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# RECENT ADMINISTRATIVE REFORMS OF THE HATCH-WAXMAN ACT: LOWER PRICES NOW IN EXCHANGE FOR LESS PHARMACEUTICAL INNOVATION LATER?

## I. INTRODUCTION

Throughout the twentieth century, researchers building on the pioneering work of Louis Pasteur<sup>1</sup> developed an incredible array of chemicals to treat many diseases which, for much of humanity's existence, had caused certain death.<sup>2</sup> Perhaps the greatest example of the good that pharmaceutical research brings is the polio vaccine developed by Jonas Salk.<sup>3</sup> As a result of pharmaceutical advances, Americans expect science to solve their most vexing health problems. For the most part, science has succeeded in meeting this huge expectation, as even today there remains hope that an effective AIDS vaccine can be developed.<sup>4</sup> In addition, scientists and lay people alike expect that new and more effective drugs to combat diseases such as cancer,<sup>5</sup> cystic fibrosis,<sup>6</sup> and even Alzheimer's

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1. See, e.g., David V. Cohen, *The Life and Times of Louis Pasteur*, Address at the Centennial Celebration of the Death of Louis Pasteur, Louisville University (1996), at [http://www.labexplorer.com/louis\\_pasteur.htm](http://www.labexplorer.com/louis_pasteur.htm). "The crowning achievements of Pasteur's career were development of the germ theory of disease and the use of vaccines to prevent these diseases." *Id.*

2. James Fitzgerald, *The Troubled Healer*, UNIVERSITY OF TORONTO MAGAZINE, Spring 2002, available at <http://www.magazine.utoronto.ca/02spring/f07.htm> (detailing the life of Canadian scientist John Gerald FitzGerald, who "studied at the Pasteur Institute in Paris and Brussels, learning how to make rabies, diphtheria and smallpox vaccines and antitoxins under the mantle of Dr. Emile Roux, Louis Pasteur's right-hand man and a co-creator of the world's first diphtheria antitoxin").

3. See *People and Discoveries: Salk Produces Polio Vaccine, 1952* (1998), at <http://www.pbs.org/wgbh/aso/databank/entries/dm52sa.html>. "The impact [of the Salk vaccine] was dramatic: In 1955 there were 28,985 cases of polio; in 1956, 14,647; in 1957, 5,894. By 1959, 90 other countries used Salk's vaccine." *Id.*

4. Associated Press, *AIDS Vaccine Fails but Shows Some Promise* (Feb. 24, 2002), available at [http://abcnews.go.com/wire/Living/ap20030224\\_2112.html](http://abcnews.go.com/wire/Living/ap20030224_2112.html) (describing a recent experimental AIDS vaccine that gave no statistically significant benefit to the overall experimental population, but did appear to confer at least some benefit to the small number of African- and Asian-American volunteers who participated in the study).

5. See, e.g., *New Anti-Cancer Drug to be Tried on Humans*, MESOTHELIOMA WEB, at <http://www.mesotheliomaweb.org/solbecabc.html> (indicating that a drug developed by an Australian pharmaceutical company that cured thirty percent of mice with malignant mesothelioma, a form of lung cancer, with one dose, will be tested on humans) (last visited Nov. 30, 2003).

6. See Press Release, Emory Health Sciences, *Emory Tests Promising New Cystic Fibrosis Drug* (June 1, 1998), available at <http://www.emory.edu/WHSC/HSNEWS/releases/jun98/060198cf.html> (describing an experimental drug called CPX that may ameliorate a protein defect that causes cystic fibrosis symptoms).

disease<sup>7</sup> can be developed.<sup>8</sup> While the reasons for these advances are surely varied, many feel that the basic driving force behind pharmaceutical innovation is the incentive structure provided by the United States patent system,<sup>9</sup> which allows companies to recoup the enormous costs associated with developing a new drug<sup>10</sup> and still make a healthy profit.<sup>11</sup> However, while people expect new medicines, they do not wish to pay the prices that brand-name pharmaceutical companies charge for them.<sup>12</sup>

Congress attempted to deal with this fundamental conflict by implementing the Drug Price Competition and Patent Term Restoration Act,<sup>13</sup> more commonly known as the “Hatch-Waxman Act.”<sup>14</sup> This statute was enacted in 1984 in response to the dearth of generic pharmaceutical products on the market.<sup>15</sup> The Hatch-Waxman Act has increased the

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7. *New Alzheimer's Drug Seems to Slow Disease Progression, Research Shows* (July 12, 2000), at <http://www.cnn.com/2000/HEALTH/aging/07/12/alzheimers.drug/index.html> (discussing results of an experiment involving the drug memantine).

8. *See, e.g., supra* notes 5-7.

9. *Update: Bush to Close Hatch-Waxman Loopholes*, PHARMA MARKETLETTER, Oct. 28, 2002 at 1. When introducing the proposed regulation that is central to this Note, President Bush stated: “with patent protection, America’s brand-name drug companies have become the greatest in the world, and health care systems around the world depend on American inventions they could not possibly duplicate.” *Id.* Bush also stated: “we recognize innovators must be able to be financially rewarded for their creativity and hard work so they will continue investing and researching . . . we want these breakthroughs to become affordable and widely available. Both of these goals, innovation and accessibility, are essential, and both are possible.” *Id.*

10. Charles Boersig, *Patent Woes for Big Pharma: Generic Manufacturers Are Becoming Increasingly Aggressive in Their Efforts to Invalidate Drug Patents*, MED AD NEWS, Nov. 2002, at 60. “On average, bringing a new medicine to market takes ten to fifteen years and costs about \$800 million.” *Id.* “Without patents to protect all the invention necessary to develop a drug, at least for a limited time, others could copy the drugs immediately, offering their versions at a reduced price since they did not incur the high costs to develop the drug.” *Id.* “This process would seriously impact research-based pharmaceutical companies’ ability to recoup costs and invest in other research projects.” *Id.*

11. For example, Pfizer’s drug Zolofit, which is Pfizer’s second-best selling drug, made a profit of \$2.742 billion in 2002. *In Brief*, WORLD MARKET ANALYSIS 1, Feb. 25, 2003.

12. Ben Peck, CONSUMER VIEWS ON HATCH-WAXMAN REFORMS, *available at* [http://www.fdpi.org/conf/handouts/hw02/hw\\_peck.PDF](http://www.fdpi.org/conf/handouts/hw02/hw_peck.PDF) (online version of a handout prepared by Public Citizens’ Congress Watch describing recent increases in average drug costs and arguing for reforms to the Hatch-Waxman Act that would likely increase the availability of less-expensive generic alternatives to brand-name pharmaceuticals).

13. Drug Price Competition and Patent Term Restoration Act of 1984 [hereinafter Hatch-Waxman Act], Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2003) and 35 U.S.C. § 271(d)-(h) (2003)).

14. *Id.*

15. *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* [hereinafter FTC Study] (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. “By 1984, the FDA estimated that there were approximately 150 brand-name drugs whose patents had expired for which there was no generic equivalent.” *Id.* at 4.

availability of generic pharmaceuticals, as intended, and this in turn has resulted in large savings to consumers.<sup>16</sup>

Although previous law<sup>17</sup> allowed generic competitors to make and sell pharmaceutical products with the same chemical make-up as brand-name pharmaceuticals after the patent on the brand-name pharmaceutical ended,<sup>18</sup> the process by which such generics could be approved was cumbersome.<sup>19</sup> The expense and time required to obtain approval for a generic version of a brand-name drug was substantial.<sup>20</sup> As a result, few companies attempted to obtain approval for generic versions of drugs from the Food and Drug Administration (“FDA”).<sup>21</sup> Thus, even after the brand-name drug’s patent protection ended, the manufacturer of that pharmaceutical retained a de facto patent on the product<sup>22</sup> because it did not make economic sense for a different manufacturer to attempt to obtain FDA approval.<sup>23</sup>

This setting created a situation in which pharmaceutical prices stayed extremely high even after patent protection for individual pharmaceuticals ended.<sup>24</sup> Congress recognized this problem and passed the Hatch-Waxman Act in order to facilitate and expedite generic competitors’ entrance into the pharmaceutical market.<sup>25</sup> The Hatch-Waxman Act encouraged the development of generic pharmaceuticals by allowing generic pharmaceutical manufacturers to expedite the FDA approval process by relying on the trade secret information held by the name-brand

16. See FTC Study, *supra* note 15, at 9. “The [Congressional Budget Office] estimated that, in 1994, the availability of generic drugs saved purchasers between \$8 billion and \$10 billion.” *Id.* (citing CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>).

17. See FTC Study, *supra* note 15, at 3. The 1962 amendments to the Food, Drug and Cosmetic Act were the controlling law before the passage of the Hatch-Waxman Act. *Id.*

18. See PhRMA, THE HATCH-WAXMAN ACT IN PERSPECTIVE: PHARMACEUTICAL INDUSTRY CONTEXT FOR THE FTC’S GENERIC DRUG STUDY-FTC FILE NO. V000014 2 7 (2002) [hereinafter Hatch-Waxman in Perspective], at <http://www.phrma.org/publications/policy/2002-06-24.435.pdf>.

19. See FTC Study, *supra* note 15, at 3. “Those seeking to market a generic version of an existing post-1962 brand-name drug also had to perform their own safety and efficacy studies, much like the brand-name companies had to demonstrate the safety and efficacy of the brand-name drug[s].” *Id.*

20. See *id.* at 3, 5 (indicating that the process generic companies had to follow to get a generic drug approved by the FDA was similar to the expensive and time-consuming process required of brand-name companies).

21. See FTC Study, *supra* note 15, at 4.

22. See FTC Study, *supra* note 15, at 4.

23. *Id.*

24. *Id.* See also Hatch-Waxman in Perspective, *supra* note 18, at 3.

25. See, e.g., Gerald D. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process* 187 (1999).

pharmaceutical companies.<sup>26</sup> In addition, the Hatch-Waxman Act provided incentives for generic pharmaceutical manufacturing companies to challenge and design around name-brand pharmaceutical manufacturers' patents.<sup>27</sup> Provisions benefiting brand-name pharmaceutical companies were also included.<sup>28</sup> The Hatch-Waxman Act achieved its intended effect, as the number of generic entrants into the pharmaceutical market increased markedly after 1984.<sup>29</sup>

Despite the Hatch-Waxman Act's success, in recent years it has become apparent that brand-name pharmaceutical makers are still able to keep generic pharmaceutical manufacturers who challenge the brand-name company's patents from gaining FDA approval.<sup>30</sup> In July of 2002, the Federal Trade Commission ("FTC") released a study that examined the practical effects of the Hatch-Waxman Act provisions that encourage generic pharmaceutical makers to challenge brand-name pharmaceutical manufacturers' patents.<sup>31</sup> This study proposed various amendments to the Hatch-Waxman Act in order to close loopholes in the Act.<sup>32</sup> The Senate passed a bill containing amendments similar to these recommendations in 2002,<sup>33</sup> but the House of Representatives did not pass the analogous bill.<sup>34</sup>

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26. FTC Study, *supra* note 15, at 4. "[G]eneric applicants were permitted to rely on the brand-name company's trade secret data demonstrating the safety and efficacy of the brand-name drug product." *Id.*

27. *Id.* at 5; *see also* FOOD AND DRUG ADMINISTRATION, IN THE MATTER OF APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; PATENT LISTING REQUIREMENTS AND APPLICATION OF 30-MONTH STAYS ON APPROVAL OF ABBREVIATED NEW DRUG APPLICATIONS CERTIFYING THAT A PATENT CLAIMING A DRUG IS INVALID OR WILL NOT BE INFRINGED 17 [hereinafter FTC Comments] (Dec. 23, 2002), available at <http://www.ftc.gov/be/v030002.pdf>.

28. FTC Study, *supra* note 15, at 4. To compensate the brand name drug manufacturers for the time and money they have invested in developing the pharmaceuticals, the Hatch-Waxman Act also contains various provisions that extend the length of certain patent classes. *Id.* *See also* Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) ("[The Hatch-Waxman Act] emerged from Congress's efforts to balance two conflicting policy objectives: to induce name-brand drug manufacturers to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.") (citations omitted). The patent extension aspects of the Hatch-Waxman Act are beyond the scope of this Note.

29. *See* FTC Study, *supra* note 15, at 9. In addition, the Congressional Budget Office estimated that the availability of generic alternatives to brand-name drugs had saved buyers between \$8 billion to \$10 billion by 1994. CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.

30. FTC Study, *supra* note 15, at 40.

31. *Id.* at 1. "The study was designed to determine whether [anti-competitive] agreements are isolated instances or more typical, and whether particular provisions of the Hatch-Waxman Amendments are susceptible to strategies to delay or deter consumer access to low-cost generic alternatives to brand-name drug products." *Id.*

32. *See generally* FTC Study, *supra* note 15.

33. S. 812, 107th Cong. §§ 103–105 (2002). *See infra* note 100 and accompanying text. *See also*

In response to the FTC study, the FDA, through its rulemaking authority,<sup>35</sup> issued a notice of a proposed rule on October 24, 2002.<sup>36</sup> After receiving various comments regarding this proposed rule, the FDA promulgated a regulation on June 18, 2003, that implements some, but not all, of the changes proposed in the initial FTC study.<sup>37</sup> The remainder of this Note will briefly discuss the development of the statutory and regulatory standards for the approval of pharmaceutical products as well as the changes to the Hatch-Waxman Act and FDA regulations proposed in 2002 by the FTC, the FDA, and Congress, as well as those promulgated by the FDA in 2003. This discussion will focus primarily on the topics raised in the 2002 FTC study. This Note will also explain how some of the changes will benefit consumers, while others will stifle innovation, thereby causing a reduction in the rate at which new drug treatments for various diseases are discovered and marketed.<sup>38</sup>

## II. HISTORY

### A. *The Statutory Framework*

In 1962, Congress amended the Food, Drug, and Cosmetics Act<sup>39</sup> (“FDCA”) to require companies seeking to sell new pharmaceuticals to

Press Background Briefing by Senior Administration Officials on Prescription Drugs, 2002 WL 31369479, \*1 (Oct. 21, 2002).

34. H.R. 1862, 107th Cong. (2001). *See also* *Senators Tout Support for Generics Bill, Urge House Action*, GENERIC LINE, Vol. 20, No. 12 (June 18, 2003) (noting that H.R. 1862 did not pass). For a discussion of the process by which federal legislation is introduced and passed, see MORRIS L. COHEN ET AL., *HOW TO FIND THE LAW* 219–41 (1989).

35. 21 U.S.C. § 371(a) (2003).

36. Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed [hereinafter FDA Proposed Rule], 67 Fed. Reg. 65,448 (proposed Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314).

37. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, [hereinafter 2003 FDA Hatch-Waxman Regulation], 68 Fed. Reg. 36,676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). The effective date of this rule was August 18, 2003. *Id.* For an overview of the rulemaking process, see generally RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE*, 411–15 (4th ed. 2002). The Food and Drug Administration’s rulemaking authority is based on the provisions of 21 U.S.C. § 371 (2000).

38. “[I]nnovation . . . will be harder in [the] future because the easy fruit has been picked off and the diseases now being investigated involve harder science and more sophisticated problems.” *Waxman-Hatch Has Boosted Generics, But Jury Still Out on Effects on Innovators*, PHARMA MARKETLETTER, Jan. 6, 2003 LEXIS, Nexis Library, Pharma Market letter file.

39. 21 U.S.C. § 301-397 (2000).

“prove that new drugs are safe and effective prior to FDA approval.”<sup>40</sup> The FDCA required pharmaceutical companies to conduct clinical trials on new pharmaceuticals and submit the results to the FDA along with their “new drug application” (“NDA”).<sup>41</sup> The 1962 amendments required pharmaceutical companies seeking to sell generic versions of these drugs to perform the same studies to show the safety and efficacy of the generic products.<sup>42</sup> This requirement was very expensive and resulted in very few generic pharmaceuticals on the market.<sup>43</sup> In addition, the FDCA stated that companies selling generic drugs could not begin the FDA approval process for their generic pharmaceuticals until after the patents on the analogous brand-name pharmaceutical had expired, restricting those companies’ access to the market.<sup>44</sup>

In response to the dearth of generic pharmaceuticals, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>45</sup> commonly known as the “Hatch-Waxman Act” (“Hatch-Waxman” or “the Act”). Hatch-Waxman allows generic pharmaceutical companies to rely on the safety and efficacy data compiled by the brand-name companies during the FDA approval process.<sup>46</sup> The Act also allows the generic drug manufacturers to begin the approval process before the patents on brand-name drugs expire.<sup>47</sup> Finally, the Act requires brand-name companies that file NDAs to provide the FDA with information about the patents covering the pharmaceutical products.<sup>48</sup> The FDA lists these patents in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,”<sup>49</sup> known as the “Orange Book” because of its cover’s color.<sup>50</sup>

Instead of requiring a generic pharmaceutical manufacturer to follow the strict NDA requirements, the Act allows it to file an “Abbreviated New Drug Application”<sup>51</sup> (“ANDA”), with the obligation

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40. FTC Study, *supra* note 15, at 3.

41. *Id.*

42. *Id.*

43. *Id.* at 4. “[B]y 1984 . . . there were approximately 150 brand-name drugs whose patents had expired for which there was no generic equivalent.” *Id.* See also *supra* note 20 and accompanying text.

44. FTC Study, *supra* note 15, at 4. See also *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

45. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

46. FTC Study, *supra* note 15, at 4.

47. 21 U.S.C. § 355(b)(1) (2000).

48. *Id.*

49. FDA Proposed Rule, 67 Fed. Reg. 65,448 (proposed Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314).

50. *Id.*

51. 21 U.S.C. § 355(j) (2000).

to demonstrate that the generic drug product has the same active ingredient, route of administration, dosage form and strength, and proposed labeling as the brand-name drug. The ANDA also must contain sufficient information to demonstrate that the generic drug is “bioequivalent”<sup>52</sup> to the relevant brand-name product.<sup>53</sup>

The ANDA must also have a certification for each patent listed in the Orange Book that is related to the brand-name pharmaceutical at issue.<sup>54</sup> The Act provides the generic drug manufacturers with four different certification options:<sup>55</sup> (1) the brand-name company has not filed the required patent information for the pharmaceutical product;<sup>56</sup> (2) the patent for the brand-name pharmaceutical has expired;<sup>57</sup> (3) the patent on the brand-name product has not yet expired but will expire on a specified date, at which time the generic drug manufacturer will begin marketing its product;<sup>58</sup> or (4) the patent held by the brand-name drug manufacturers is either invalid or will not be infringed by the product that the generic drug manufacturer will produce and sell.<sup>59</sup> This last certification option is referred to as a paragraph IV certification.<sup>60</sup>

A paragraph IV certification by a generic drug manufacturer implicates two provisions of the Hatch-Waxman Act, and “these two provisions are at the heart of the FTC’s study.”<sup>61</sup> First, the ANDA filer must provide notice to the patent holder and NDA filer.<sup>62</sup> If the patent holder files a

52. “Bioequivalence means that the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the listed drug when administered at the same dosage.” FTC Study, *supra* note 15, at 5 n.26.

53. *Id.* at 5.

54. 21 U.S.C. § 355(j)(2)(A)(vii) (2000).

55. *Id.* See also FTC Study, *supra* note 15, at 6 for a graphic representation of the various certification options available under 21 U.S.C. § 355(j)(2)(A)(vii).

56. 21 U.S.C. § 355(j)(2)(A)(vii)(I) (2000). This certification is referred to as a “paragraph I certification.” FTC Study, *supra* note 15, at 6. If the ANDA filer makes this type of certification, the FDA may approve the sale of the generic product immediately. See *id.*

57. 21 U.S.C. § 355(j)(2)(A)(vii)(II) (2000). This is referred to as a “paragraph II certification.” FTC Study, *supra* note 15, at 6. Upon submission of this type of certification, the FDA may immediately approve the sale of the generic product. See *id.*

58. 21 U.S.C. § 355(j)(2)(A)(vii)(III) (2000). This is referred to as a “paragraph III certification.” FTC Study, *supra* note 15, at 6. If the ANDA filer makes this type of certification, the FDA may approve the ANDA with a stipulation that the approval is effective on the date that the patent held by the brand-name company expires. See *id.*

59. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). This is referred to as a “paragraph IV certification.” FTC Study, *supra* note 15, at 6. Approval of an ANDA filed under this type of certification is the focus of the recent proposed changes to the Hatch-Waxman Act and the regulatory scheme that exists under the Hatch-Waxman Act. *Id.*

60. FTC Study *supra* note 15, at 6.

61. *Id.*

62. The Act States:



lawsuit for patent infringement within forty-five days of the notice, the FDA automatically stays approval of the ANDA for thirty months.<sup>63</sup> Once this occurs, FDA approval of the generic drug is stayed until “the earliest of: (1) the date the patent(s) expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification.”<sup>64</sup> In addition, the first generic applicant who files an ANDA with the FDA is entitled to 180 days of marketing exclusivity, during which time the FDA is not allowed to approve any other ANDAs for the same pharmaceutical.<sup>65</sup>

### B. *The FTC’s 2002 Study of the Hatch-Waxman Act*

The FTC study, relying in part on an earlier study performed by the Congressional Budget Office,<sup>66</sup> found that the Hatch-Waxman Act made pharmaceuticals much less expensive overall by promoting generic entrants<sup>67</sup> but resulted in a slight increase in the cost of brand-name pharmaceutical products.<sup>68</sup> The study also found that the Hatch-Waxman Act has resulted in much greater availability of generic versions of brand-

An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

- I. each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and
- II. the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

21 U.S.C. § 355(j)(2)(B)(i) (2000).

63. 21 U.S.C. § 355(j)(5)(B)(iii) (2003). *See also* FTC Study, *supra* note 15, at 7.

64. FTC Study, *supra* note 15, at 7.

65. The Act states:

If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

- I. the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
- II. the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2000).

66. *See* FTC Study, *supra* note 15, at 9 (citing CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.)

67. FTC Study, *supra* note 15, at 9.

68. *Id.* *See also* Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331 (1992).

name drugs.<sup>69</sup> Despite the success of the Hatch-Waxman Act in promoting generic entrance into the pharmaceutical market, the FTC study found that the Act contained various loopholes that allowed brand-name manufacturers to extend the life of their monopoly over the sales of their pharmaceutical products by keeping generic entrants out of the market.<sup>70</sup>

### 1. Loopholes Allow for Extensions of the Thirty-Month Stay

One way that brand-name drug manufacturers are able to exclude generics from entering the market is to list a new patent in the Orange Book.<sup>71</sup> Although there are guidelines governing what can be listed in the Orange Book,<sup>72</sup> at least one court has held that there is no private right of action to force the FDA to delist an improperly listed patent.<sup>73</sup> Exacerbating the problem, the FDA has refused to examine the Orange Book for improperly listed patents,<sup>74</sup> stating that its resources are better spent elsewhere.<sup>75</sup> If a thirty-month stay has already begun when the new patent is listed, the generic drug manufacturers must re-certify the new listing.<sup>76</sup> At this point the brand-name drug manufacturers has forty-five days to sue for patent infringement on this newly listed patent.<sup>77</sup> If the brand-name manufacturer does sue, a new thirty-month stay on approval of the ANDA begins to toll.<sup>78</sup> The FTC study found that delays of up to sixty-five months have resulted.<sup>79</sup>

69. Boersig, *Patent Woes for Big Pharma*, *supra* note 10, at 60. In 2002, generic drugs comprised over forty-seven percent of the prescriptions filled for pharmaceutical products. *Id.* This is up from nineteen percent in 1984, when Congress passed the Hatch-Waxman Act. *Id.* Also, “[b]y 2005, generic drugs are expected to represent 57% of the market.” *Id.*

70. *See generally* FTC Study, *supra* note 15, at 9.

71. FTC Study, *supra* note 15, at 40 “In 8 instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product.” *Id.*

72. 21 C.F.R. § 314.53(b) (2003).

73. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

74. 2003 FDA Hatch-Waxman Regulation, *supra* note 37, at 36,683. “We also decline to create a new process for de-listing patents or for internal FDA review of patents beyond the limited review of the patent declaration described in this final rule.” *Id.* *See also* FTC Study, *supra* note 15, at 44.

75. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994) (explaining the rule codified at 21 C.F.R. pt. 314). “FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims.” *Id.*

76. FTC Study, *supra* note 15, at 43-44. *See also* Robert Coakley, *Limited 30-month stays; News from Rockville; Generic Drug Approvals*, MED AD NEWS, No. 11, Vol. 21, at 86 (Nov. 1, 2002) (stating that brand-name pharmaceutical companies have been able to obtain delays in the entry of generic competitors of up to sixty-five months by filing multiple patent infringement suits against generic companies who have filed Paragraph IV certifications).

77. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

78. FTC Study, *supra* note 15, at 44.

79. *Id.* at 49 (Table 4-3). The patent holder for the patents covering the drug Hytrin (Terazosin)

## 2. Another Loophole Allows “Parking” of the 180-Day Exclusivity Period

The FTC study also found that in many cases where the patent holder sued the potential generic entrant, the ensuing litigation ended in a settlement.<sup>80</sup> One form of such settlements allows the generic manufacturer to market the brand-name product under its generic name.<sup>81</sup> In such a situation, the generic manufacturer is not selling its form of the pharmaceutical; rather, it is essentially acting as a distributor for the brand-name producer.<sup>82</sup> If this generic company is the first to file an ANDA for the pharmaceutical, it obtains the 180-day marketing exclusivity rights to the generic product.<sup>83</sup> However, because the generic company is not selling its own product, the 180-day period does not begin to run.<sup>84</sup> Thus, this agreement, in effect, precludes other generic companies from entering into the generic market.<sup>85</sup> Although this scenario has not yet occurred,<sup>86</sup> the FTC viewed it as a strong possibility.<sup>87</sup> The FTC has the authority to nullify such agreements and prosecute the participants under its antitrust enforcement authority<sup>88</sup> if the agreements are anti-competitive.<sup>89</sup> However, the FTC has been somewhat reluctant to find antitrust liability in these agreements;<sup>90</sup> in 2002, an FTC Commissioner spoke of the difficulty in

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in tablet form obtained three stays that had the potential to last up to seventy months, but the stays were not overlapping. *Id.* The total stay length in the litigation involving Paxil (Paroxetine Hydrochloride) was sixty-five months. *Id.*

80. FTC Study, *supra* note 15, at 27. Twenty out of fifty-three cases included in the FTC Study in “which a brand-name company sued the first generic applicant who had filed an ANDA containing a paragraph IV certification settled.” *Id.*

81. *Id.* at 28.

82. *Id.* at 30. This was the case in two of the settlements studied by the FTC. The study does not state the parties involved in these settlements. *Id.*

83. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

84. FTC Study, *supra* note 15, at 57.

85. *Id.* at 63.

86. *Id.*

87. *Id.* Such agreements have “the potential to ‘park’ the first generic applicant’s 180-day exclusivity for some period of time, thus preventing FDA approval of any subsequent eligible applicants.” *Id.* (footnote omitted) (emphasis added).

88. Scott P. Perlman & Jay S. Brown, *FTC Targets Patent Settlement Agreements*, NAT’L L.J., Nov. 11, 2002, at C1. “Since the late 1990s, U.S. antitrust enforcement authorities have greatly increased their scrutiny of the potential anti-competitive effects of patent settlements.” *Id.*

89. *Id.*

90. *Id.* In recent years, the FTC has successfully sought consent decrees in a number of enforcement actions involving pharmaceutical companies. *Id.* See, e.g., Biovail Corp., 67 Fed. Reg. 44,606 (July 3, 2002); Hoechst Marion Roussel Inc., 66 Fed. Reg. 18,636 (Apr. 10, 2001); Abbott Labs., 65 Fed. Reg. 17,502 (Apr. 3, 2000). However, a recent failure by the FTC, in *In re Schering-Plough Corp.*, 2002 FTC Lexis 40 (June 27, 2002), “has reinforced the original notion that genuine settlements that do not extend the reach of the patent should not be condemned as anti-competitive.”

determining whether these agreements should ever be subject to easy-to-apply per se rules.<sup>91</sup> The FTC regarded the possibility of anti-competitive settlement agreements as another possible loophole that could undermine the intent of the Hatch-Waxman Act.<sup>92</sup>

### C. The FTC's Proposed Changes to the Hatch-Waxman Act

Based on its findings, the FTC proposed amendments to the Hatch-Waxman Act.<sup>93</sup> The FTC proposed that only one thirty-month stay be issued for each pharmaceutical patent listed in the Orange Book.<sup>94</sup> The FTC also sent a Citizen Petition to the FDA<sup>95</sup> wherein the FTC requested the FDA to clarify its position on what properly may be listed in the Orange Book.<sup>96</sup> To combat settlement agreements that “park”<sup>97</sup> the 180-day period of exclusivity,<sup>98</sup> the FTC recommended that Congress “[p]ass legislation to require brand-name drug manufactures and first generic applicants to provide copies of certain agreements to the [FTC]”.<sup>99</sup>

Perlman & Brown, *supra* note 88, at C1. For more in-depth treatment of the antitrust issues implicated by agreements between brand-name and generic pharmaceutical companies, see Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317 (2002), and Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch-Waxman Act*, 10 GEO. MASON L. REV. 345 (2002).

91. Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (2001), available at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm>. Commissioner Leary refers to payments, as part of agreements between brand-name and generic pharmaceutical manufacturers, flowing from the brand-name company to the generic company in return for delayed generic entry into the market as “reverse payments.” *Id.* “The presence of reverse payments, therefore, may provide an objective test for finding likely consumer harm without a difficult inquiry into the merits of the patent litigation.” *Id.* However, the Commissioner goes on to state that he “would not suggest at this stage that the presumption be conclusive (which would be another way of saying reverse payments are illegal per se) until we learn more from ongoing investigations and from the responses to our industry survey.” *Id.*

92. See, e.g., FTC Study, *supra* note 15, at 63.

93. *Id.* at ii.

94. *Id.*

95. See *id.* at 65-68 for a detailed explanation of FDA citizen petitions.

96. See *id.*

97. See *supra* notes 79-83, 87 and accompanying text.

98. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

99. FTC Study, *supra* note 15, at vi. For a Congressional response to this recommendation, see Drug Competition Act of 2002, S. 754, 107th Cong. § 5 (2002), *infra* note 104. Additionally, the FTC also made two “minor” recommendations: “Clarify that ‘commercial marketing’ includes the first generic applicant’s marketing of the brand-name product” and “[c]odify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a ‘court decision’ sufficient to start the running of the 180-day exclusivity.” *Id.* at ix. A third minor recommendation made by the FTC is beyond the scope of this Note. See *id.* at x.

#### *D. Proposed Amendments to the Hatch-Waxman Act in 2002*

In response to the FTC's recommendations, the Senate passed a bill<sup>100</sup> to amend the Hatch-Waxman Act in the summer of 2002 that would have, in large part, implemented the FTC recommendations.<sup>101</sup> However, the House of Representatives did not pass the analogous bill,<sup>102</sup> despite President Bush's support for the amendments.<sup>103</sup> The Senate also passed a bill that would have required certain settlement agreements to be filed with the FTC.<sup>104</sup> The House of Representatives has not yet passed this bill.<sup>105</sup>

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100. Greater Access to Affordable Pharmaceuticals Act of 2002, S. 812, 107th Cong. §§ 103-105 (2002). This bill would have enacted a number of changes to the Hatch-Waxman Act. First, the bill allowed an automatic thirty-month stay only when a paragraph IV certification was filed for a patent that was listed within thirty days after approval of the brand name drug manufacturer's NDA. *Id.* at § 104(a)(1)(A)(ii). Additionally, the bill contained a forfeiture provision that allowed subsequent ANDA to take the place of the first ANDA. *Id.* at § 105(a)(2). The bill also would have created a limited private right of action allowing a party to challenge the propriety of patents in the Orange Book; the bill allowed the challenging party to recover damages. *Id.* at § 103(a)(1). For practical analysis of the provisions of S. 812, see Christopher T. Griffith, *Senate Passes Bill Revising Hatch-Waxman Framework for Generic Drug Approval* (2002), at [http://www.leydig.com/News/raf\\_sep2002.asp](http://www.leydig.com/News/raf_sep2002.asp). *Cf. infra* note 146.

101. Press Background Briefing by Senior Administration Officials on Prescription Drugs, 2002 WL 31369479, \*4 (Oct. 21, 2002). *See also* *Generic Drug Backers Look To Congress for Patent Law Reform*, GENERIC LINE, Vol. 19, No. 21 (Nov. 8, 2002) (stating that the Senate passed the proposed bill in July of 2002).

102. Greater Access to Affordable Pharmaceuticals Act of 2001, H.R. 1862, 107th Cong. (2001). *See Tighter Patent Rules May Also Boost Brand Approvals*, THE FOOD AND DRUG LETTER, No. 667 (Jan. 17, 2003) (stating that H.R. 1862 did not make it out of the House Energy and Commerce Committee despite passing in the Senate). In response, "Sens. John McCain (R-Ariz.) and Charles Schumer (D-N.Y.) recently reintroduced [the] bill (S.54) that would restrict brand companies to one 30-month stay on generic approval when a generic firm challenges a brand drug's patent and the brand manufacturer files an infringement lawsuit." *Patent Expirations, Generic Biologics Face Industry in 2003*, GENERIC LINE, Vol. 20, No. 2, Jan. 31, 2003.

103. *See* Remarks by the President on Prescription Drugs, 2002 WL 31369474, \*3 (Oct. 21, 2002).

104. Drug Competition Act of 2002, S. 754, 107th Cong. (2002). The bill required that when a generic pharmaceutical company filed a Paragraph IV certification under the Hatch-Waxman Act and then entered into an "agreement" with the brand-name pharmaceutical company regarding the Paragraph IV certification, before the subject of the ANDA enters the market, the two parties must file the text of the agreement with the Assistant Attorney General and the Federal Trade Commission. *Id.* at § 5. The bill defined "agreements" that must be filed as:

- (A) the manufacture, marketing or sale of the brand name drug that is the subject of the generic drug applicant's ANDA;
- (B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or
- (C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

*Id.* at § 5(a)(2). The FTC supported S. 754, and incorporated the goals of the bill into its study on generic drug entry prior to patent expiration. Press Release, Federal Trade Commission, FTC Recommends Legislative Changes to Hatch-Waxman Act (Jul. 30, 2002), *available at*

In response to Congress' failure to codify the FTC's recommendations, the FDA proposed a new rule on October 24, 2002,<sup>106</sup> which was backed by President Bush.<sup>107</sup> This rule as proposed would have restricted the number of thirty-month stays a brand-name pharmaceutical company can obtain in response to a generic company's Paragraph IV certification to one.<sup>108</sup> The proposed rule also would have restricted the types of patents that could be listed in the Orange Book,<sup>109</sup> as well as required companies to fill out more detailed declarations for listing.<sup>110</sup> The FDA hoped these

<http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm>. The bill's sponsor, Senator Patrick Leahy stated "[c]onsumers pay the price when drug makers collude to stifle competition and drive up the cost of prescription drugs . . . our bill discourages these sweetheart deals by ensuring that antitrust authorities can take quick and decisive action against these companies." *Senate Passes Leahy Bill Targeting Sweetheart Deals that Delay Low-Cost Generic Drugs*, U.S. NEWSWIRE, National Desk Section, Nov. 20, 2002, at 1.

105. *Drug Patent Reform Proposal Faces Uphill Battle in Congress*, THE FOOD AND DRUG LETTER, Dec. 6, 2002, at 8. The last action taken on the bill was a pass by voice vote in the Senate. *Id.* "The bill isn't expected to pass the House, but Leahy plans to reintroduce it next year, a Leahy representative said." *Id.*

106. FDA Proposed Rule, *supra* note 36, at 65,448.

107. *See* Remarks by the President on Prescription Drugs, *supra* note 103. This issue had strong political overtones, as indicated by the comments of Senator Edward Kennedy, who stated, "[this regulatory proposal] is a down payment, but no substitute for the more comprehensive generic drugs legislation which passed the U.S. Senate only to die in the Republican-controlled House of Representatives." *Bush Proposes Generic-Drug Regulations*, ANTITRUST LITIGATION REPORTER, Nov. 2002, at 17.

108. FDA Proposed Rule, *supra* note 36, at 65,448. "The proposal also would state that there will be only one opportunity for a 30-month stay in the approval date of each ANDA or 505(b)(2) application." *Id.*

109. *Id.* at 65,451. The limitation applies to NDAs and amendments to NDAs. *Id.* Listable patents would be:

drug substance (ingredient) patents, drug product (formulation and composition) patents, *product by process patents*, and method of use patents. Process patents, *patents claiming packaging*, *patents claiming metabolites*, and *patents claiming intermediates* are not covered by this section, and information on these patents may not be submitted to FDA. *For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application within the meaning of section 505(j)(2)(A)(ii) of the Act. For patents that claim a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application. For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are the subject of a pending or approved application. For approved applications, the applicant shall identify the indication or other condition of use in the approved labeling that corresponds to the listed patent and claim identified.*

*Id.* The italicized portion of the above quote indicates the new or revised language in this section of the proposed rule. The current regulation is codified at 21 C.F.R. § 314.53(b). *Id.*

110. *Id.* at 65,453-54.

The proposed rule would . . . revise [21 C.F.R.] § 314.53(c)(1) and (c)(2) by rewording the general patent declaration requirement in paragraph (c)(1) and by replacing the existing,

changes would increase the number of challenges to the drug patents held by brand-name pharmaceutical companies,<sup>111</sup> which is one of the goals of the Hatch-Waxman Act.<sup>112</sup> The FDA also hoped these changes would streamline the ANDA process by reducing the number of patent disputes that can lead to automatic thirty-month stays.<sup>113</sup>

#### *E. Reactions to the FTC Study and the FDA Proposal*

Consumer groups and the generic pharmaceutical industry predictably supported the proposed FDA rules.<sup>114</sup> The Generic Pharmaceutical Association issued a press release in support of the proposed changes,<sup>115</sup> claiming that the proposed rules would decrease the number of frivolous lawsuits and increase access to affordable medication.<sup>116</sup> Likewise, the Business for Affordable Medicine organization<sup>117</sup> stated that the rules were necessary to close loopholes in the Hatch-Waxman Act.<sup>118</sup> However, FamiliesUSA<sup>119</sup> argued that the rules were not stringent enough, as they

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general declaration at paragraph (c)(2)(i) with a more detailed declaration that would act as a “checklist” that would focus on patent claims and would ensure that applicants submit only appropriate patent information and stand behind the accuracy of that information.

*Id.* at 65,453. The checklist, which is too lengthy to reproduce here, required the filer to explicitly fill in answers to specific questions so as to allow the FDA to more easily identify attempts to list inappropriate patents in the Orange Book. *Id.* at 65, 463-54.

111. *Id.* at 65,456.

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

113. FDA Proposed Rule, *supra* note 36, at 65,449.

114. For a listing of links to websites containing writings in support of the proposed amendments, see *The Hatch-Waxman Act and New Legislation to Close Its Loopholes*, at <http://www.cptech.org/ip/health/generic/hw.html>.

115. Press Release, Generic Pharmaceutical Association, GPhA Welcomes President’s Commitment to Issue Federal Regulation to Remove Barriers to Generic Competition (Oct. 21, 2002), at [http://www.prnewswire.com/cgi-bin/micro\\_stories.pl?ACCT=913120&TICK=GPHA&STORY=/www/story/06-10-2003/0001963169&EDATE=Oct+21,+2002](http://www.prnewswire.com/cgi-bin/micro_stories.pl?ACCT=913120&TICK=GPHA&STORY=/www/story/06-10-2003/0001963169&EDATE=Oct+21,+2002). The press release also states that even more than the \$3.5 billion the proposed rule is expected to save could be saved if Congress takes stronger measures. *Id.*

116. *Id.*

117. Business for Affordable Medicine describes itself as a “national coalition of employers, governors, and labor leaders.” Media Release, Business for Affordable Medicine, Employers, Governors Applaud White House Prescription Drug Initiative: Regulatory Action Is Important First Step to Save Purchasers Billions of Dollars (Oct. 21, 2002), at <http://www.bamcoalition.org/Press/10.21.02PressRelease.pdf>.

118. *Id.* South Dakota Governor Bill Janklow stated “[o]ur job now will be to ensure this important action brings an immediate end to abusive pharmaceutical industry practices.” *Id.*

119. FamiliesUSA describes itself as a “nonprofit and nonpartisan [organization that] advocates for high-quality, affordable health care for all Americans.” FamiliesUSA, “Administration’s Generic Drug Rule Provides Weak, Diluted Relief for America’s Consumers,” formerly available at <http://www.familiesusa.org/1021Bushproposedrxrule.htm> (on file with author).

did not sufficiently prohibit brand-name pharmaceutical companies from preventing generic pharmaceutical products from entering the market.<sup>120</sup> In addition, the tactics employed by brand-name drug manufacturers drew the attention of state attorneys general and plaintiffs' attorneys, many of whom viewed the brand-name drug manufactures as "the next tobacco."<sup>121</sup> They felt that growing public support for decreasing pharmaceutical costs, combined with some of the marginally legal tactics used by brand-name drug manufacturers,<sup>122</sup> would compel courts to rule against brand-name companies and award huge punitive damages, similar to those handed down in the tobacco litigation of the 1990s.<sup>123</sup>

Conversely, the brand-name pharmaceutical industry and other groups weighed in against the proposed rule changes.<sup>124</sup> Included in this group was PhRMA,<sup>125</sup> which stated that the proposed rules would stifle innovation and result in fewer drugs being developed in the future.<sup>126</sup> These groups also stated that the American patent system produced the

120. *Id.*

121. Terry Carter, *Drug Wars: Coalition Tactics Make Price Fight Look Like Battle Over Tobacco*, 88 A.B.A.J. 40, 41 (Dec. 2002). Lobbyist and tort-reform lawyer Victor Schwartz indicates that drug companies are "up against an 'iron triangle' of bad publicity, lobbying efforts, and litigation." *Id.* at 43. These factors coalesce to put brand name drug manufacturers on the defensive, forcing them to justify the high prices they charge for patented drugs. *Id.* The article indicates this is an especially difficult task now, as a combination of a sagging economy, an aging population with great political clout, and corporations and insurance companies seeking lower health-care costs are banding together in an attempt to restrict the ability of brand-name companies to recoup their research and development costs through high prices on patented drug products. *Id.* at 41-45. The brand-name industry's response has thus far consisted mainly of public relations initiatives to educate the public of the need for incentives to encourage innovation. *Id.* at 43. However, drug price reform is becoming increasingly attractive to politicians who hope to cater to segments of the population that vote in large numbers, especially seniors. *Id.* at 43-44. As such, brand-name drug manufacturers face a difficult task in attempting to stave off amendments to the Hatch-Waxman Act that will give generic companies more access to the pharmaceutical market, thereby lowering prices and the profits enjoyed by brand-name drug manufacturers. *Id.* at 40-45.

122. *See, e.g., id.* at 44.

123. *Id.*

124. Pharmaceutical Research and Manufacturers of America, *Efforts to Alter Balance of Hatch-Waxman Law Based on Faulty Premises* [hereinafter PhRMA Backgrounder] (Jan. 2002), at [http://www.allhealth.org/recent/audio\\_06-13-02/hatchwaxman-backgrounder.pdf](http://www.allhealth.org/recent/audio_06-13-02/hatchwaxman-backgrounder.pdf).

125. PhRMA's mission statement states:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. The industry invested more than \$30 billion in 2001 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures.

Pharmaceutical Research and Manufacturers of America, *Mission Statement*, at <http://www.phrma.org/whoweare/>.

126. *See* PhRMA Backgrounder, *supra* note 124.



most successful and useful drug companies in the world<sup>127</sup> as a result of the strong patent protection afforded to innovators under the American system.<sup>128</sup> These groups claim that future innovation depends on strong pharmaceutical patent protections<sup>129</sup> and that the promise of strong returns on research and development investments facilitates new drug discoveries. They say new drug discoveries actually save money in the long run.<sup>130</sup> Thus, they claim that rules which would weaken brand-name pharmaceutical makers' abilities to make a strong profit on new pharmaceutical products will curtail pharmaceutical innovations,<sup>131</sup> because the process of new drug discovery and approval is so expensive and time-consuming.<sup>132</sup> Regulations that inhibit brand-name companies from recouping the development costs and making a profit will reduce the incentive to continue developing new drugs, resulting in fewer new drugs in the future—a situation that will hurt consumers in the long run.<sup>133</sup>

#### F. The FDA's 2003 Hatch-Waxman Act Regulation

On June 18, 2003, the FDA released its final rule<sup>134</sup> in response to the FTC Study<sup>135</sup> and comments<sup>136</sup> on the proposed rule.<sup>137</sup> This final rule

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127. *Update: Bush to Close Hatch-Waxman Loopholes*, PHARMA MARKETLETTER, *supra* note 9, at 1 (quoting remarks delivered by President Bush on Oct. 24, 2002).

128. *Id.*

129. *Id.*

130. PhRMA Backgrounder, *supra* note 124. "Groundbreaking research shows that new medicines lead to higher prescription drug costs but significantly lower total health spending. . . . [A] study found that an \$18 increase in money spent on new prescription drug expenditures reduces non-drug spending by \$71.09, resulting in a net savings of \$53.09." *Id.*

131. *Id.*

132. *Update: Bush to Close Hatch-Waxman Loopholes*, PHARMA MARKETLETTER, *supra* note 9, at 1 (stating that it can cost up to \$800 million to develop and bring a new drug to market).

133. PhRMA Backgrounder, *supra* note 124. "All of this means that changing the Hatch-Waxman balance will lead to fewer new medicines. This will mean lost opportunities to cure disease, promote more productive lives, and save money." *Id.* See also *Hatch-Waxman Has Boosted Generics, But Jury Still Out on Effects On Innovators*, PHARMA MARKETLETTER 1 (Jan. 6, 2003) (quoting Gregory Glover of Ropes & Gray, a law firm, who stated "innovation . . . will be harder in the future because the easy fruit has been picked off and the diseases now being investigated involve harder science and more sophisticated problems[; thus,] [f]ailures will be more costly . . . and innovation is unlikely to continue at the same pace as previously").

134. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). The effective date of the new rule was August 18, 2003, and the compliance date for the submission of information on polymorph patents was December 18, 2003. *Id.* See also *infra* note 139 and accompanying text.

135. FTC Study, *supra* note 15.

136. For a listing of and links to comments received by the FDA in this matter, see 02N-0417 Applications for FDA Approval to Market a New Drug, at <http://www.fda.gov/ohrms/dockets/dockets/02n0417/02n0417.htm>.

137. FDA Proposed Rule, 67 Fed. Reg. 65,440 (proposed Oct. 24, 2002) (to be codified at 21

affects five aspects of the FDA's Hatch-Waxman implementation regulations.<sup>138</sup> First, the rule clarifies which patents must be submitted for listing in the Orange Book and which patents must not.<sup>139</sup> Next, the final rule modifies the pre-existing regulation to ensure that only one thirty-month stay is allowed per ANDA or 21 U.S.C. § 355(b)(2) application (referred to in the final rule as a "505(b)(2) application" in reference to the Food, Drug, and Cosmetics Act section).<sup>140</sup> Additionally, the final rule changes the patent declaration forms that must be submitted by an entity submitting or holding an NDA.<sup>141</sup> The new rule also "modifies the statement used to describe the fact that the NDA applicant or holder believes there are no relevant patents to be submitted."<sup>142</sup> Finally, the final rule comports with the proposed rule in that it does not affect the 180-day exclusivity period enjoyed by the first ANDA holder.<sup>143</sup>

The FDA estimates that the net economic benefit of this regulation will exceed \$2 billion over a ten-year period.<sup>144</sup> Somewhat surprisingly, the

C.F.R. pt. 314).

138. See 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. at 36,697.

139. *Id.* This aspect of the final rule changes 21 C.F.R. § 314.53(b). *Id.* Under the new regulation, the NDA holder must submit patents that claim the "drug substance (active ingredient), [t]he drug product (formulation and composition), and [a] method of use." *Id.* Additionally, patents that claim a polymorph of the active ingredient of the drug substance described in the NDA "must be submitted if the applicant has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA." *Id.* Next, method of use patents must only be submitted if they "claim indications or other conditions of use that are the subject of a pending or approved application." *Id.* Finally, "information on patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must not be submitted." *Id.*

140. *Id.* The regulation "modifies §§ 314.95(a) and 314.52(a) to state that, if an ANDA or 505(b)(2) [21 U.S.C. § 355(b)(2)] application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay." *Id.* This change ensures that there is only one opportunity for a thirty-month stay per ANDA or 505(b)(2) application, since "[n]otice to the NDA holder and patent owner is one of the requirements for a 30-month stay . . ." *Id.* at 36,688.

141. *Id.* at 36,697. This change affects 21 C.F.R. § 314.53(c)(1) and (c)(2)(ii). *Id.* This change is notable because of the adoption of more specific attestation statements that must be signed by the applicant. *Id.* at 36,686. A warning is also included that informs "the submitter that a willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001." *Id.*

142. *Id.* at 36,697. This aspect of the regulation affects 21 C.F.R. § 314.53(c)(3). *Id.*

143. *Id.* at 36,695. "[E]ligibility for 180-day exclusivity will follow the same general principles as before implementation of this final rule. . . . We are not altering our interpretation of exclusivity in the final rule." *Id.*

144. *Id.* at 36,703.

We estimate the 10-year cost of this final rule to be \$51.584 billion and the annualized cost to be \$4.871 billion. The 10-year benefit of this final rule is estimated to be \$53.940 billion and the annualized benefit is \$5.093 billion . . . . Thus, the 10-year net benefit is \$2.356 billion and the annualized net benefit is \$ 222 million.

*Id.*

new regulation has initially enjoyed only lukewarm support from the generic drug industry.<sup>145</sup> The generic industry would prefer legislation over the final FDA regulation, and it may get its wish; two bills introduced in 2003 would amend the Hatch-Waxman Act as a part of Medicare reform.<sup>146</sup> While the full implications of these bills are beyond the scope of this Note, those sections of the bills that would affect the Hatch-Waxman Act have been described as “complementary” to the FDA’s final rule.<sup>147</sup> Many brand-name pharmaceutical companies believe that the new regulation goes too far in favor of generic drug companies.<sup>148</sup>

### III. ANALYSIS

#### A. *The Statutory Framework*

The 1962 amendments to the Food, Drug, and Cosmetic Act<sup>149</sup> were an important step in American medicine, as they ensured that new drugs placed on the market were safe and effective<sup>150</sup> while retaining the

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145. See Press Release, Generic Pharmaceutical Association, Pending Hatch-Waxman Legislation Coupled With FDA Rule Will Achieve Meaningful Savings for American Consumers (Aug. 15, 2003), at [http://www.pnnewswire.com/cgi-bin/micro\\_stories.pl?ACCT=913120&TICK=GPHA&STORY=/www/story/08-15-2003/0002001805&EDATE=Aug+15,+2003](http://www.pnnewswire.com/cgi-bin/micro_stories.pl?ACCT=913120&TICK=GPHA&STORY=/www/story/08-15-2003/0002001805&EDATE=Aug+15,+2003) (stating “more measures outside of FDA’s authority are necessary if consumers and healthcare purchasers are to have meaningful relief from unsustainable prescription drug costs.”). See also *Final Patent Rule Brings Significant Changes to Brand, Generic Competition*, FOOD AND DRUG LETTER, Aug. 1, 2003, at 680 (stating “[o]n first blush, the two key pharmaceutical trade groups [GPhA and PhRMA] offered tepid support of the rule”).

146. Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Congress (2003); Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Congress (2003). According to Dan Troy, FDA Chief Counsel for Food and Drugs, “We are pleased that both versions of this legislation include key ideas embodied in FDA’s regulation to improve access to generic drugs, and do not include certain other problematic provisions contained in legislation (S. 812) that passed the Senate last year.” *Promoting Availability of Lower Cost Generic Drugs: Hearing Before the Committee on Senate Judiciary*, 108th Cong. (2003) (testimony of Dan Troy, Chief Counsel for Food and Drugs, Food and Drug Administration). S. 1. also “would eliminate the 180 days of exclusivity for any generic drug company that enters such anticompetitive deals or fails to come to market in a timely manner.” *Generic Rx: Schumer Criticizes DOJ Concerns About Measure*, AMERICAN HEALTH LINE, Aug. 4, 2003, at Politics & Policy. Cf. *supra* note 100.

147. *U.S. FDA Generic Drug Access Reg Takes Effect*, PHRMA MARKETLETTER, Aug. 11, 2003 (stating “[t]he FDA says it is pleased the generic legislation passed by the House and the Senate and included in the Medicare legislation, S 1 and HR 1, complements the Final Rule”).

148. See, e.g., *FDA Patent Rule Closes Most, Not All, Loopholes, Troy Says*, GENERIC LINE, VOL. 20, NO. 13, July 16, 2003 (“Bruce Kuhlik, senior vice president and general counsel of PhRMA, told senators in Judiciary Committee the current law ‘has been an enormous boon to the generic industry.’ He cautioned that any changes to the 1984 Hatch-Waxman Act could undermine incentives for pharmaceutical innovation.”).

149. 1962 Amendments to the Food, Drug and Cosmetics Act, Pub. L. No. 87-781, 76 Stat. 780 (1962).

150. FTC Study (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

financial incentives that compelled pharmaceutical researchers to create new and more powerful drugs.<sup>151</sup> However, these amendments also created a system where brand-name pharmaceutical companies enjoyed what amounted to a perpetual monopoly on their products.<sup>152</sup> This situation resulted in a pharmaceutical market with very few inexpensive, generic products,<sup>153</sup> which meant that pharmaceutical prices stayed high even after the patents on the original pharmaceuticals had expired.<sup>154</sup> The Hatch-Waxman Act of 1984 effectively ended these perpetual monopolies by streamlining the process by which generic drugs could be introduced into the market.<sup>155</sup>

Since the passage of the Hatch-Waxman Act, generic pharmaceutical companies have flourished.<sup>156</sup> This success is due, in large part, to the incentives Hatch-Waxman gives to generic companies to challenge<sup>157</sup> and “design around”<sup>158</sup> the existing patents held by brand-name pharmaceutical producers. Despite its successes, however, the Hatch-Waxman provisions that allow for an automatic thirty-month stay on the approval of the generic’s ANDA, if the brand-name company files suit for infringing a patent listed in the Orange Book,<sup>159</sup> have been particularly prone to abuse by brand-name drug manufacturers.<sup>160</sup> The thirty-month stay extends the brand-name drug manufacturers’s intellectual property rights,<sup>161</sup> as it is, in effect, an “automatic injunction.”<sup>162</sup> The provision allows for a stay longer than the average time it takes for the FDA to acknowledge the bioequivalence<sup>163</sup> between the generic product and the

151. *Id.* at 4.

152. *Id.* “By 1984, the FDA estimated that there were approximately 150 brand-name drugs whose patents had expired for which there was no generic equivalent.” *Id.* (citing H.R. REP. NO. 98-857, Part I at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649).

153. FTC Study, *supra* note 15, at 4.

154. *Id.*

155. *Id.*

156. FTC Study, *supra* note 15, at 10. “According to the FDA, from the time Hatch-Waxman became effective in 1984 through December 31, 2000, 8,019 ANDAs were filed with the FDA.” *Id.* See also Boersig, *Patent Woes for Big Pharma*, *supra* note 10. Jeff Trewitt, spokesman for PhRMA, states, “Since [Hatch-Waxman] passed 18 years ago, about 8,000 generic drugs have been approved to go onto the market, the portion of the marketplace that is generic has increased dramatically from 19% to about 49%, and is still growing.” *Id.*

157. See *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C.Cir. 1990) (Edwards, J., dissenting).

158. FTC Comments at 17, available at <http://www.ftc.gov/be/v030002.pdf>.

159. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

160. FTC Study, *supra* note 15, at 40.

161. “The 30-month stay provision of the Hatch-Waxman Amendments protects brand-name companies beyond their existing intellectual property rights.” FTC Study, *supra* note 15, at 39.

162. *Bill Aims to Speed Market Entry of Generics*, CHAIN DRUG REVIEW, NO.4, Vol. 24, Feb. 18, 2002, at pg. RX7, LEXIS, Nexis Library, Chain Drug Review file.

163. See *supra* note 52.

brand-name product.<sup>164</sup> Thirty months is also longer than the average time it takes for a district court to rule on the issues of patent infringement<sup>165</sup> and patent invalidity.<sup>166</sup>

*B. The FDA's Final Rule Will Greatly Reduce Abuses of the Thirty-Month Stay Provision*

Brand-name pharmaceutical manufacturers have been able to extend the length of the stay to up to sixty-five months by listing additional patents in the Orange Book.<sup>167</sup> When a generic drug manufacturer challenges the patent that covers a brand-name pharmaceutical product by filing a paragraph IV certification in conjunction with an ANDA,<sup>168</sup> the patent holder has forty-five days to file suit for patent infringement.<sup>169</sup> At this point, the automatic thirty-month stay on the generic's entrance into the market begins to run.<sup>170</sup> However, before the new FDA regulation, the brand name drug manufacturers could have then listed another patent in the Orange Book,<sup>171</sup> forcing the generic company to file another paragraph IV certification.<sup>172</sup> If the brand-name company then filed suit on this second certification within forty-five days of receiving notice, *another* thirty-month stay was automatically effective.<sup>173</sup> Thus, by manipulating the Orange Book, a brand-name company could extend the generic approval process for a much longer time than contemplated by the Hatch-Waxman Act.<sup>174</sup>

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164. "FDA approval of generic applicants that filed paragraph IV certifications and were not sued took, on average, 25 months and 15 days from the filing date." FTC Study, *supra* note 15, at 39.

165. *Id.* "On average, the time between the complaint and a district court decision in litigation between a brand-name company and first or second generic applicants was 25 months and 13 days. The average time between the complaint and an appellate decision was 37 months and 20 days." *Id.*

166. *Id.*

167. FTC Study, *supra* note 15, at 49 (Table 4-3).

168. 21 U.S.C. § 355(j) (2000).

169. 21 U.S.C. § 355(c)(3)(C) (2000).

170. *Id.*

171. FTC Study, *supra* note 15, at 40. "[B]y the timely listing of additional patents in the Orange Book *after* a generic applicant has filed its ANDA (later-issued patents), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant's ANDA." *Id.* (emphasis in original).

172. *Id.* "Although the generic applicant has already certified to the patents previously listed in the Orange Book for a particular drug product, it must re-certify to the newly listed patent(s) and notify the brand-name company of its re-certification." *Id.*

173. *Id.* "If the brand-name company sues for patent infringement on the new certification within 45 days of notification, a new 30-month stay will begin to run. The FDA is prohibited from approving the ANDA until the new 30-month stay expires." *Id.*

174. *See* 21 U.S.C. § 355(c)(1) (2000).

The FDA regulation comports with the time-frame contemplated by the Hatch-Waxman Act<sup>175</sup> by allowing only one thirty-month stay on the approval of the generic product for each brand-name pharmaceutical, while avoiding the possibility of manipulation by ANDA filers seeking to avoid *any* 30-month stay.<sup>176</sup> The new rule also eliminates the previous incentive for brand name drug manufacturers to abuse the Orange Book requirement by listing additional patents that are sometimes marginally related to the actual pharmaceutical.<sup>177</sup> This aspect of the proposed regulation also eliminates the incentive for brand-name companies to prolong patent litigation unnecessarily, because the generic drug manufacturers would legally be able to market its product after the thirty-month stay regardless of the posture of the ongoing patent litigation with the brand name drug manufacturers.<sup>178</sup>

### C. The FDA Proposal Reduces Improper Orange Book Listings

The new regulation also cuts down on Orange Book abuse by further restricting the types of patents that may be listed in the Orange Book.<sup>179</sup>

175. See 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676, 36,692–93 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) (indicating that the FDA believes that the Hatch-Waxman Act's drafters intended there to be one, but only one, thirty-month stay per ANDA application).

176. *Id.* at 36,693.

Our revised interpretation of section 505(j)(2)(B)(iii) of the [Food, Drug and Cosmetics] act accomplishes two statutory objectives: (1) It closes a possible loophole that would have allowed ANDA applicants to avoid any 30-month stay and (2) it prevents multiple 30-month stays per ANDA application. A similar conclusion applies to the parallel provisions of section 505(b)(2) of the act.

177. FTC Study, *supra* note 15, at v. "To permit only one 30-month stay per drug product per ANDA should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays." *Id.* (citation omitted).

178. *Id.* at 7. "Filing of the lawsuit stays the FDA's approval of the ANDA until *the earliest of*: (1) the date the patent(s) expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of 30 months from the receipt of notice of the paragraph IV certification." *Id.* (emphasis added).

179. See *supra* note 139 and accompanying text. See also FTC Comments, at 10 available at <http://www.ftc.gov/be/v030002.pdf>. The FTC agreed with the FDA's proposed rule that "[p]atents claiming packaging, metabolites, and intermediates do not meet the listing requirements and, therefore, should not be listed in the Orange Book." *Id.* However, the FTC also indicated that the final form of the FDA rule should be refined to clarify that "claims reciting a *known* product and a *novel* process that are drafted in the product-by-process format" cannot be listed. *Id.* at 11 (emphasis in original). Additionally, the FTC indicated in its comments on the FDA's proposed rule that the proposed rule was incorrect in allowing NDA filers to list claims reciting polymorphs. *Id.* at 13-14. "Patents claiming a chemical compound (sic) that differ by water-of-hydration or that form a crystalline structure different from the active ingredient are referred to as 'polymorphs.'" *Id.* at 13 n.50. Furthermore, the FTC suggested that the FDA tweak its proposed amendment to 21 C.F.R. § 314.53, the patent declaration regulation regarding the Orange Book. *Id.* at 13. The FTC suggested the following

This aspect is not redundant in light of the single thirty-month stay provision, as there is the possibility that fraudulent Orange Book listings could delay the generic approval process without lengthening the automatic thirty-month stay.<sup>180</sup> For instance, a brand name drug manufacturer could learn that a generic drug manufacturer is planning on filing a paragraph IV ANDA on one of its products, or assume this will happen because the brand-name company sees the patent as being weak.<sup>181</sup> In response, the brand name drug manufacturer would likely file additional, stronger patents in the Orange Book.<sup>182</sup> By filing patents that are stronger but marginally related to the actual pharmaceutical product, the brand name drug manufacturers could discourage the generic manufacturer from filing the ANDA because of the generic manufacturer's belief that it would be unable to win a noninfringement or invalidity decision at trial.<sup>183</sup> The extra Orange Book-listed patents could also ensure that any litigation would take longer than the thirty-month stay, thereby practically ensuring that the brand-name company would have the full benefit of the stay provisions.<sup>184</sup>

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additions to ensure that the FDA can more easily identify Orange Book declarations regarding patents that should not be listed:

First, the certification should require that the person attesting to the certification is either senior patent counsel with the NDA holder or an outside patent counsel specifically designated to act as the NDA holder's agent. . . . Second, the FDA may wish to consider adding a knowledge requirement to the certification. . . . Third, the FDA should consider adding two additional declarations on patents with product-by-process claims and terminal disclaimers.

*Id.* at 19. The final rule comports with the FTC comment in that it does not allow patents claiming packaging, metabolites, or intermediates to be listed. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. at 36,697. The final regulation also alters the declaration requirements to ensure that only true product-by-process patents are submitted. *Id.* at 36,686. The final regulation also changes the attestation requirements, although the final attestation requirements are not as specific as those called for by the FTC Comment. *See Id.* Lastly, the final rule allows polymorph patents to be listed, although it requires accompanying test data that shows bioequivalence. *See supra* note 139 and accompanying text.

180. FTC Study, *supra* note 15, at 41.

181. *Id.*

182. *Id.*

183. *Id.*

184. Table 4-1 of the FTC Study indicates that the average length of patent litigation cases in district courts that arise in response to a paragraph IV certification is 25 months and 13 days. FTC Study, *supra* note 15, at 47. By listing more patents in the Orange Book for a particular drug product, the brand-name company would introduce more issues to a trial and thereby lengthen the time required for a trial court decision on the questions of validity and infringement. *Id.* at 47-48.

*D. 180-Day Exclusivity Period Abuse Is Correctable by the FTC*

The FTC recommended that parties be required to report certain settlement agreements to the FTC.<sup>185</sup> If a brand name drug manufacturer files an infringement suit against the first paragraph IV ANDA filer, and the parties reach a settlement whereby the generic drug manufacturer agrees not to market its version of the drug, then the 180-day period will not begin to run.<sup>186</sup> The FTC did not find any actual incidents where an agreement between a brand name drug manufacturer and a generic drug manufacturer resulted in the 180-day exclusivity period being “parked.”<sup>187</sup> Such an agreement would have the effect of precluding subsequent generic entrants from entering the market for the product produced by the brand name drug manufacturer.<sup>188</sup>

Although such settlement agreements involve pharmaceutical approval and patent issues, those agreements could also be dealt with by antitrust laws.<sup>189</sup> As such, the FTC would have authority to investigate such agreements,<sup>190</sup> and sanction the involved parties based on its antitrust

185. FTC Study, *supra* note 15, at vi. “Recommendation 2: Pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission.” *Id.*

186. Scott P. Perlman & Jay S. Brown, *FTC Targets Patent Settlement Agreements*, NAT’L L. J. (Nov. 11, 2002) at C1 (“As the FDA has noted, if the gains to the brand-name manufacturer from delaying generic entry exceed the potential gains to the generic entrant from 180-days of exclusivity, the parties will have incentives the share that incremental gain by postponing the 180-day period . . . [A] settlement under which the generic company agrees not to market its products would extend the 180-day period indefinitely”) (emphasis added).

187. “14 of the 20 of the [sic] settlement agreements obtained through the study, at the time they were executed, had the potential to ‘park’ the first generic applicant’s 180-day exclusivity for some period of time, thus preventing FDA approval of any subsequent eligible applicants.” FTC Study, *supra* note 15, at 63. However, in a footnote to its study, the FTC states, “[w]hether FDA was actually prevented from approving subsequent eligible generic applicants depends on a number of factors, including whether there were subsequent generic applicant(s) and the result of any patent litigation with those applicants.” FTC Study, *supra* note 15, at 63 n.26.

188. *Id.* at 63.

189. *Id.* at 57

The [FTC’s] antitrust law enforcement actions have alleged that certain brand-name and generic companies have entered into agreements that, among other things, have had the effect of delaying entry by the first generic that otherwise would trigger the running of the 180-day exclusivity, thereby creating a bottleneck for any subsequent eligible generic entry.

*Id.* at 57 (footnote omitted).

190. 15 U.S.C. § 45 (2003). The Senate bill “would eliminate the 180 days of exclusivity for any generic drug company that enters such anticompetitive deals or fails to come to market in a timely manner.” *Generic Rx: Schumer Criticizes DOJ Concerns About Measure*, AMERICAN HEALTH LINE, Aug. 4, 2003, at Politics & Policy. “Robert Armitage, senior vice president and general counsel for Eli Lilly, said lawmakers should eliminate the measure concerning the 180-day exclusivity cause, saying it could lead to market ‘monopoly’ by one generic drug maker.” *Id.*



enforcement authority.<sup>191</sup> The final regulation promulgated by the FDA does not address the 180-day exclusivity provisions of the Hatch-Waxman Act.<sup>192</sup>

#### IV. PROPOSAL

Congress should codify legislation similar to the rules promulgated by the FDA<sup>193</sup> in response to the recommendations made by the FTC.<sup>194</sup> Although the FDA rules will likely be effective, the FDA's power to promulgate such rules is questionable.<sup>195</sup> Additionally, statutory violations, as opposed to rule violations, would be tried in courts rather than in administrative settings, which would make the process more accessible to the public.<sup>196</sup>

##### A. Only One Thirty-Month Stay Should Be Available

The automatic thirty-month stay of a generic's paragraph IV ANDA extends the brand name drug manufacturer's intellectual property rights.<sup>197</sup> In a paragraph IV certification, the generic manufacturer proposes that the brand name drug manufacturer's patent is either invalid or would not be infringed by the generic product.<sup>198</sup> Thus, absent the automatic thirty-month stay, the generic manufacturer could take a calculated risk and begin marketing its product before a court decision regarding the brand-

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191. *Id.* See also Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch-Waxman Act*, GEO. MASON L. REV. 345, 348-50 (2002).

192. See *supra* note 143 and accompanying text.

193. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314).

194. See FTC Study, *supra* note 15.

195. Steve Seidenberg, *Rule On Generics Faces Hurdles*, NAT'L L.J., Nov. 11, 2002, at C1. While adoption of the proposed rules by the FDA benefits consumers by making generic drugs more available, the legal hurdles that the regulations will have to get past are much more extensive than those for legislation. *Id.* at C1 & C4. According to Marc Scheineson, a former FDA official, it is unclear whether the Hatch-Waxman Act gives the FDA the right to limit the automatic stay to one time only. *Id.* at C3. Before the adoption of the proposed, some predicted a lengthy court battle would likely ensue if the FDA adopted the proposed regulations. See *Id.* A better route than the adoption of administrative rules would be for Congress to amend the Hatch-Waxman Act to integrate the proposed changes directly into it. This is the approach favored by Senator John McCain, who stated: "What is truly needed is legislation that will codify into law provisions that will guarantee that these drugs are affordable for those who need them." *Congress Plans Hearings on Access to Generic Drugs*, GENERIC LINE, Vol. 19, No. 23 (Dec. 6, 2002).

196. See RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 530-31 (4th ed. 2002) (describing the differences in procedural requirements between judicial proceedings and informal agency adjudication, which is the type of adjudication most commonly used by agencies).

197. FTC Study, *supra* note 15, at 39.

198. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000).

name producer's patent. If this occurred, and the brand-name producer lost at trial, it would have lost out on the monopoly profits it could have charged during the trial.<sup>199</sup> Hatch-Waxman prevents the generic drug manufacturers from taking this course of action.<sup>200</sup> Thus, the thirty-month stay exclusively benefits the brand-name producer.<sup>201</sup> The thirty-month stay provision of Hatch-Waxman<sup>202</sup> gives the FDA enough time to determine the bioequivalence<sup>203</sup> between the brand-name and generic products<sup>204</sup> and gives the courts enough time to decide on the merits of the nearly inevitable patent infringement suit filed in response to a paragraph IV certification.<sup>205</sup> Allowing brand-name companies to extend the stay beyond thirty months in order to protect their monopolies does not comport with the Hatch-Waxman Act's goals.<sup>206</sup> There is no compelling reason to allow multiple thirty-month stays, and the only reason to attempt to acquire a longer stay is to keep the generic product off the market.<sup>207</sup> The issue of whether a generic product should or should not be available on the market is best left to the courts and the FDA and should not be contingent upon a company's adeptness at "creative compliance."<sup>208</sup> Because the Hatch-Waxman Act contemplates that these decisions should be completed within thirty months of the infringement suit,<sup>209</sup> the stay should be limited to this amount of time.

*B. The Changes to the Orange Book Listing Requirements and the Listability Declaration Requirement Comport with Hatch-Waxman*

The new FDA regulation<sup>210</sup> regarding the clarification of standards for Orange Book listings will benefit consumers by reducing spurious patent

199. FTC Study, *supra* note 15, at 7.

200. 21 U.S.C. § 355(c)(3)(C) (2000). *See also* FTC Study, *supra* note 15, at 7 ("A 30-month stay of FDA approval of an ANDA applicant is invoked when a brand-name company receives notice of a generic applicant's paragraph IV certification and files suit for patent infringement within 45 days of that notice.").

201. FTC Study, *supra* note 15, at 7.

202. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

203. *See supra* note 52.

204. *Id.* at 39. "One 30-month period to resolve disputes over patents listed in the Orange Book prior to the ANDA's filing date appears unlikely to delay generic entry, however, because it historically has approximated the time necessary for FDA review and approval of the ANDA and the duration of a patent lawsuit." *Id.*

205. *Id.*

206. *Id.* at 40.

207. *Id.*

208. *See* 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676, 36,688 (June 18, 2003).

209. FTC Study, *supra* note 15, at 39.

210. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676.

litigation over patents listed in the Orange Book that are only marginally related to the drug product.<sup>211</sup> The purpose of the Orange Book is to provide a central location for the listing of pharmaceutical patents.<sup>212</sup> The stricter requirements for Orange Book listing should be accompanied by an FDA commitment to more closely scrutinize the legitimacy of Orange Book listings.<sup>213</sup> Such scrutiny is a job better suited to the FDA than to the courts.<sup>214</sup> FDA scrutiny of Orange Book listings would lead to greater consistency than judicial scrutiny of the listings, because the FDA is the entity that rules on the bioequivalence of generic products, which in turn challenge the products protected by the patents listed in the Orange Book.<sup>215</sup>

While this proposal makes theoretical sense, it is important to remember the practical restraints on its implementation imposed by the FDA's budget.<sup>216</sup> Thus, unless the FDA's budget is enlarged to accommodate such expanded authority, a more cost-effective measure would be to create a private cause of action by which generic companies could sue brand-name companies for improperly listing patents in the Orange Book. By creating this cause of action, Congress could also implement penalties against companies that improperly list patents, such as fines or loss of patent rights under a patent misuse theory.<sup>217</sup>

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211. See *supra* note 177 and accompanying text.

212. "One function of the Orange Book is to provide notice to ANDA applicants of relevant patents." FTC Study, *supra* note 15, at 54.

213. The FDA, unfortunately, continues to refuse to provide an administrative process to review the listability of Orange Book patents. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. at 36,683. "An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority." *Id.*

214. Sarah Yoho, Note, *Reformation of the Hatch-Waxman Act, An Unnecessary Resolution*, 27 NOVA L. REV. 527, 550–51 (2003).

215. An ANDA must demonstrate that the generic product is the bioequivalent of the brand-name product, and must make a certification regarding each Orange Book patent that is related to the relevant NDA. FTC Study, *supra* note 15, at 5. Implicit in this is that the FDA is the final determiner of whether a generic is the bioequivalent of a brand-name drug. Because the FDA reviews NDAs and bioequivalence claims, it holds greater familiarity with the drugs and patents at issue than courts, and thus is theoretically better-equipped to review listability issues than the courts.

216. Nevertheless, it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings or permitting third parties to submit patents for listing. We lack both the *resources* and the expertise to resolve such matters." 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. at 36,683 (emphasis added). See also Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28873–4 (July 10, 1989); FTC Study, *supra* note 15, at 41.

217. *But see* Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001) (holding that parties do not have a private right of action to delist patents from the Orange Book).

*C. Abuses of the 180-Day Exclusivity Provision Should Continue to Be Dealt with by the FTC's Antitrust Division.*

Finally, no changes should be made to the 180-day marketing exclusivity provisions of the Hatch-Waxman Act.<sup>218</sup> Even though these provisions have the potential to preclude subsequent generic entrants from entering the market,<sup>219</sup> the FTC study found no evidence that such agreements have ever been adopted.<sup>220</sup> Also, these provisions provide incentives for generic companies to challenge the validity of<sup>221</sup> and design around<sup>222</sup> the patents held by brand-name companies, resulting in increased competition between drug companies and thereby lowering the prices of pharmaceutical products.<sup>223</sup>

Instead of amending the 180-day exclusivity provisions, preventing agreements that would park the marketing exclusivity period would be better accomplished by the FTC in its antitrust enforcement capacity.<sup>224</sup>

218. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

219. FTC Study, *supra* note 15, at 57. "If the 180-day exclusivity for the first generic applicant does not run, then the FDA may not approve any subsequent eligible generic applicants. Thus, if the first generic applicant agrees not to trigger the 180-day exclusivity, the possibility exists that no generic applicant may enter the market." *Id.*

220. *Id.* at 63 n.26.

221. "The grant of the 180-day exclusivity to the first generic applicant creates an incentive for a generic company to challenge a brand-name company's drug product patents." FTC Study, *supra* note 15, at 57. *See also* *Mova v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998).

222. FTC Comments, *supra* note 27, at 17.

223. "The CBO estimated that, in 1994, the availability of generic drugs saved purchasers between \$8 billion and \$10 billion." FTC Study, *supra* note 14, at 9 (citing CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at 28 (July 1998)).

224. *See* Scott P. Perlman & Jay S. Brown, *FTC Targets Patent Settlement Agreements*, NAT'L L.J., Nov. 11, 2002, at C1. The FTC has recently been involved in four cases involving agreements between brand-name and generic pharmaceutical companies that the agency viewed as anticompetitive agreements. In *Abbott Labs.*, 65 Fed. Reg. 17,502 (Apr. 3, 2000), Abbott agreed to pay a generic entrant \$4.5 million per month to keep a generic version of Hytrin off the market while a district court judge decided its case. The FTC opposed this agreement because, first, it was viewed as an impermissible non-compete agreement, and, second, the agreement prohibited other generic entrants from entering the market because it kept the 180-day period of exclusivity for the first generic entrant from beginning to toll while the payments were being made and while the generic company was not marketing its product. *Id.* at 17,504. The FTC obtained a consent decree from the two companies whereby the agreement was nullified. *Id.* at 17,503. The FTC obtained a similar consent decree in a case involving facts similar to those in *Abbott Labs. Hoechst Marion Roussel, Inc.*, 66 Fed. Reg. 18,636 (Apr. 10, 2001). The agreement in that case involved quarterly payments of \$10 million to the generic company in return for keeping its generic product off the market. *Id.* at 18,637. In *Biovail Corp.*, 67 Fed. Reg. 44,606 (July 3, 2002), the FTC obtained a consent decree nullifying an agreement between two generic manufacturers not to compete with each other, effectively allowing the two to split the profits from the 180-day period exclusivity period. *Id.* However, the FTC failed to prevail in *Schering-Plough Corp.*, 2002 FTC Lexis 40 (June 27, 2002). In that case, the FTC failed to prove that Schering-Plough had enough market share to violate per se the Sherman Act. *Id.* at 279. The FTC also

Agreements between a brand name drug manufacturer and a generic drug manufacturer to park the exclusivity period would have the effect of preventing other competitors from entering the market.<sup>225</sup> Such agreements could reasonably be viewed as a violation of the Sherman Antitrust Act.<sup>226</sup> Legislation similar to that passed by the Senate in 2002<sup>227</sup> requiring parties to report certain settlement agreements<sup>228</sup> to the FTC would facilitate antitrust enforcement, and thus should be passed by Congress.<sup>229</sup> The threat of FTC enforcement of the antitrust laws in response to these types of agreements is likely to be a disincentive for companies to enter into them.<sup>230</sup>

## V. CONCLUSION

The Hatch-Waxman Act<sup>231</sup> significantly changed the pharmaceutical industry<sup>232</sup> by encouraging generic drug manufacturers to challenge and design around patents held by brand name drug manufacturers,<sup>233</sup> leading to a huge increase in the availability of low-cost generic alternatives to

was unable to prove that the licensing agreement between the two companies was a sham, or that the agreement delayed generic entry into the market. *Id.* These cases indicate that the FTC believes that it has the authority to prohibit drug companies from exploiting the 180-day period of exclusivity for the first generic entrant through its enforcement of the Sherman Act, Clayton Act, and FTC Act. More recently, the Chairman of the FTC, Timothy Muris, has indicated that the FTC will continue to target agreements that seek to park the 180-day exclusivity period granted by the Hatch-Waxman Act. *FTC Chief Promises More Scrutiny over Drugs*, *GENERIC LINE*, Vol. 19, No. 22 (Nov. 22, 2002). However, recent legislation would change the statutory landscape in this regard, and thus possibly affect the FTC's ability to pursue these types of cases. *See supra* note 190 and accompanying text.

225. *See supra* note 87 and accompanying text.

226. 15 U.S.C. § 1-7 (2000).

227. Drug Competition Act of 2002, S. 754, 107th Cong. § 5 (2002). For a discussion of the provisions of this bill, which was not passed by the House of Representatives, see *supra* note 104.

228. Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes*, Part II (2001), available at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm>.

[T]here may be a number of considerations that may help determine whether the pioneer manufacturer's payment to the generic is a genuine or sham transaction, without embarking upon a too-detailed inquiry into the technical attributes of the property. The following factors may be relevant. . . . 1. The history of the negotiations. . . . 2. Other offers for the intellectual property at issue. . . . 3. The apparent value of the property as determined by subsequent events. . . . 4. The existence of comparable offers for intellectual property with similar attributes. . . . 5. The structure of the payment terms.

*Id.*

229. *Cf. supra* note 227.

230. Leary, *supra* note 228.

231. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

232. *See* FTC Study, *supra* note 15, at 4.

233. FTC Study, *supra* note 15, at vi. "Through this 180-day provision, Hatch-Waxman provides an incentive for companies to challenge patent validity and 'design around' patents to find alternative, non-infringing forms of patented drugs." *Id.*

brand-name drugs.<sup>234</sup> However, the Hatch-Waxman Act contained loopholes that allowed brand-name pharmaceutical companies to keep legitimate generic products off the market.<sup>235</sup> In response, the FTC<sup>236</sup> recommended that there should only be one automatic thirty-month stay of an ANDA approval<sup>237</sup> and that the FDA should more strictly review the patents listed in the Orange Book.<sup>238</sup> The FDA has largely adopted these recommendations in its 2003 Hatch-Waxman regulation,<sup>239</sup> and the substance of this regulation should be codified by Congress. Congress could also create a private cause of action for improperly listing patents in the Orange Book. Such a law would comport with the purposes of the Hatch-Waxman Act, and combined with the threat of antitrust liability for exploiting other aspects of the Hatch-Waxman Act,<sup>240</sup> would continue to ensure that generic drugs are available while protecting the intellectual property rights of brand name drug manufacturers. While a perfect compromise between Americans' needs for innovative and affordable drugs and the revenue needs of drug companies may not be possible, the Hatch-Waxman Act needs only to be tweaked, not overhauled. The Act has resulted in a good balance of lower-priced drugs and continued development, and, if legislatively augmented to account for a few loopholes, will continue to give hope to those afflicted with diseases that do not currently have effective treatments.

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234. *See supra* note 69. Additionally, the Congressional Budget Office estimated that the availability of generic alternatives to brand-name drugs had saved buyers between \$8 billion and \$10 billion by 1994. FTC Study, *supra* note 15, at 9.

235. "In spite of this record of success, two of the provisions governing generic drug approval prior to patent expiration (the 180-day exclusivity and the 30-month stay provisions) are susceptible to strategies that, in some cases, may have prevented the availability of more generic drugs." FTC Study, *supra* note 15, at i. The 2003 FDA regulation closes the thirty-month stay loophole. *See supra* note 140 and accompanying text.

236. *See* FTC Study, *supra* note 15.

237. FTC Study, *supra* note 15, at ii.

238. "[T]he FTC staff has submitted a Citizen Petition to the FDA that seeks guidance concerning the criteria that a patent must meet before it can be listed in the Orange Book." FTC Study, *supra* note 15, at 55-56. The FDA provided such guidance through its 2003 regulation. *See supra* note 139 and accompanying text.

239. 2003 FDA Hatch-Waxman Regulation, 68 Fed. Reg. 36,676 (June 18, 2003).

240. "The [FTC] has taken antitrust law enforcement actions against certain brand-name and generic companies whose allegedly anticompetitive agreements took advantage of one or the other of [the automatic 30-month stay or 180-day marketing exclusivity] provisions. Through the rigorous enforcement of the antitrust laws, the FTC has taken an active role in ensuring that consumers benefit from competition in the pharmaceutical industry." FTC Study, *supra* note 14, at i.

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