

# *Nova Law Review*

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*Volume 27, Issue 3*

2003

*Article 6*

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## Reformation of the Hatch-Waxman Act, an Unnecessary Resolution

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Sarah M. Yoho\*

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## I. INTRODUCTION

In an era flourishing with scientific innovation, the importance of pharmaceutical drug development is evident. Pharmaceutical drugs aid in the fight against cancer, heart disease, mental illness, and a plethora of other diseases that affect the daily lives of many Americans.<sup>1</sup> However, for

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1. See Pharmaceutical Research and Manufacturers of America, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable*

something that affects life so tremendously, there is a drawback—the cost of pharmaceuticals. Due to the patent protection provided for new drugs, pioneer companies may enjoy a twenty-year monopoly.<sup>2</sup> Patent exclusivity available for an innovator is a key factor in promoting the entrance of new drugs to the market. Without the exclusivity provided to pioneer drug companies, the rate of innovation would likely be dampened. With the temporary monopoly, pioneer drug companies may set drug prices at a level necessary to regain the investment of discovery and research. Yet, with the approval of new drugs comes the opportunity for a generic company to rely on a pioneer company's studies to apply for approval of a generic drug even before the patent expires on the pioneer drug.<sup>3</sup>

The complicated process of pioneer drug and generic drug approval is detailed in the Hatch-Waxman Act ("Act").<sup>4</sup> Although criticized for containing loopholes that allegedly allow pioneer companies to extend their exclusivity,<sup>5</sup> the Act serves the purpose Congress originally intended.<sup>6</sup> Currently, a bill is being reviewed by Congress,<sup>7</sup> which will amend the Act in order to promote an increase in generic drug marketing. However, the provisions of the bill do not accurately address the problems of the Hatch-Waxman Act. Instead, an alternate solution is more advisable to precisely reflect the original purposes of the Act. Furthermore, it is the Food and Drug Administration (FDA) that ultimately decides whether a new or generic drug is approved for marketing.<sup>8</sup>

The purpose of this note is to examine whether reformation of the Hatch-Waxman Act is the appropriate solution to further promote the dual purposes of the Act. Part II reviews the importance of patent rights in

*Intellectual Property Rights 4*, available at <http://www.phrma.org/publications/policy/2002-06-24-436.pdf> (Apr. 22, 2002).

2. See 35 U.S.C. § 154(a)(2) (2000).

3. See 35 U.S.C. § 271(e)(1) (2000).

4. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (2000); 35 U.S.C. §§ 156, 271 (2000)).

5. Julie Appleby & Jayne O'Donnell, *Consumers Pay as Drug Firms Fight Over Generics*, USA Today, June 6, 2002, at 1A. Senator Charles Schumer, D-N.Y., criticized the pioneer companies when stating, "These companies figure out a new way to keep the dollars rolling in, stooping to a new low every day to maintain their exclusivity rights." *Id.* at 2A.

6. See H.R. Rep. No. 98-857, at 1, 37 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2670.

7. See Greater Access to Affordable Pharmaceuticals Act of 2001, S. 812, 107th Cong. (2001).

8. *Am. Bioscience, Inc. v. Thompson*, 141 F. Supp. 2d 88, 90 (D.D.C. Cir. 2001).

stimulating innovation, especially in the pharmaceutical industry. Part III explores the history and provisions of the Act, which create a balance between the interests of generic drug and pioneer drug companies. Part IV discusses the successful enforcement of the Act by the FDA and the courts. Part V details the inadequate provisions of the bill introduced in the Senate to reform the Act. Finally, the note concludes by suggesting a possible alternative to revising the Act to further maintain balance between promoting generic marketing and pioneer innovation.

## II. THE RELATIONSHIP BETWEEN PATENT LAW AND DRUG APPROVAL

Patent rights are an important part of society, stemming back to the United States Constitution.<sup>9</sup> Patents serve “to promote invention, to encourage development and commercialization of inventions, and to encourage inventors to disclose their inventions.”<sup>10</sup> A patent issued by the United States Patent and Trademark Office provides an inventor with the right to exclude others from manufacturing, using or selling the patented invention for twenty years.<sup>11</sup> The right to exclude others is exemplified in the right to sue those who infringe upon the patent. “Patent infringement is defined as making, using, offering to sell, or selling a patented invention without authority.”<sup>12</sup> Without patent protection, an invention could be copied by competitors at significantly lower prices, thereby reducing an inventor’s ability to recover costs associated with innovation.<sup>13</sup>

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9. U.S. Const. art. I, § 8, cl. 8.

10. Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 Harv. J.L. & Tech. 389, 426 (2002) (citing *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974)). The author discusses how the purpose of the Constitution’s intellectual property clause was to instill in Congress the power to promote public interest by providing patent rights. *Id.* at 447–48.

11. 35 U.S.C. § 154(a)(2); Laura Giles, Note, *Promoting Generic Drug Availability: Reforming the Hatch-Waxman Act to Prevent Unnecessary Delays to Consumers*, 75 St. John’s L. Rev. 357, 360 (2001). “The [Patent and Trademark Office] was established under the Department of Commerce to create a government agency to decide what ideas and products were worthy of this protection.” *Plain Talk About Prescription Drug Patents*, at <http://www.phrma.org/publications/policy/02.21.2002.426.cfm> (last visited Apr. 4, 2003).

12. Giles, *supra* note 11, at 364; see 35 U.S.C. § 271(a).

13. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 229 (2001).

The profit protection provided by patents is clearly evidenced in statutes regarding drug innovation.<sup>14</sup> In 1984, Congress enacted the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, which amended Title 21, section 355 of the *United States Code* (known as the Federal Food, Drug, and Cosmetic Act) and Title 35, sections 156 and 271 of the *United States Code*, which are sections of the patent code.<sup>15</sup> In relation to patent protection, section 156 was amended in order to provide pioneer drug companies with an extension on their patents based on the time lost in obtaining FDA approval.<sup>16</sup> In addition, section 271 was amended to allow generic drug companies to apply for FDA approval before the pioneer drug patent expires.<sup>17</sup> The provision authorizes generic drug companies to conditionally infringe on pioneer drug patents without the consequences of a patent infringement lawsuit.<sup>18</sup> However, the authorization has its limits. The exemption from infringement only allows generic drug companies to infringe so long as it is related to gaining FDA approval.<sup>19</sup> If generic drug companies go beyond simply seeking approval by the FDA, pioneer drug companies may seek money damages or injunctive relief in order to protect their patent interests.<sup>20</sup>

### III. HISTORY OF THE HATCH-WAXMAN ACT

#### A. Drug Approval Process Before 1984

Before the Act was introduced in 1984, the drug industry was regulated by the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, "which required proof that a drug was safe and effective" before the FDA submitted approval.<sup>21</sup> However, the 1962 amendments did not include

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14. *See id.* at 231.

15. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1598, 1603 (1984) (codified at 21 U.S.C. § 355 (2000); 35 U.S.C. §§ 156, 271 (2000)).

16. H.R. Rep. No. 98-857, at 37.

17. *See* 35 U.S.C. § 271(e)(1); Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device, and Drug Laws*, 17 Computer & High Tech. L.J. 1, 42-43 (2000).

18. *See* § 271(e)(3).

19. Upadhye, *supra* note 17, at 43.

20. 35 U.S.C. § 271(e)(4)(B)-(C).

21. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA 389, 396 (1999) (citing 21 U.S.C. § 355(b) (1994)).

provisions for a separate and more economical approval process for generic drugs.<sup>22</sup> Instead, generic drug companies were forced to go through the same procedures for FDA approval as pioneer drug companies—filing a New Drug Application (NDA).<sup>23</sup> However, the procedure for filing an NDA is complex and costly considering that:

The NDA is a massive report on the drug, and contains summaries of all the animal and human studies conducted, demonstrating that the new drug is safe and efficacious, details of how and where the new drug will be manufactured, how the manufacturing process is validated, how the drug's performance will be maintained, stability tests on the drug, and how the drug will be packaged, labeled, and marketed.<sup>24</sup>

Due to the lack of finances to undertake the expensive process of clinical studies to prove a drug was safe and effective, few generic drugs entered the market by filing NDAs.<sup>25</sup>

#### B. *Provisions of the Hatch-Waxman Act*

As a result of long debates over the contents of the Act, Congress finally came to a compromise and President Ronald Reagan enacted the bill into law on September 24, 1984.<sup>26</sup> Provisions of the Act enable inventors to have an opportunity to recover development costs, and to ultimately make a profit off of the specified exclusivity period.<sup>27</sup> In addition to recovering development time, the Act also gives generic drug companies advantages unavailable before 1984.

The first advantage to generics is evident in Title I of the Act, which amended section 355 of Title 21 of the *United States Code* by introducing an

22. *Id.*

23. *Id.* at 396–97 (citing Alan H. Kaplan, *Fifty Years of Drug Amendments Revisited: In Easy-To-Swallow Capsule Form*, 50 Food & Drug L.J. 179, 188–89 (1995)).

24. William M. Brown, A “Highly Artificial Act of Infringement,” *Indeed, But It Can Still Cost You Attorneys’ Fees . . . Comment on Yamanouchi v. Danbury*, 33 U.W.L.A. L. Rev. 117, 125 (2001).

25. *See Engelberg, supra* note 21, at 397.

26. *Id.* at 407; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1605 (1984) (codified at 21 U.S.C. § 355 (2000); 35 U.S.C. §§ 156, 271 (2000)).

27. Engelberg, *supra* note 21, at 406. *See generally* 35 U.S.C. § 156 (discussing the patent extension period available to NDA applicants).

abbreviated process for generic drug availability.<sup>28</sup> Through an Abbreviated New Drug Application (ANDA), a generic drug company may rely on the accomplishments of pioneer drug companies to obtain faster FDA approval.<sup>29</sup> Ultimately, the ANDA allows generic drugs to reach the market at reasonable costs to consumers.<sup>30</sup> Furthermore, Title II aided generics by amending section 271 of Title 35 of the *United States Code* to allow generic drug companies to conditionally infringe on pioneer drug companies patents.<sup>31</sup> So long as the infringement is for the purpose of obtaining FDA approval of a generic drug, a generic drug company's use of patented methods or products does not constitute infringement.<sup>32</sup> In addition to allowing generic drugs to be approved based upon the safety and efficacy of a pioneer drug, the Act also provides a way for a generic drug company to challenge a pioneer's patent.<sup>33</sup>

### 1. Generic Drug Approval Process

As discussed, one of the purposes of the Act is to "enabl[e] competitors to bring low-cost, generic copies of [pioneer] drugs to the market."<sup>34</sup> Instead of filing an NDA with the FDA, as was required before 1984, generic drug companies may file an ANDA with information detailing that the generic drug is the bioequivalent of a previously approved pioneer drug, referred to as the "listed drug."<sup>35</sup> Essentially, a generic drug must contain the same active ingredient as the listed drug, but the inactive ingredients may vary.<sup>36</sup> Along with bioequivalency information, the ANDA applicant must certify

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28. Pub. L. No. 98-417, 98 Stat. 1585.

29. See 21 U.S.C. § 355(j).

30. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

31. See 35 U.S.C. § 271(e)(1).

32. *Id.* Section 271(e)(1) states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

*Id.*

33. See 21 U.S.C. § 355(j)(2)(A)(vii).

34. *Andrx Pharms., Inc.*, 276 F.3d at 1371. The other purpose of the Act is to "induc[e] pioneering research and development of new drugs." *Id.*

35. 21 U.S.C. § 355(j)(2)(A).

36. *Am. Bioscience, Inc. v. Shalala*, 142 F. Supp. 2d 1, 3 (D.D.C. 2000) (citing *United States v. Generix Drug Corp.*, 460 U.S. 453, 455 (1983)).

that the drug will not interfere with the listed drug patents of an NDA holder by submitting

a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug

. . .

- (I) that such patent information has not been filed,
- (II) that such patent has expired,
- (III) of the date on which such patent will expire, or
- (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .<sup>37</sup>

The specific certification submitted by the generic drug company is referred to as either a Paragraph I, II, III, or IV certification.<sup>38</sup>

Furthermore, if a generic drug company files an ANDA with a Paragraph IV certification, the company is required to give the patent holder and the NDA holder notice of the reasons why the patent listed is invalid or why the generic drug does not infringe on the listed patent.<sup>39</sup> According to the Act, the requisite notice must include a “detailed statement of the factual and legal basis of the [ANDA] applicant’s opinion that the patent is not valid or will not be infringed.”<sup>40</sup> The purpose of the notice is to provide NDA and patent holders with an opportunity to protect their patent rights through “inquiry, investigation or litigation.”<sup>41</sup> However, the ANDA applicant is not required to submit the notice to the FDA.<sup>42</sup> The FDA does not review the notice because

it lacks the expertise in patent law. Moreover, neither the FDA nor the United States Patent and Trademark Office currently has access to the additional resources that would be necessary to review these notices, and a patent certification review system would subject the agency’s decisions to questioning that would require further re-

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37. 21 U.S.C. § 355(j)(2)(A)(vii)(I–IV).

38. *Andrx Pharms., Inc.*, 276 F.3d at 1371.

39. 21 U.S.C. § 355(j)(2)(B)(i–ii).

40. 21 U.S.C. § 355(j)(2)(B)(ii).

41. *Astrazeneca AB v. Mut. Pharm. Co.*, 221 F. Supp. 2d 528, 534 (E.D. Pa. 2002).

42. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 787 (Fed. Cir. 2002) (Garjarsa, J., concurring).



source expenditures and create delays in the statutory patent certification and challenge process.<sup>43</sup>

In addition, Paragraph IV certification brings forth another obstacle generic drug companies must tackle. Pursuant to Title 35, section 271(e)(2)(A), the filing of a Paragraph IV certification is considered an act of infringement.<sup>44</sup> Subsequent to receiving notice from the ANDA applicant, the NDA and patent holders have forty-five days to commence a lawsuit against the generic drug company for patent infringement.<sup>45</sup> The Act states:

If the [ANDA] applicant made a [Paragraph IV] certification . . . the [FDA] approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice . . . is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided . . . or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . . .<sup>46</sup>

The thirty-month stay allows the parties to litigate the patent infringement suit, thereby guaranteeing that the generic drug will not immediately enter the market.<sup>47</sup>

Generic drug companies take a significant risk by filing a Paragraph IV certification. If the patent holder timely files suit, initiating the stay of generic drug approval up to thirty months, the generic drug company is forced to await a court's decision concerning the patent before the generic may hit the market.<sup>48</sup> However, generic drug companies have a great

43. *Id.* at 788 (Garjarsa, J., concurring).

44. 35 U.S.C. § 271(e)(2)(A); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002).

45. 21 U.S.C. § 355(j)(5)(B)(iii).

46. *Id.*

47. *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001).

*Id.* It is important to remember that the purpose of the 30-month stay is not necessarily to extend the patent holder's monopoly, but to create an adequate window of time, during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.

48. 21 U.S.C. § 355(j)(5)(B)(iii).

incentive to file a Paragraph IV certification with their ANDA.<sup>49</sup> Under the Act, the first company to file an ANDA with a Paragraph IV certification is granted a 180-day marketing exclusivity period.<sup>50</sup>

Although the 180-day period enables the first ANDA filer with a Paragraph IV certification to temporarily block out other ANDA applicants from marketing their versions of the drug, subsequent ANDA filers may be able to bypass this provision. According to Title 21, section 355(j)(5)(B)(iv), if a second ANDA also containing a Paragraph IV certification is submitted, the FDA will not approve the application until 180 days after:

- (I) the date the Secretary [of the FDA] 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 an action . . . holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.<sup>51</sup>

Section 355(j)(5)(B)(iv)(II) of the Act includes not only court decisions finding that the first ANDA filer has not infringed or that the patent is invalid, but also decisions involving the second ANDA filer.<sup>52</sup> If the NDA or patent holder sues a second ANDA filer, the case could be resolved prior to a case against the first ANDA filer. Therefore, a second ANDA filer may ultimately succeed in obtaining the 180-day exclusivity period, thereby excluding the first ANDA filer from the market for the period.<sup>53</sup> “The provision allowing a second ANDA filer to trigger the period by a ‘court decision’ comports with the statute and the intent of Congress.”<sup>54</sup>

The various provisions of the Act enable generic drug companies to reap benefits. The benefits of the 180-day exclusivity period, in addition to the financial advantages of relying on a pioneer drug company’s studies,

49. See *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/K, 2001 U.S. Dist. LEXIS 18361, at \*53 (S.D. Ind. Oct. 12, 2001).

50. 21 U.S.C. § 355(j)(5)(B)(iv).

51. *Id.*

52. *Minn. Mining & Mfg.*, 289 F.3d at 778 (citing *Teva Pharms., USA, Inc. v. United States FDA*, 182 F.3d 1003, 1010 (D.C. Cir. 1999)).

53. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002). “The District of Columbia Circuit has explicitly held that § 355(j)(5)(B)(iv)(II) is triggered by the termination of an action commenced by the second ANDA filer . . . .” *Id.* (citing *Teva Pharms.*, 182 F.3d at 1010).

54. *Id.* at 786 (Garjarsa, J., concurring).

allow generic drugs to gain approval by the FDA and enter the market at a rate unknown before 1984. Yet, the Act goes beyond benefiting simply generic drug companies. Besides promoting competition of low-cost generics, the Act also allows patent term restoration for pioneer drug companies.<sup>55</sup>

## 2. Patent Right Protection

As a compromise to the provisions of the Act allowing a generic drug company to rely on a pioneer company's studies to obtain FDA approval, the patent provisions of the Act provide pioneer drug companies with an incentive. Since obtaining FDA approval for an innovator drug takes a considerable amount of time, the patent holder loses time available to profit from marketing the drug.<sup>56</sup> Thus, an additional purpose of the Act is to provide pioneer companies with patent term extensions to make up for the time involved in regulatory approval.<sup>57</sup> Pioneer companies receive "an extension [of the patent] term equal to one-half of the time of the investigational new drug (IND) period."<sup>58</sup> The IND period begins when the pioneer company commences human clinical studies and ends when the FDA approves the NDA.<sup>59</sup>

Along with patent term extension, the Act also protects the patent rights of pioneer companies. If a generic drug company files an ANDA with a Paragraph IV certification, the pioneer company has forty-five days to file a lawsuit against the generic company for patent infringement.<sup>60</sup> If the pioneer company does not file a lawsuit by then, the FDA may approve the ANDA upon expiration of the forty-five day period.<sup>61</sup> However, if the pioneer company does file a lawsuit within the time allotted, approval of the ANDA is stayed pending

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55. See 35 U.S.C. § 156 (2000).

56. Giles, *supra* note 11, at 361 (citing David J. Bloch, *If It's Regulated Like a Duck . . . Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, 54 Food & Drug L.J. 111, 112 (1999)). "This loss of patent protection as a result of regulatory delay is referred to as 'front end distortion.'" *Id.*

57. *Id.*

58. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 190 (1999) (citing 35 U.S.C. §156 (1994)).

59. *Id.* at 192.

60. 21 U.S.C. § 355(j)(5)(B)(iii).

61. *Id.*

the expiration of the thirty-month period beginning on the date of the receipt of notice provided [to the NDA and patent holder] or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders . . . or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.<sup>62</sup>

The thirty-month stay provision of the Act enables pioneer companies to protect their patent rights prior to approval of generic drugs for marketing.<sup>63</sup> The provision “is a trade-off for having stripped the pharmaceutical industry of the other patent protection afforded to every other U.S. industry.”<sup>64</sup> However, if pioneer companies do not list applicable patents appropriately relating to FDA approved drug, then pioneer companies cannot take advantage of the ANDA stay in order to protect their rights.<sup>65</sup>

Restoration of time, which pioneer companies lose in the FDA approval process, is an adequate measure, considering the tremendous investment pioneer companies make in developing drugs. Pioneers are able to take advantage of the extended patent term to regain finances while generics take advantage of pioneers’ financial investments to develop generic versions. Although the procedures to obtain these advantages are complex, the success of the intricate drug approval process is evident through the interaction between pioneers, generics, the FDA, and the courts.

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62. *Id.*

63. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002).

64. *Plain Talk About Prescription Drug Patents*, at <http://www.phrma.org/publications/policy/02.01.2002.426.cfm> (last visited Apr. 4, 2003).

65. *aaiPharma*, 296 F.3d at 232.

## IV. ENFORCEMENT OF THE ACT

A. *FDA Review and Approval*

The FDA is responsible for supporting the public interest,<sup>66</sup> which may be a difficult task considering the complex role it has in approving drugs. The FDA accepts applications for drug approval, and determines whether approval for marketing is appropriate based on safety and efficacy studies.<sup>67</sup> Since an ANDA for a generic drug relies on the studies performed by pioneer companies, the generic drug companies, in certifying their application, are required to refer to a pioneer's listed patent.<sup>68</sup> Thus, the Act requires that pioneer drug companies provide the FDA with a list of all patents that claim an FDA approved drug or a method of using the drug.<sup>69</sup> When a related patent is issued subsequent to NDA approval, the NDA holder has thirty days to list the patent with the FDA.<sup>70</sup> However, if the NDA holder does not notify the FDA of the patent, an ANDA applicant is not required to amend its application to include the late-listed patent.<sup>71</sup> Late listing comports with the dual purposes of the Act by protecting ANDA filers from having to re-certify late patent submissions, yet allowing NDA holders to "benefit from the public notice that stems from listing."<sup>72</sup>

Regardless of the timing of the submission of patents, the list of patents is published by the FDA in the *Approved Drug Products with Therapeutic*

66. *Am. Bioscience, Inc. v. Shalala*, 142 F. Supp. 2d 1, 16, n.11 (D.D.C. 2000).

67. 21 U.S.C. § 355(b)(1).

68. 21 U.S.C. § 355(b)(2)(A).

69. *aaPharma*, 296 F.3d at 230; *see* 21 U.S.C. § 355(b)(1), (c)(2).

70. 21 U.S.C. § 355(c)(2).

71. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001). The FDA refers to the listing of patents subsequent to the thirty days provided as "late listing." *See Shalala*, 142 F. Supp. 2d at 11. The FDA regulation regarding "late listing" provides:

If a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an abbreviated new drug application for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification. An applicant whose abbreviated new drug application is submitted after a late submission of patent information, or whose pending abbreviated application was previously submitted but did not contain an appropriate patent certification at the time of the patent submission, shall submit a certification . . . as to that patent.

*Id.* at 11 n.6 (citing 21 C.F.R. 314.94(a)(12)(vi) (2001)).

72. *Id.* at 14.

*Equivalence Evaluations*, generally referred to as the Orange Book.<sup>73</sup> However, the FDA only plays a ministerial role in overseeing the Orange Book listings.<sup>74</sup> The role of the FDA “is not to ensure the correctness of the list of patents submitted for Orange Book listing, but simply to ensure that either a patent list has been filed or a declaration has been made that there are no patents to be listed.”<sup>75</sup>

Although the Act does not contain a provision allowing a cause of action to challenge a listing in the Orange Book,

the FDA has provided a limited process for disputing the accuracy or relevance of patent information submitted to the FDA and listed in the Orange Book. One who questions the accuracy of the patent information may write to the FDA, and the FDA will request that the applicant confirm the information. According to the FDA’s regulations, however, “[u]nless the application holder withdraws or amends its patent information in response to FDA’s request, the agency will not change the patent information in the list” and an ANDA applicant must still make certifications for each patent despite its disagreement.<sup>76</sup>

Even so, the FDA warns that if a pioneer company does submit an invalid list, the company may be liable to the FDA.<sup>77</sup>

In addition, the generic drug company may still gain approval despite the improper listing if established by a court order.<sup>78</sup> Since the Act does not require the FDA to review listing of patents in the Orange Book, the approval of an ANDA with Paragraph IV certification rests on a court’s decision that the ANDA does not infringe upon the listed patent.<sup>79</sup>

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73. See *Thompson*, 269 F.3d at 1079.

74. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002).

75. *Id.* at 239.

76. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001) (alteration in original) (citations omitted).

77. *aaiPharma*, 296 F.3d at 242.

78. *Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997).

79. See 21 U.S.C. § 355(j)(5)(B)(iii).

## B. Court Decisions Reflecting Balance

### 1. Listing of Additional Patents

The listing of additional patents in the Orange Book has not only caused lawsuits filed by pioneer drug companies against generic drug companies, but has also led to lawsuits initiated by generic drug companies against the FDA. A pinnacle case discussing the listing of additional patents was *Mylan Pharmaceuticals, Inc. v. Thompson*.<sup>80</sup> In *Mylan*, a generic drug company was ready to market their approved drug upon expiration of the listed pioneer drug, but hours before expiration the pioneer company listed additional patents in the Orange Book.<sup>81</sup> Mylan filed suit against the pioneer company and the FDA seeking a declaratory judgment that the pioneer improperly listed the patent.<sup>82</sup> The United States Court of Appeals for the Federal Circuit reversed the district court's decision, which directed the pioneer company to delist its patent from the Orange Book.<sup>83</sup> The court held that there is no private right of action for delisting a patent under the Act.<sup>84</sup> In rendering this decision, the court reviewed the purpose and relevant legislative history of the Act, and it stated the generic drug company's

claim is not a recognized defense to patent infringement. There is no indication in 21 U.S.C. § 355(j)(5)(B)(iii)(III) that Congress intended to provide an additional defense. Instead it indicates that Congress only envisioned that recognized *defenses could be raised in declaratory judgments in patent infringement actions*. . . . Finally, the parties have shown nothing in the scant legislative history of the amendments pointing to an intent to provide such a defense, or to create a private action for delisting a patent from the Orange Book for a patentee's failure to comply with section 355.<sup>85</sup>

Even though there is no private right of action for delisting a patent, there may be other avenues to obtain ANDA approval. In another case

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80. 268 F.3d 1323 (Fed. Cir. 2001).

81. *Id.* at 1327–28.

82. *Id.* at 1328.

83. *Id.* at 1325. The district court reasoned that Mylan was entitled to relief because Mylan could have used the claim of improper listing as a defense in an infringement suit initiated by the pioneer company. *Id.* at 1328.

84. *Mylan Pharms.*, 268 F.3d at 1332.

85. *Id.* (emphasis added) (citations omitted).

before the Federal Circuit, *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*,<sup>86</sup> the court suggested in dicta that a generic ANDA applicant could sue the FDA directly under the Administrative Procedure Act (APA).<sup>87</sup> Under the APA, if the FDA's denial of the ANDA is "arbitrary, capricious, or not in accordance with law," the FDA may be compelled to approve the ANDA.<sup>88</sup> Therefore, if a generic drug company prevails in an APA claim, the remedy usually will be vacature of the FDA's order and immediate approval of the ANDA.<sup>89</sup> In addition, the Federal Circuit in *Abbott Laboratories v. Novopharm Ltd.* affirmed a lower court decision that a court may order an additional patent to be delisted by the patent holder.<sup>90</sup>

The United States Court of Appeals for the District of Columbia has also rendered a decision involving a claim brought against the FDA under the APA.<sup>91</sup> In *American Bioscience v. Thompson, Inc.*,<sup>92</sup> the patent holder of a listed drug patent sued the FDA, claiming that the agency acted contrary to the APA when it approved an ANDA, regardless of the listing of a related patent in the Orange Book.<sup>93</sup> The court vacated the FDA's order approving the generic, holding that the agency's actions were "arbitrary and capricious."<sup>94</sup>

Ultimately, the courts have enforced patent listing in the Orange Book. The Act specifically empowers the *courts* to review the validity of patents in patent infringement suits initiated according to section 355(j)(5)(B)(iii) of Title 21 of the *United States Code*.<sup>95</sup>

## 2. Paragraph IV Certification

In addition to patent listing disputes, Paragraph IV certification has stimulated various lawsuits between drug companies. Since a company submitting a Paragraph IV certification with their ANDA has to wait for FDA approval to market the drug, there is technically no actual infringement of the listed patent. However, in *Eli Lilly & Co., v. Medronic, Inc.*,<sup>96</sup> Justice

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86. 276 F.3d 1368 (Fed. Cir. 2002).

87. *Id.* at 1378; *see* 5 U.S.C. §§ 702–706.

88. *Id.*

89. *Id.* at 1379.

90. 104 F.3d 1305, 1309 (Fed. Cir. 1997).

91. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077 (D.C. Cir. 2001).

92. *Id.*

93. *Id.* at 1083.

94. *Id.* at 1086.

95. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

96. 496 U.S. 661 (1990).



Scalia, writing for the United States Supreme Court, stated that submitting an ANDA with a Paragraph IV certification is a “highly artificial act of infringement.”<sup>97</sup> Therefore, the court is allowed to decide whether infringement will occur, once the drug is marketed upon FDA approval of the ANDA.<sup>98</sup> In order to succeed in a patent infringement lawsuit, the patentee must prove “by a preponderance of the evidence that the alleged infringer will likely market an infringing product.”<sup>99</sup> In conducting infringement analysis the court reviews the ANDA, the materials submitted to the FDA, and other evidence submitted by the parties.<sup>100</sup>

The Federal Circuit recently heard a case concerning the controversial use of the requirements of the Paragraph IV certification to obtain the 180-day exclusivity.<sup>101</sup> In *Minnesota Mining & Manufacturing Co. v. Barr Laboratories, Inc.*,<sup>102</sup> a second ANDA filer did not provide enough information in the required notice of Paragraph IV certification to the NDA holder.<sup>103</sup> The NDA holder subsequently filed a lawsuit against the second ANDA filer within the forty-five day statutory window of time.<sup>104</sup> The initiation of the suit caused ANDA approval of the generic drug to be stayed for thirty months or until termination of the litigation.<sup>105</sup> Through discovery, the NDA holder was convinced that the second generic applicant did not infringe on the listed patent held by the pioneer drug company.<sup>106</sup> The NDA holder filed a motion to dismiss the case without prejudice in order to

97. *Id.* at 678.

98. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The court stated:

[S]ection 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent. If the court determines that the patent is not invalid and that infringement *would* occur, and that therefore the ANDA applicant’s paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires. *See* 21 U.S.C. § 355(j)(4)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

*Id.* (alteration in original) (emphasis in original).

99. *Id.* at 1570. In *Glaxo*, the court affirmed the district court’s decision that the patentee, Glaxo, Inc., had not proven infringement of its patents by Novopharm, Ltd. by a preponderance of the evidence. *Id.* at 1572.

100. *Id.* at 1570.

101. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002).

102. *Id.*

103. *See id.* at 779.

104. *Id.*

105. *Id.*

106. *Minn. Mining & Mfg.*, 289 F.3d at 779.

prevent the second ANDA filer from obtaining the 180-day exclusivity.<sup>107</sup> The district court, however, dismissed the case with prejudice, thereby triggering the exclusivity period.<sup>108</sup> Subsequently, the NDA holder filed an appeal of the decision in the Federal Circuit.<sup>109</sup> The main issue on appeal was whether the district court erred in determining that the second ANDA filer complied with the notice requirement of the Act.<sup>110</sup> On appeal, the court held that the NDA holder could not “seek a judicial determination of whether a private party’s Paragraph IV certification complies with 21 U.S.C. § 355(j)(2)(B).”<sup>111</sup>

### 3. Allegations of Patent Infringement

Although lawsuits initiated by pioneer drug companies have recently been scrutinized,<sup>112</sup> it is up to the courts to decide whether the cases are meritorious. Patent infringement suits initiated by pioneer companies against ANDA applicants are literally provided for as a method for a generic drug to enter the market before patent expiration.<sup>113</sup> However, it is the court’s obligation as a tribunal to review the cases for merit and decide whether the ANDA actually infringes on the listed patent. Patents for pharmaceutical drugs may be extremely complex and difficult to determine if they infringe on another patent; therefore, it may be necessary to review every component of the patent before deciding on the issue of infringement. For example, in *Biovail Corp. International v. Andrx Pharmaceuticals, Inc.*,<sup>114</sup> the court was faced with determining whether a “homogeneous admixture” was formed in the generic product, thus infringing on the pioneer company’s patent.<sup>115</sup> The patent history was reviewed and expert testimony was heard in order for the court to properly determine the meaning of terms

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107. *Id.* The NDA holder, 3M, felt that the second ANDA filer had tricked 3M into filing an infringement lawsuit in order to gain the 180-day exclusivity period, although the ANDA did not infringe the listed patent. *Id.*

108. *Id.* The district court found that the second ANDA filer’s assurances that the generic drug did not infringe the listed patent were “sufficient to satisfy the notice requirements of the [Act].” *Id.* (quoting *Minn. Min. & Mfg. Co. v. Bar Labs. Inc.*, 139 F. Supp. 2d 1109, 1115 (D. Minn. 2001)).

109. *Minn. Mining & Mfg.*, 289 F.3d at 779.

110. *Id.* at 779–80.

111. *Id.* at 783.

112. Appleby & O’Donnell, *supra* note 5.

113. 21 U.S.C. § 355(j)(5)(B)(iii).

114. 239 F.3d 1297 (Fed. Cir. 2001).

115. 239 F.3d 1297, 1303 (Fed. Cir. 2001).

contained in the patents.<sup>116</sup> The court ultimately determined that the generic patent did not infringe upon the pioneer patent.<sup>117</sup> However, without a thorough review by the court, the issues of infringement could not have been properly determined.

Recently, the patent infringement lawsuits commenced by pioneer companies have been labeled as a frivolous attempt to enjoy the financial benefits of the thirty-month stay.<sup>118</sup> A recent case decided by the District Court for the Southern District of New York was confronted with this proposition.<sup>119</sup> In *In re Buspirone Antitrust Litigation*,<sup>120</sup> the pioneer company, Bristol-Myers, listed an additional patent in the Orange Book hours before its original patent was to expire.<sup>121</sup> Bristol-Myers claimed that the new patent “covered a method of using the [pioneer] drug,” when the patent actually did not.<sup>122</sup> However, Bristol-Myers filed suit against the generic drug company for patent infringement, thereby initiating the thirty-month stay.<sup>123</sup> The district court judge granted summary judgment of non-infringement against Bristol-Myers.<sup>124</sup>

Following the court’s decision, the plaintiffs filed suit alleging that Bristol-Myers abused the provisions of the Act in order to obtain “an unlawful monopoly over the market.”<sup>125</sup> Essentially, the plaintiffs alleged that Bristol-Myers exercised bad faith in interfering with the marketing of a generic version of its drug by abusing the provisions of the Act to obtain the thirty-month stay.<sup>126</sup> In granting a pre-trial motion in this case, the court

116. *Id.*

117. *Id.* at 1305.

118. See Appleby & O’Donnell, *supra* note 5. The authors discuss the problems with the thirty-month stay, stating:

Because blockbuster drugs—those earning more than \$1 billion a year—are so profitable, antitrust enforcers say the firms will try almost anything to keep the market to themselves, even for a few additional months. The companies spend millions of dollars pursuing patent-infringement lawsuits or cutting deals with potential generic competitors because the potential payoff is so huge.

*Id.*

119. *In re Buspirone Antitrust Litig.*, 208 F.R.D. 516 (S.D.N.Y. 2002).

119. *Id.* at 516.

121. *Id.* at 518–19.

122. *Id.* at 519.

123. *Id.*

124. *Buspirone*, 208 F.R.D. at 518.

125. *Id.* at 519.

126. *Id.*

stated that Bristol-Myers had to be active in the litigation process or the court would order the stay terminated.<sup>127</sup>

The courts involved in Bristol-Myers' attempt to delay the introduction of generic drugs onto the market have disposed of the cases properly. The case is an example of courts' roles in assuring that pioneer companies do not take unfair advantage of the stay provided to them in patent infringement suits. Although pioneer companies at times abuse the provisions of the Act establishing the thirty-month stay of generic drug approval, the courts have adequately prevented the abuse by granting motions for summary judgment in favor of generic companies.<sup>128</sup> In fact, provisions of the Act specifically authorize courts to shorten the thirty-month stay if "either party to the action fail[s] to reasonably cooperate in expediting the action."<sup>129</sup>

As part of a litigious society, pioneer companies are justified in protecting their legal rights and interests. It is up to the courts "to determine whether the parties are complying with that requirement of the statute."<sup>130</sup> Although a trend has been set by *Mylan* and *Andrx* regarding the consistently discussed issues of the Act, involving patents to be settled by the APA,<sup>131</sup> courts are still "in the best position to assess the conduct of the parties and grant appropriate relief."<sup>132</sup> Furthermore, if a pioneer company alleges patent infringement and a court rules that the generic company did not infringe on the patent, the generic company also has the opportunity to sue for attorneys' fees.

#### 4. Exceptional Cases for Attorneys' Fees

The patent code allows the court to award attorneys' fees to the prevailing party "in exceptional cases."<sup>133</sup> Types of misconduct that lead to

127. *Id.* at 525.

128. *See, e.g.*, *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.* 289 So. F.3d 775 (Fed. Cir. 2002); *Abbott Labs. V. Vovopharm Ltd.*, 104 F.3d 1305 (Fed. Cir. 1997); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002).

129. 21 U.S.C. § 355(j)(5)(B)(iii) (2000); *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 295 F.3d 1274, 1276 (Fed. Cir. 2002) (stating "if an NDA holder sought to delay the litigation [and thus prolong its exclusivity] by challenging compliance with § 355(j)(2)(B)(ii), the district court could expedite the suit so as to mitigate any timing advantage the NDA holder might have gained.").

130. *Minn. Mining & Mfg.*, 295 F.3d at 1276.

131. *Id.* at 1277 (referring to *Mylan Pharms, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx Pharms., Inc., v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002)).

132. *Id.*

133. 35 U.S.C. § 285 (2000).

an exceptional case include “willful infringement, inequitable conduct before the [Patent Trademark Office], offensive litigation tactics, vexatious or unjustified litigation, or frivolous filings.”<sup>134</sup> Exceptions have been based not only on the actions of pioneer companies, but also on the actions of generic drug companies. For example, in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*,<sup>135</sup> the court found that the generic drug company, Danbury, had willfully infringed on the pioneer company’s patent.<sup>136</sup> The court determined that the actions by Danbury, in willfully infringing on the patent, constituted an exceptional case for an award of attorney fees to Yamanouchi.<sup>137</sup>

Conversely, there have been cases in which courts have not found an exceptional case to merit an award of attorneys’ fees. In *Merck & Co. v. Mylan Pharmaceuticals, Inc.*,<sup>138</sup> the generic drug company, Mylan, was granted summary judgment on non-infringement and later initiated a motion to recover attorneys’ fees on the basis that Merck “engaged in vexatious or unjustified litigation techniques in order to delay FDA approval of Mylan’s generic compound and increase the burdens on Mylan.”<sup>139</sup> The court denied the motion, holding that “the evidence . . . does not meet the clear and convincing standard of outrageous or exceptional behavior which warrants an award of attorney fees.”<sup>140</sup> The judge further acknowledged:

Merck’s infringement claim, albeit erroneous, was not baseless. Its course of conduct in pursuing the claim was neither vexatious, unusual nor disproportionate to the rather high stakes involved. Finally, Merck’s alternate form of relief, whether meritorious or not, cannot alone support an award of one and a half million dollars in attorneys fees, especially when the claim was never pursued by either party.<sup>141</sup>

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134. *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000) (internal citation omitted) (citing *Avia Group Int’l., Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1548 (Fed. Cir. 1984); *Hoffmann-La Roche, Inc. v. Invamed, Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)).

135. *Id.* at 1339.

136. *Id.* at 1341.

137. *Id.* at 1343.

138. 79 F. Supp. 2d 552 (E.D. Pa. 2000).

139. *Id.* at 553.

140. *Id.* at 558.

141. *Id.*

Ultimately, the interpretation of whether actions meet the “exceptional” standard is up to the courts to determine in awarding attorneys’ fees.

## V. UNNECESSARY REFORMATION OF THE ACT

### A. *Proposed Reformation*

On May 7, 2001, Senators John McCain and Charles Schumer introduced a bill in the United States Senate to amend the Act in order “to loosen the restrictions on generic ANDA applicants.”<sup>142</sup> The proposed purposes of the Greater Access to Affordable Pharmaceuticals Act of 2001 are: “(1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medication; and (2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.”<sup>143</sup> The bill is estimated to save consumers sixty billion dollars in prescription drugs, but, this estimate is “highly speculative” according to the Pharmaceutical Research and Manufacturers of America.<sup>144</sup> The terms of the bill include, among other things, amending the thirty-month stay provision “by preventing any stay for patents listed after the *initial NDA filing* (even if they are listed before an ANDA is submitted).”<sup>145</sup>

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142. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1333 (Fed. Cir. 2001); see Greater Access to Affordable Pharmaceuticals Act of 2001, S. 812, 107th Cong. (2001).

143. S. 812.

144. *Senator Schumer Claims His Bill Saves Consumers Money—But How Much?*, at <http://www.phrma.org/mediaroom/press/releases/25.07.2002.467.cfm> (July 25, 2002). The Pharmaceutical Research and Manufacturers of America notes that

over 60% of total savings are predicted to take place in 2010–12—and nominal in comparison to the savings conferred by a prescription drug benefit. Further, these savings do not consider the ultimate cost of S.812. The uncertainty created by the bill may jeopardize the lengthy, costly research needed to develop new cures and better treatments.

*Id.*, at <http://www.phrma.org/mediaroom/press/releases/25.07.2002.467.cfm> (July 25, 2002).

145. *Points on the FTC Report vs. S. 812*, at <http://www.phrma.org/publications/quickfacts/30.07.2002.295.cfm> (last visited Apr. 4, 2003) (emphasis in original).

## B. *Compromising Patent Rights*

The major problem with the proposed bill is it does not comply with the original purposes of the Act. Recall that one of the purposes of the Act is to provide pioneer companies with patent term restoration for the time spent in obtaining FDA approval.<sup>146</sup> The bill instead “*would forfeit the patent rights of the innovator companies altogether* if they do not comply with the bill’s arbitrary procedural requirements.”<sup>147</sup>

Moreover, a patent is presumed to be valid unless proven by clear and convincing evidence to the contrary.<sup>148</sup> Perhaps some drug companies are initiating infringement suits against generic companies to illegitimately prolong entrance of generics on the market; however, other infringement suits are created to resolve valid patent disputes.<sup>149</sup> Patent rights give pioneer companies an incentive to devote time and finances to research and develop new drugs “that are expensive to [initially] produce but quite inexpensive to copy.”<sup>150</sup> Generic drug companies take advantage of the benefits of provisions of the Act, and then criticize the parts of the Act that benefit pioneer companies. However, the Act was not written solely to benefit generic drug companies.<sup>151</sup> The Act is a compromise between patent restoration for pioneer companies and the speedy introduction of generics into the market.<sup>152</sup>

## C. *Reduction of Incentives for New Drug Innovation*

The reformation of the Act would also contravene the very purpose of Title II of the Act, which “is to create a new incentive for increased expenditures for research and development of certain products which are

146. H.R. Rep. No. 98-857, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

147. *Points on the FTC Report vs. S.812*, at <http://www.phrma.org/publications/quickfacts/30.07.2002.295.cfm> (last visited Apr. 4, 2003) (emphasis in original).

148. Engelberg, *supra* note 21, at 422 (citing 21 U.S.C. § 355(b) (1994)); *see* 35 U.S.C. § 282 (2000).

149. *See* Glasgow, *supra* note 13, at 238-39.

150. Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. Ill. L. Rev. 173, 181 (2001).

151. *See* H.R. Rep. No. 98-857, at 15, 37 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648, 2670.

152. H.R. Rep. No. 98-857, at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647.

subject to premarket government approval.”<sup>153</sup> The process of introducing a new drug to the market is very time consuming. The drug development process itself takes an estimated fourteen years and seven months to complete.<sup>154</sup> Generic drug development, on the other hand, takes only approximately three to five years.<sup>155</sup> However, “there is no real incentive to develop a generic drug until the market has been established and any post-approval issues of safety and efficacy have been resolved by broad use in the general population.”<sup>156</sup> The fact is that forty-nine percent of drugs prescribed are generic.<sup>157</sup> Moreover, since 1984, “[o]f the 8,000 drugs that have come off patent . . . 94% moved from brand name to generic without a patent dispute.”<sup>158</sup>

Nevertheless, without the option to litigate a patent dispute, the purpose of the Act’s patent term restoration provision would be meaningless.<sup>159</sup> Patent term restoration gives drug companies the incentive to introduce new drugs into the market.<sup>160</sup> By revising the Act to prevent “the ability of brand-name companies to automatically win those 30 months of exclusivity,”<sup>161</sup> there will be no way to adequately assure that pioneer companies are provided with the patent term restoration they deserve. Pioneer companies should not be disadvantaged by a loss in ability to enforce their patent rights. Regardless, the ability of pioneer companies to protect their finances gained through the marketing exclusivity of drugs further promotes discovery and research of new drugs, which in turn may later be copied into an inexpensive generic version.

153. H.R. Rep. No. 98–857, at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

154. Richard J. Findlay, *Originator Drug Development*, 54 *Food & Drug L.J.* 227 (1999). There are four phases to the drug development process:

During the clinical testing period, originators conduct tests for safety in Phase I, efficacy in Phase II, and for side effects and long-term use effects in Phase III . . . prior to submitting a new drug application (NDA) and receiving Food and Drug Administration (FDA) approval. After FDA approval, postmarketing testing continues in Phase IV for, *inter alia*, side effects, clinical education, and possible new indications.

*Id.*

155. *Id.* at 229.

156. Engelberg, *supra* note 21, at 406.

157. Appleby & O’Donnell, *supra* note 5, at 2A.

158. *Id.* (discussing the response of Jeff Trewhitt, spokesman for the Pharmaceutical Research and Manufacturers of America, to the proposed legislation to change the Act).

159. H.R. Rep. No. 98–857, at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

160. H.R. Rep. No. 98–857, at 17, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

161. Appleby & O’Donnell, *supra* note 5, at 2A.



## VI. CONCLUSION

“The Congressional policy with respect to generic drugs is clear: generic manufacturing of a drug should be allowed as soon as it is determined that it does not *violate patent rights*.”<sup>162</sup> Congress was not only concerned with marketing generics faster in order to save consumers money, but also with not violating the patent rights of pioneer companies. However, problems have arisen that have instigated the idea in the minds of generic drug companies and legislators that the Act needs to be reformed. Through analysis of the Act and court cases, it is apparent that the true problem with the Act is the Paragraph IV certification. It allows generic drug companies to challenge a pioneer company’s listed patent. In essence, when a generic drug company files an ANDA with a Paragraph IV certification, it should expect the pioneer company to fight for its patent rights. If a generic drug company wants to enter the market before the pioneer patent has expired, the generic is going to have to fight for the position. Patent rights provide innovators with the exclusive right to sell the product for the patent term. “Exclusive” is the key term. If a generic drug company wants to challenge the validity of a patent listed in the Orange Book, then it must take the issue to court. Complaining about the drafting of the Act does not further the goals the Act was set forth to accomplish.

To review, the purpose of the Act is to promote the availability of generic drugs and to give back pioneers some of the patent protection time lost in the drug approval process.<sup>163</sup> Redrafting the Act to make the provisions of the Act weigh more heavily towards only promoting the availability of generics would go against the very purpose of the Act. If the Act were meant to only benefit generic drug companies then the official name of the Act would not have included the terms “Patent Term Restoration.” The Act has provided generic drug companies with an opportunity to save money in discovery and research, which in turn saves consumers millions of dollars. If any reform is necessary, it is the reform of the FDA’s role in administering the Act. The FDA should be responsible for overseeing that a patent listed in the Orange Book actually “claims the drug . . . or which claims a method of using such drug.”<sup>164</sup> Although the FDA claims

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162. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 786 (Fed. Cir. 2002) (emphasis added).

163. See H.R. Rep. No. 98-857, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

164. 21 U.S.C. § 355(c)(2) (2000). The pioneer company is required to file any patents issued after the NDA was approved, no later than thirty days after the patent was issued. *Id.*

that this may not be feasible due to the scientific expertise required to interpret the patents, perhaps the FDA should consider hiring a few patent attorneys and pharmaceutical experts. Reformation of the Act is an unnecessary resolution to the underlying problem—administration of the Act.

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However, according to the provisions of the Act, the courts are responsible for determining whether the patent is valid. *See* § 355(j)(5)(B)(iii).