alleged infringer.<sup>151</sup> However, commentators have identified the chemical and pharmaceutical industries as areas where patent rights are more certain.<sup>152</sup> These commentators have stated that in these industries there are “comparatively clear standards [that] can be applied to assess a chemical patent’s validity and to defend against infringement.”<sup>153</sup> Therefore, certainty is less of an issue in the pharmaceutical industry, allowing litigants to better evaluate the merits of their case than in other industries.

Those who are risk averse – often those with less money – are more likely to be scared away by the possibility of having to pay all the fees.<sup>154</sup> In this respect, the British rule tends to favor wealthy deep-pocket defendants such as corporations.<sup>155</sup> This aspect of the British rule doesn’t coincide with the Hatch-Waxman purpose of encouraging generic drug entry because it could discourage the typically more risk-averse generic manufacturers from engaging in litigation with the deep-pocket brand-name drug manufacturer patent holder. Any potential for prejudice of patent holders<sup>156</sup> by unexpectedly having to pay the alleged infringer’s attorney’s fees that they could not have expected, this would be outweighed by the British Rule’s effect on the risk-averse but meritorious generic drug manufacturer who would otherwise be scared away from litigation or be pressured into a disfavorable settlement early in litigation. However, the British rule still causes a chilling effect towards risk-averse ANDA applicants resulting from the two-way shift of fees that serves to undermine the Hatch-Waxman goal of encouraging generic market entry.<sup>157</sup>

Another set of problem cases in which the incentives for litigants to file

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rule as a corrective mechanism towards the American rule’s over-deterrence of small but meritorious claims).

149. *Id.*

150. See Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 8 (2005); Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time is Ripe for a Consistent Claim Construction Methodology*, 8 J. INTEL. PROP. L. 175, 202–03 (2001) (arguing that claim construction in patent law is particularly prone to uncertainty until it reaches the appellate level).

151. Jay P. Kesan, *Carrots And Sticks To Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 796 (2002). A pro-defendant fee-shifting rule “would marginally affect innocent parties by lowering enforcement of valid patents.” *Id.*

152. Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 796–797 (1987). In a survey on patent effectiveness for products, respondents had the pharmaceutical and chemical industries ranked the most highly for effect of patent rights. *Id.*

153. *Id.* at 798.

154. Fischbach & Fischbach, *supra* note 135, at 331; Kesan, *supra* note 151, at 790, 796.

155. Kesan, *supra* note 151, at 790.

156. See *id.* at 793 (finding some injustice in forcing the patentee loser of a close case to pay all of the attorney’s fees).

157. See Fischbach & Fischbach, *supra* note 135, at 331.

suit disappear with both the American rule and British rule are “cases in which the benefits of litigating far outweigh the costs but where litigation is still unattractive because the benefits take the form of a public good.”<sup>158</sup> This is partially the situation in Hatch-Waxman litigation because the benefit to the ANDA applicant in being able to compete may not outweigh the costs and uncertainty of litigation and the rewards of possible settlements.<sup>159</sup> However, the benefits to the public of competition and lower prices, a core purpose of the Hatch-Waxman Act, are substantial if the ANDA applicant challenges the validity of or designs around the patent.<sup>160</sup> The 180-day exclusivity period provides the existing incentive for generic manufacturers to subject themselves to litigation to further this purpose of the Hatch-Waxman Act.<sup>161</sup> As discussed earlier, this may not provide enough incentive to encourage litigants to stay the course in litigation and challenge patents, providing for more of an opportunity for anti-competitive settlements between the brand name and generic manufacturer.<sup>162</sup> In some cases, it may not be possible to convince the generic manufacturer to compete, rather than accept an anti-competitive settlement, but one-way fee shifting may be a way to so tip the balance in many cases.

## 2. One-Way Fee-Shifting

One-way fee shifting has been used in areas of the law where the benefits to the public at large far outweigh the benefits to a single litigant.<sup>163</sup> One-way fee shifting statutes have been utilized for the public interest in the protection of civil rights and the environment.<sup>164</sup> One-way fee shifting statutes are unique in that they encourage litigation, rather than settlements.<sup>165</sup> By providing the incentive of no costs for a litigant to bring suit if they are successful, meritorious claims will be brought even if there is very little monetary incentive to the litigant.<sup>166</sup> While the ANDA applicant is not technically the plaintiff, by filing the ANDA they are essentially initiating the litigation.<sup>167</sup> This “private attorney general” rationale for one-way fee shifting fits Hatch-Waxman litigation because the incentives are far less for the generic

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158. *Id.* at 327–28.

159. Meiklejohn, *supra* note 52, at 925.

160. *See id.* (providing an example of how a settlement can monetarily benefit the pioneer drug company and the generic drug company at the expense of the public).

161. FTC STUDY, *supra* note 15, at 7.

162. *See supra* Part III.A.

163. *See* Abizer Zanzi, *The Constitutional Battle Over the Public Interest Litigant Exception to Rule 82*, 21 ALASKA L. REV. 329, 334 (2004) (describing the litigant as a “private attorney general” fighting for the public interest).

164. Paul Taylor, *The Difference Between Filing Lawsuits and Selling Widgets: The Lost Understanding that Some Attorneys’ Exercise of State Power Is Subject to Appropriate Regulation*, 4 PIERCE L. REV. 45, 58 (2005).

165. Katherine M. Mongoven, *Impact of Contingency Fee Agreements on “Reasonable” Attorney Fees Awarded Pursuant to Wisconsin Fee-Shifting Statutes*, 88 MARQ. L. REV. 1013, 1017 (2005); Zanzi, *supra* note 163, at 334.

166. Mongoven, *supra* note 165, at 1017.

167. *See supra* notes 26–27 and accompanying text.

applicant to challenge the patent validity than they are for the public interest as a whole in the interest of drug price competition.<sup>168</sup> By providing one-way fee shifting for successful paragraph IV ANDA applicants as an incentive, the public interest in drug price competition would be in the hands of these “private attorney generals.”<sup>169</sup> Cases that are meritorious are more likely to be brought and fully litigated. This polices invalid pharmaceutical patents<sup>170</sup> and encourages other generic manufacturers to design around pharmaceutical patents, the effect being more legitimate competition and therefore lower drug prices to the American consumer.

Most one-way fee shifting regimes are in areas such as consumer protection, environmental protection, and civil rights, where the pecuniary harm is very small or valueless to each individual and we require these “private attorney generals” to fight for the rights of the public interest.<sup>171</sup> These are important issues of public interest that justify the legislative imposition of a one-way fee shifting regime. Ensuring the availability of generic drugs on the market is a matter of public interest and a stated purpose of the Hatch-Waxman Act.<sup>172</sup> The use of fee shifting statutes in these classic “private attorney general” cases differs slightly from Hatch-Waxman litigation because they typically involve an aggregation of small or valueless claims as is the case with environmental and consumer protection.<sup>173</sup> In Hatch-Waxman litigation, however, the ANDA applicant is seeking the declaration that the drug that they have yet to market is within the scope of an invalid patent or does not infringe the brand name drug’s patent so they can act as the sole competitor with the brand name manufacturer for 180 days.<sup>174</sup> While the guaranteed 180 days of exclusivity to compete solely with the patentee provides incentive to file an ANDA with a paragraph IV certification, the cost of the litigation still acts as a large barrier to the potential paragraph IV applicant whose challenge will serve the public’s interest of making generic drugs available.<sup>175</sup>

Previous analysis revealed that problems with anti-competitive settlements in Hatch-Waxman litigation may arise because there is not enough incentive for generic manufacturers to initiate and then subsequently follow through with the litigation.<sup>176</sup> Generic ANDA applicant challengers may be

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168. The purpose of the 180 days of exclusivity in the Hatch-Waxman Act was to give incentive to generic drug manufacturers to vindicate the public interest of lower drug prices by challenging invalid patents and designing noninfringing alternatives. Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 174 (2005).

169. Zanzi, *supra* note 163, at 334.

170. Kesan, *supra* note 151, at 795. “Patentees that manage to get overbroad or invalid patent claims granted by the Patent Office by taking advantage of the Patent Office’s lack of knowledge regarding some prior art, may be penalized under such a regime.”

171. Fischbach & Fischbach, *supra* note 135, at 333.

172. Caffrey & Rotter, *supra* note 138, at 3, 5.

173. See Fischbach & Fischbach, *supra* note 135, at 333.

174. Caffrey & Rotter, *supra* note 138, at 3, 5, 6.

175. This barrier is epitomized by the high success rate of 73% of paragraph IV applicants challenging patents in an FTC study. FTC STUDY, *supra* note 15, at 13.

176. See *supra* Part III.A.

content with taking a share of the patentee's monopoly profits in part to avoid the costs of extended litigation, lacking the incentive to turn down a piece of the anti-competitive pie. Absent the incentive to challenge invalid patents, patentees are allowed to squat on invalid patents and maintain undeserved breadth of claims due to the lack of a challenge.<sup>177</sup>

A one-way fee shifting regime can be supported by "incentive costs."<sup>178</sup> Also, requiring the patent holder to pay the fees if it loses, this will disincentivize opportunistic behavior during prosecution of the patent and will ensure that the patentee seeks patent rights that align with their invention.<sup>179</sup> The result without one-way fee shifting may be the inadequate policing of pharmaceutical patents, therefore imposing a barrier to a generic pharmaceutical's entry into the market. Moreover, one-way fee shifting can provide some incentive for ANDA applicants to see the litigation of patent invalidity or non-infringement to its conclusion.<sup>180</sup>

Even though this may cause more costs and risk to brand name patent holders, the dual purpose of the Hatch-Waxman Act provides a rationale for imposing these extra costs on the patent holder. First, as part of the Hatch-Waxman compromise, the patent holders were given time back on their patents in exchange for a policy removing barriers to encourage generic drugs to enter the market when patent rights do not exclude them.<sup>181</sup> This compromise met two goals.<sup>182</sup> The first goal of compensating patent holders for time lost due to FDA approval has been implemented with a scheme to give patent holders back a maximum of five years of time lost to FDA approval.<sup>183</sup> The second goal of providing procedures to encourage generic drugs to make it to the market has been met with some opportunity for abuse, particularly in the paragraph IV ANDA application process where generic drug companies are more inclined to engage in anti-competitive settlements rather than challenge pharmaceutical patent validity or design around existing patents.<sup>184</sup> This suggests that the brand-name patent holders may have to bear some extra costs or risk to implement this second goal in exchange for the compensation of time back on their patent. Furthermore, as suggested, some have said that one-way pro-defendant fee shifting in patent law will encourage patent holders to ensure

177. Kesan, *supra* note 151, at 787. Some commentators already claim that overly broad patents are a rampant problem and there is need for litigation reform. *Id.*

178. *Id.* at 788. A pro-plaintiff (in Hatch-Waxman where the ANDA applicant is essentially the plaintiff) rule encourages suit. *Id.* at 791.

179. *Id.* at 791. "Optimal deterrence is achieved when the penalties are high and the enforcement costs are low because this produces the most compliance at the lowest cost to society." *Id.*

180. *See id.* at 795 (claiming one-way pro-defendant fee shifting may encourage the alleged infringer to stay in the fight longer).

181. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 717, 727 (2005).

182. *Id.*

183. Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 504 (2006).

184. *See generally* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004) (analyzing reverse payment settlements in patent law).

the quality of their patents.<sup>185</sup> The policing of patents therefore has the desired effect both *ex ante* in the prosecution of patents where the patentee has the incentive to carefully distinguish the claimed invention from the prior art,<sup>186</sup> and *ex post* in litigation where the patent's claims will be construed with certainty, so that generic manufacturers can determine the drugs covered by the patent claims and market generic drugs outside of those patent claims. With more certainty in the patent law, this would encourage settlements based more on the merits of the case rather than on the fear of the "cost and uncertainty of patent litigation."<sup>187</sup>

#### D. Brand Payments and Antitrust Law

With regard to brand payments, courts have taken different views as to violation of the antitrust laws.<sup>188</sup> On June 13, 2003, the Sixth Circuit ruled that reverse payments in regards to Hatch-Waxman settlements are per se violations of antitrust laws.<sup>189</sup> The court found that the settlement agreement with the brand payment was for the sole purpose of "eliminat[ing] competition in the market for Cardizem CD."<sup>190</sup> The court rejected the defendant's argument that the agreement was designed to enforce its legitimate patent rights and recognized that the large sum paid to the generic drug manufacturer was not in an effort to take advantage of the monopoly naturally arising out of the patent, but was a pay-off to maintain the monopoly by inhibiting its potential competitor from entering the market.<sup>191</sup>

In a similar Hatch-Waxman reverse payment settlement, the Eleventh Circuit took a much different approach, adopting an analytical approach that determines whether the restraint falls within the scope of the patent.<sup>192</sup> In another case, Judge Posner in dicta supported this decision reasoning that if no settlement is reached and the patentee goes on to win the suit, the competition will be just as restricted.<sup>193</sup> He also stated that by taking away settlement options for the potential challenger, it would take away valuable incentives to challenge the patent.<sup>194</sup> The FTC's view on the reverse payments seems to be somewhere in the middle finding that reverse payments are presumptively unlawful.<sup>195</sup> The recent FTC scrutiny has compelled pharmaceutical

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185. Kesan, *supra* note 151, at 795.

186. *See id.* at 791.

187. *See* Meiklejohn, *supra* note 52, at 925.

188. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *with* *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (illustrating different approaches to whether reverse payments in Hatch-Waxman settlements violate the antitrust laws).

189. *In re Cardizem*, 332 F.3d at 908.

190. *Id.*

191. *Id.*

192. *Valley Drug Co.*, 344 F.3d at 1311 ("To the extent that these or other effects of Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to per se antitrust condemnation.").

193. *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

194. *Id.*

195. *In re Schering-Plough Corp.*, Opinion of the Commission, Docket No. 9297, 13 (Federal Trade

companies to seek less anti-competitive settlement options,<sup>196</sup> but the per se approach must be solidified in precedent to ensure reverse payment settlements do not keep generic drug companies off the market down the road.

To serve the purpose of the Hatch-Waxman Act in encouraging generic drug manufacturers to make it to market, it is essential to discourage these settlements that act to keep generic drugs off the market. Many commentators believe that patent holders will only enter into these reverse payment settlements if they believe there will be less competition than if they go forward with the litigation.<sup>197</sup> For example, if there are ten years left on a patent term, and each party's chance of winning is 50%, the parties would settle for five years of patent and five years of generic competition.<sup>198</sup> But with the prospects of monopoly pricing as opposed to drug price competition during the latter five years, this provides incentive for the patent holder to pay the potential generic competitor to further the term of the monopoly, denying the benefit to consumers.<sup>199</sup>

Adopting a one-way pro-defendant fee shifting mechanism mitigates Posner's argument that valuable settlement options which provide incentives to challenge patents are taken away. A different incentive is provided that encourages the generic manufacturer to see the litigation through if they have a meritorious case.<sup>200</sup> If in regards to Hatch-Waxman litigation, per se invalidity of reverse payments is chosen along with the one-way fee shifting mechanism, this will provide incentives for generic manufacturers who are optimistic about their claims to litigate towards competition, while discouraging those with speculative claims from filing an ANDA application with the sole hope of sharing in the monopoly profits via an anti-competitive settlement agreement. This will ensure that those ANDA applicants filing paragraph IV certifications will be the best representatives in terms of merit fighting for competition.

#### IV. RECOMMENDATION

The results of the FTC study conducted in 2002 regarding the outcomes in Hatch-Waxman litigation shed light on the incentives given to both brand

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Comm'n Dec. 8, 2003), available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

196. See COMPETITION STUDY FY 2004, *supra* note 90, at 4 (finding that after the FTC began to investigate reverse payments in 1999, no final settlements in 2000 and 2001 involved such payments). However, more recent studies have found a resurgence of anti-competitive behavior. See COMPETITION STUDY FY 2005, *supra* note 91, at 4 (finding that in FY 2005, three agreements covering five products involved some sort of reverse compensation from brand-name to generic manufacturers).

197. Schildkraut, *supra* note 184, at 1037. "According to Hovenkamp, Janis, and Lemley, 'if a pioneer pays a generic to delay entry, the likelihood is that the delay does not in fact represent the expected outcome of litigation, but rather has been biased toward later entry by the payment.'" *Id.* (quoting Herbert Hovenkamp et al., *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1762 (2003)).

198. Schildkraut, *supra* note 184, at 1037, 1038.

199. *Id.*

200. Kesan, *supra* note 151, at 795.

name patent holders and the generic ANDA applicants.<sup>201</sup> The results of the litigation show that ANDA applicants who are sued for patent infringement are successful 73% of the time when litigated to a final decision,<sup>202</sup> indicating that incentives for ANDA applicants to subject themselves to litigation by challenging the validity of a patent, or designing around a patent are only prevalent for the most meritorious of cases. Furthermore, in more than 40% of concluded cases, there were settlements, the majority of which resulted in anti-competitive payments from patent holders to the generic ANDA applicants for an artificial extension of the patent term.<sup>203</sup> The results of the FTC study show that there may be an imbalance in the incentives for each party to litigate in Hatch-Waxman litigation, and suggest that in order to completely validate the purpose of generic competition, we may need to provide more incentives for generic manufacturers to file paragraph IV certifications and follow through with the litigation to a final judgment.

The amendments to the Hatch-Waxman Act have helped to eliminate some loopholes preventing generic competition, yet have not gone far enough. The amendments, by limiting brand name patent holders to only one thirty-month stay per pharmaceutical product eliminated the loophole of filing frivolous patents to trigger multiple thirty-month stays.<sup>204</sup> Furthermore, the imposition of forfeiture events of failure for the generic to market within seventy-five days of certain triggering events<sup>205</sup> ensures that generic drugs get to market as soon as they receive FDA approval. However, the amendments do not adequately address anti-competitive settlements that park the running of the first ANDA applicant's 180-day exclusivity period which precludes approval of subsequent ANDA applicants.<sup>206</sup> While requiring all settlements to be filed with the FTC has reduced the abuse of reverse payment settlements, further steps need to be taken. In order to allow subsequent ANDA applicants the ability to vindicate their legal rights with a declaratory action provided for in the amendments when a patentee decides not to sue them for infringement, it is essential that Congress legislatively declare that this scenario meets the case and controversy requirement of the Constitution and is not subject to the traditional application of the patent law reasonable apprehension test.

One-way fee shifting offers an interesting incentive for ANDA applicants – first and subsequent – to challenge the validity of overly broad

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201. See generally FTC STUDY, *supra* note 15 (analyzing the results of Hatch-Waxman litigation between 1992 and 2001).

202. *Id.* at 15.

203. See *id.* at 25.

204. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173 § 1101(b)(2)(B), 117 Stat. 2066, 2448, 2453–55 (2003) (to be codified as amended at 21 U.S.C. § 355(c)(3)(C)).

205. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173 § 1102(a)(2), 117 Stat. 2066, 2457, 2458–59 (2003) (to be codified as amended at 21 U.S.C. § 355(j)(5)(D)(i)(I)).

206. See Meiklejohn, *supra* note 52, at 924 (describing how the 180-day exclusivity period can be used to delay the entry of generic competition into the market).

pharmaceutical patents and design around others. It is left open whether a one-way fee shifting regime would work best in lieu of the 180-day period of exclusivity incentive or in congress with it. The most pro-competitive incentive for generic drug companies to challenge these patents may be a replacement of the 180-day exclusivity period with one-way fee shifting. After all, it may not make the most sense to encourage competition in a market by offering an anti-competitive reward when there exists an alternative method to incentivize competition. Not only will this encourage more ANDA applicants to make paragraph IV certifications, but it will also provide incentives for meritorious applicants to resist anti-competitive settlements and to fully litigate the matter, vindicating the public's interest in competitive drug prices. Furthermore, it has the potential to reduce litigation by providing disincentives for drug manufacturers to seek overly broad patents, clearly defining patent rights, and allowing competitive noninfringing alternatives.

Finally, to necessarily vindicate the public interest in competitive drug prices, it is necessary to characterize "brand payments" from brand-name pharmaceutical companies to generic drug companies as per se violations of antitrust law. Even though taking this settlement option away affects valuable settlement options to generic drug companies, this option is only tempting to them because it is anti-competitive, offering more money than they could receive by competing, at the expense of consumers. Furthermore, providing incentives in the form of one-way fee shifting counters this loss of a settlement option and maintains incentives for paragraph IV certifications in vindication of the public's right to competitive drug prices. Settlements based upon each party's estimation of their merits should still be allowed, either in the form of licensing or dividing the remainder of the patent term. By restricting "brand payments," this will encourage the most competition by generic drug manufacturers.

## V. CONCLUSION

The Hatch-Waxman compromise, enacted to compensate patent holders for time lost for FDA approval and to encourage generic drugs to reach the market upon the expiration of a patent term, has been successful but has seen some opportunity for abuse by brand-name and generic drug companies. Recent amendments have helped to close some of the loopholes that existed but are not likely to be completely successful. First of all, "brand payments" must be considered per se invalid due to their anti-competitive nature. It is also necessary to prevent the parking of the 180-day exclusivity period by either eliminating the incentive completely, or ensuring that subsequent ANDA applicants can vindicate their rights via a declaratory action. In order to implement the purpose of encouraging generic competition to its designed effect, it may be necessary to provide an additional incentive other than the 180-day period of marketing exclusivity for generic drug companies.