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# Hatch-Waxman – Thoughtful Planning or Just Piling On: A Consideration of the Federal Trade Commission’s Proposed Changes\*

Brian Urevig

## INTRODUCTION

The regulatory environment governing the pharmaceutical development process attempts to achieve two seemingly opposing goals – promoting new drug innovation and expediting the entry of generic versions of the same drugs into the market. The most recent attempt to achieve these goals is The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act.<sup>1</sup> Although unquestionably successful in achieving these goals,<sup>2</sup> the Hatch-Waxman Act may also have created incentives for anticompetitive activity within the pharmaceutical industry.<sup>3</sup> Brand-name manufacturers have arguably found ways to subvert the law’s intent.<sup>4</sup> For example, brand-name manufacturers have been accused of filing patent extensions for inconsequential changes to existing pharmaceuticals shortly before the original patent expires in order to stave off generic

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

2. The Congressional Budget Office estimates that the Hatch-Waxman Act results in consumer savings of \$8 to \$10 billion annually. *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing before the S. Comm. on the Judiciary, 107th Cong. 17* (2001) (statement of Molly Boast, Director, Bureau of Competition, Federal Trade Commission) [hereinafter Boast, Statement of the FTC]. This has been caused by the creation of an environment that encourages both new drug development and the use of generic equivalents. *See id.*

3. *See id.* at 17-18.

4. *See id.* (noting that “the commission has observed conduct suggesting that some firms may be exploiting the statutory and regulatory scheme by reaching agreements to delay the introduction of generic drugs to the market”).

competition.<sup>5</sup> In addition, recent litigation has indicated that pharmaceutical companies (both generic and brand-name manufacturers) that were, theoretically, competitors, may have been forming collusive arrangements with one other.<sup>6</sup> This has resulted in the accusation that generic equivalents are being unlawfully squeezed out of the marketplace (or never allowed to enter) through violations of the antitrust laws.<sup>7</sup> Brand-name manufacturers, however, have countered that they are not abusing the Hatch-Waxman Act, but rather are being abused by it.<sup>8</sup> They argue that some of the provisions of the Hatch-Waxman Act have created perverse incentives for generic manufacturers to initiate frivolous lawsuits designed only to result in large settlement payments to the generic manufacturer.<sup>9</sup> Furthermore, brand-name manufacturers contend that the effective length of patent protection is insufficient to allow them to recover the enormous costs required to develop, test, and market a new pharmaceutical.<sup>10</sup> Due to the complexity and importance of this situation, in 2001 the Federal Trade Commission (FTC) initiated a study designed to provide information to Congress to use in consideration of possible reform to the Hatch-Waxman Act.<sup>11</sup> In

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5. Cf. Editorial, *Right Track on Generic Drugs*, THE HARTFORD COURANT, Oct. 23, 2002, at A22, available at LEXIS, News Group File, All (citing President Bush's announcement that the FDA "would propose rules to stop drug manufacturers from filing multiple patent-infringement lawsuits, which can block generic medicines for years").

6. See Boast, Statement of the FTC, *supra* note 2, at 20.

7. See James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413 (2002). O'Reilly first notes that "the [brand-name patent holder] can pay the first generic firm to keep its drug away from the market, and block other generic competitors for at least six months." *Id.* at 414. But, as O'Reilly observes, "[the FTC] has challenged both the monopolist's practice and the generic's sellout of consumers." *Id.*

8. *Waxman-Hatch Has Boosted Generics, but Jury still out on Effects on Innovators*, PHARMA MARKETLETTER, Jan. 6, 2003.

9. *Id.*

10. See Joseph P. Reid, Note, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 332-33 (1999). Reid discusses the limitations contained within the Hatch-Waxman Act patent term extension provisions and asserts that "while congress designed the extension provisions to protect the pioneer industry's returns on its original investments, which even before the Act's passage often did not cover research and development costs, the [Congressional Budget Office] admits that protection from the extensions has been less than complete, meaning that pioneer companies operate on an even thinner margin than before." *Id.* at 333.

11. See Boast, Statement of the FTC, *supra* note 2, at 18.

July 2002, the FTC completed the study and issued its report containing proposed changes to the Hatch-Waxman Act.<sup>12</sup>

The purpose of this Note is to review the FTC's proposed changes to the Hatch-Waxman Act. This Note will first describe the regulatory and economic environment in which pharmaceutical companies currently operate. Next, a summary of recent litigation will provide an understanding of current controversial pharmaceutical industry practices. The new proposals by the FTC will be discussed thereafter, followed by a discussion of their potential effect on the pharmaceutical industry. This Note concludes that the proposed FTC changes may aid in preventing some of the collusion between pharmaceutical companies. However, this Note also concludes that there are several deficiencies in the proposals that should be addressed to more fully alleviate the problems in the pharmaceutical industry.

## I. BACKGROUND

The price of pharmaceuticals has been under intense scrutiny during the past decade.<sup>13</sup> The significance of pharmaceutical prices can be demonstrated by a review of the financial information involved. During 2000, total spending on pharmaceuticals rose 18.8% to 131.9 billion.<sup>14</sup> In 2001, spending increased again, this time by 17%.<sup>15</sup> Furthermore, pharmaceutical spending is predicted to reach approximately \$4 trillion over the next decade.<sup>16</sup> During 2001, brand-name pharmaceuticals sold for an average of \$72 per prescription,

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12. See FTC GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at ii (July 2002) [hereinafter GENERIC DRUG ENTRY STUDY]. During the past summer, the Senate passed the McCain-Schumer bill. See Greater Access to Affordable Pharmaceuticals Act, S. 812, 107th Cong. (2001). This bill provides more drastic recommendations than the recent GENERIC DRUG ENTRY STUDY. See Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 328-29 (2002). However, this bill has not been passed by the House of Representatives, and is not expected to do so. Cf. *id.* at 329 n.104. In addition, President George W. Bush recently proposed changes to the Hatch-Waxman Act that are very similar to the recommendations in the FTC report. See Scott Gottlieb, *Patent Mistakes*, WALL ST. J., Oct. 23, 2002, at A18 and compare with GENERIC DRUG ENTRY STUDY, at ii.

13. Boast, Statement of the FTC, *supra* note 2, at 17.

14. *Id.*

15. See Holly Rosenkrantz, *Bush Proposes Rules to Shrink Prescription Drug Costs*, BLOOMBERG NEWS, Oct. 21, 2002.

16. See *id.*

compared with \$17 for their generic equivalent.<sup>17</sup> Furthermore, over the next five years, patents are set to expire on brand-name drugs that currently have sales of \$20 billion.<sup>18</sup> The implications of either extending some of these patents or having generic equivalents take their place will clearly affect the financial health of both consumers and pharmaceutical manufacturers.<sup>19</sup>

However, the situation is not as simple as replacing brand-name pharmaceuticals with generic drugs in an effort to reduce costs to the lowest amount possible. There is a delicate balance to maintain. Brand-name manufacturers must continue to be given incentives to bring new and improved pharmaceuticals into the marketplace and to be compensated for doing so.<sup>20</sup> New pharmaceuticals may be increasingly expensive, but they may also minimize the need for or prevent even more expensive

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17. See Editorial, *supra* note 5.

18. See Boast, Statement of the FTC, *supra* note 2, at 18. The potential impact of this can be demonstrated by the fact that when a generic medication first competes with a brand-name pharmaceutical, the price for the brand-name medication drops by 25%. *Id.* at 14. Furthermore, when additional generic brands enter the market, the price can drop to 50% of its original price. *Id.* at 14, 18.

19. For an example of the impact of patent protection over a pharmaceutical, as well as the extent to which brand-name manufacturers rely on their successful products, consider the situation of Schering-Plough and its allergy drug "Claritin." At one time, sales of Claritin accounted for \$3 billion of Schering's \$9 billion in total annual revenue. See Matthew Herper, *Schering-Plough's Earnings Limbo*, (January 10, 2003) at [http://www.forbes.com/2003/01/10/cx\\_mh\\_0110sgp.html](http://www.forbes.com/2003/01/10/cx_mh_0110sgp.html) (last visited Mar. 01, 2003). However, the medication can now be sold without a prescription and is subject to intense generic competition. See *id.* (citing competition from Wyeth, Inc.'s sales of loratadine, the active ingredient in Claritin). Because Claritin is now sold without a prescription, Schering-Plough decreased the price from over \$3 to just \$1 per tablet. *Id.* Currently, the generic manufacturer has been marketing its equivalent at less than seventy cents per tablet. *Id.* The end result of all of this is that sales of Claritin are now expected to bring Schering-Plough only \$400 million per year. *Id.* Predictably, this has resulted in significantly lower sales and earnings estimates, along with a plummeting stock price. *Id.* Clearly consumers will benefit through lower prices on Claritin. However, the Claritin saga also demonstrates how dependant brand-name manufacturers can be on just a few successful products for a significant amount of their sales. When one of these products loses patent protection, the implications are clear. The loss of protection indicates the importance of innovation to brand-name manufacturers: innovation allows them to have a continuous pipeline of patent protected pharmaceuticals that can replace those drugs that lose patent protection.

20. A lack of innovation has obvious implications – prices will be reduced in the short-term, but in twenty years, we will have substantially the same medications in our arsenal as we have today.

surgical procedures and extended hospitalization.<sup>21</sup> Furthermore, in order to develop an approved brand-name drug, a pharmaceutical company can spend anywhere from \$200 – 500 million.<sup>22</sup> Even after a manufacturer receives Food and Drug Administration (FDA) approval for a brand-name medication there is no certainty of profit. Less than one in three drugs approved by the FDA will eventually return a profit.<sup>23</sup> Furthermore, risks of drug-design-defect litigation as well as competition from both generic and other brand-name drug manufacturers result in a highly competitive market for new pharmaceuticals.<sup>24</sup> Finally, the United States pharmaceutical industry is also an important source of innovation for the world. Unites States pharmaceutical companies “developed almost half of the new [pharmaceutical] products released worldwide between 1970 and 1992.”<sup>25</sup>

## A. REGULATORY ENVIRONMENT

### 1. Food and Drug Regulation

The current FDA regulations<sup>26</sup> require that a

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21. See *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. 36 (2002) (statement of Timothy J. Muris, Chairman, Federal Trade Commission).

22. Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 497 (2002); see also ROY LEVY, FTC, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE* 175-77 (Mar. 1999), available at <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf> (last visited Mar. 2, 2003). Levy notes that the nominal cost to produce a “new chemical entity” went from \$135.15 million in 1985 to \$423.05 million in 1995, with a high of \$504.61 million in 1994. *Id.* at 177, Table A.4.

23. See Wilson, *supra* note 22, at 499. Furthermore, prior to clinical testing, pharmaceutical companies typically screen some 5,000 to 10,000 compounds with only five of these usually reaching the clinical testing phase. LEVY, *supra* note 22, at 178. Of these five, only one typically received FDA approval. *Id.*

24. Wilson, *supra* note 22, at 499-500.

25. Reid, *supra* note 10, at 330.

26. The authority of the FDA derives from the Federal Food, Drug, and Cosmetic Act (FFDCA), ch. 675, § 701(a) 52 Stat. 1040, 1055 (1938) (codified at 21 U.S.C. § 371(a) (2000)) which states that the secretary can “promulgate regulations for the efficient enforcement of this Act.” See Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: the Original Convention* 116 HARV. L. REV. 467, 514 (2002).

pharmaceutical manufacturer complete extensive safety and efficacy testing prior to submission to the FDA for review and approval.<sup>27</sup> Recent estimates indicate that the process of preparing a new drug for review and then receiving FDA approval takes approximately eight and one half years.<sup>28</sup> At the outset of the process, even before any human clinical trials may begin, the pioneer firm must generate data on the drug's chemical structure, safety, efficacy, and toxicology both *in vitro* and in animals.<sup>29</sup> Once human studies begin, they are broken down into three phases.<sup>30</sup> Phase I trials are mainly designed to generate data from a small test population (generally less than 100 subjects) regarding potential side effects as well as metabolism and pharmacologic data.<sup>31</sup> Phase II trials are conducted on a larger population (generally several hundred) and are designed mainly to test the effectiveness of the drug.<sup>32</sup> Finally, Phase III trials are conducted involving a much larger test population (generally thousands of subjects) than either of the previous phases.<sup>33</sup> This phase is intended to reconfirm previous efficacy and effectiveness data as well as obtain data on the pharmaceutical's adverse event profile over a longer time frame.<sup>34</sup> Upon completion of these three phases, a New Drug Application (NDA) is filed with the FDA. The NDA includes detailed information obtained from all three phases.<sup>35</sup> The FDA then begins its process of review and approval. The approval time after submission is currently two and a half years.<sup>36</sup>

Currently, the FDA is asking some drug companies to

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27. Prior to the FFDCFA, there were no regulations covering the development of pharmaceutical products. The initial FDA Act covered only safety requirements. This changed in 1962, when the FDA began to require efficacy information as well. See Reid, *supra* note 10, at 313.

28. LEVY, *supra* note 22, at 182.

29. See 21 C.F.R. § 312.23(a)(8) (2002).

30. See *id.* § 312.21.

31. *Id.* § 312.21(a).

32. *Id.* § 312.21(b).

33. *Id.* § 312.21(c).

34. *Id.* Phase I trials generally last one year, Phase II trials last two years and Phase III trials last three years. LEVY, *supra* note 22, at 183.

35. See 21 U.S.C. §355(a), (b) (2000); 21 C.F.R. § 314.50 (2002).

36. LEVY, *supra* note 22, at 183. Note that aforementioned time frames do not include the pre-clinical stages of pharmaceutical development. When this is considered, the total time from initial compound synthesis to FDA approval increases to almost 15 years. See LEVY, *supra* note 22, at 183.

double the size of Phase III trials.<sup>37</sup> This is true despite the fact that drug companies already test drugs on an average of 5,000 patients, compared to only 1,500 in the 1970s.<sup>38</sup>

## 2. Hatch – Waxman Act

Prior to the early 1980's, there were few generic competitors for brand-name pharmaceuticals.<sup>39</sup> Largely in response to the public's perception that health care costs were spiraling out of control, the Hatch-Waxman Act was passed, amending the Federal Food, Drug, and Cosmetic Act.<sup>40</sup> This was viewed as a compromise between brand-name manufacturers and generic manufacturers.<sup>41</sup> Essentially, generic manufacturers benefited from changes that expedited the process of obtaining FDA approval for generic pharmaceuticals and brand-name manufacturers obtained provisions that increased the effective length of their patents.<sup>42</sup>

Since its passing, the Hatch-Waxman Act has been hailed as the "most important consumer bill of the decade."<sup>43</sup> The Hatch-Waxman Act attempted to reshape the statutory

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37. Gottlieb, *supra* note 12.

38. *Id.*

39. When this legislation was passed in 1984, eight percent of the pharmaceutical market consisted of generic drugs. See Melissa K. Davis, *Monopolistic Tendencies of Brand name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357, 365 (1995). Prior to the Hatch-Waxman Act, prescribing generics tended to be an afterthought for physicians. This largely resulted from physicians facing little pressure to prescribe a lower-cost alternative because, prior to managed care's dominance in the health care industry, physicians were rarely associated with managed care organizations and were free to prescribe more costly brand-name pharmaceuticals. In addition, insurance companies rarely reimbursed patients for prescriptions and thus paid little attention to the cost of pharmaceuticals. Furthermore, antisubstitution laws often prevented physicians from asking patients if they preferred to use a generic medication in lieu of a more costly brand-name pharmaceutical. See Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 92-93 (2002).

40. See Reid, *supra* note 10, at 313. Brand-name manufacturers were concerned that the time required to comply with the increasingly lengthy FDA approval requirements left insufficient time to recoup development costs. This resulted in a belief that there would soon be little hope for profits to fund future research. See *id.*

41. See Davis, *supra* note 39, at 363.

42. See *id.*

43. David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 324 (2000) (citing Senator Orrin Hatch's comments).



landscape of patent laws and FDA regulation over the pharmaceutical development and approval process.<sup>44</sup> The objectives of the Hatch-Waxman Act were twofold: 1) make lower-priced generic versions of brand-name pharmaceuticals more widely available;<sup>45</sup> and 2) provide adequate incentives for pharmaceutical companies to invest in the development of new drugs.<sup>46</sup>

To accomplish these broad objectives, the Hatch-Waxman Act included five key provisions: (1) Generic drug manufacturers were allowed to use brand-name drugs that were still protected by patents solely to gather data to obtain FDA approval for the generic drug.<sup>47</sup> 2) An Abbreviated New Drug Application (“ANDA”) was created for generic drugs to streamline the FDA approval process for generics.<sup>48</sup> This allows a generic manufacturer to use the safety and efficacy data previously gathered by the applicable brand-name drug company.<sup>49</sup> 3) A 180-day market exclusivity period was created

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44. *See id.*

45. *See Reid, supra* note 10, at 320. In 1984, the FDA estimated that there were 150 brand-name drugs whose patents had expired for which there was no generic equivalent. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at 4. There were three key difficulties that generic manufacturers faced in the pre-Hatch-Waxman-Act environment. First, they were required to perform their own safety and efficacy studies (which were very costly and time-consuming, a fact with which brand-name manufacturers were all too familiar). Second, there was no streamlined procedure to approve generic versions of pharmaceuticals whose patents had expired. Finally, the generic company could not begin the FDA approval process until after the relevant brand-name patent had expired. *See id.* at 3-4.

46. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at 4. Brand-name pharmaceutical companies usually obtain patents prior to FDA approval of the drug. The effective term of the patent is then shortened by the time required for the FDA to ensure safety and efficacy. In essence, the patent on a pharmaceutical begins to run before the manufacturer can begin to market and sell the product. This results in a shorter effective patent term when compared to other industries. *See id.*

47. *See* 35 U.S.C. § 271(e)(1) (2000) (“It shall not be an act of infringement to . . . use . . . 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. . .”). Thus, generic manufacturers may immediately begin using the brand-name drug they were trying to copy rather than having to wait until the brand-name patent expires. The generic manufacturer may thus have a generic equivalent ready to market as soon as the brand-name patent expired.

48. *See* 21 U.S.C. § 355(j).

49. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at 5. This expedited the generic approval process and allowed generic manufacturers to forgo expensive clinical trials. *Id.* As codified, the generic manufacturer must demonstrate that the generic product has the same active ingredient(s), route

for the first generic manufacturer to file an ANDA for a specific drug.<sup>50</sup> This allows that generic manufacturer to market their drug without any other generic competition for 180 days.<sup>51</sup> 4) The brand-name drug manufacturer was granted the *possibility* of additional patent protection for time lost during the lengthy process of drug approval by the FDA.<sup>52</sup> 5) Finally, generic manufacturers, upon filing an ANDA, were required to file one of four possible certifications regarding the status of the related brand-name patent.<sup>53</sup> The four possible certifications by the generic manufacturer are as follows: 1) that the brand-name patent was never filed;<sup>54</sup> 2) that the brand-name patent has expired;<sup>55</sup> 3) that the brand-name patent has not yet expired, but will do so on a particular date;<sup>56</sup> or 4) that the brand-name patent is either invalid or will not be infringed by the proposed generic version (also known as a “Paragraph IV Certification”).<sup>57</sup> If the generic manufacturer files a Paragraph IV Certification, the brand-name manufacturer then has forty-five days in which to bring a patent infringement suit against the generic ANDA applicant.<sup>58</sup> When such a suit is filed, the

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of administration, dosage form, and strength as the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(ii) & (iii). Additionally, the generic must demonstrate “bioequivalence,” which means that the rate and extent of absorption of the generic drug is not significantly different from that of the brand-name drug. *See id.* § 355(j)(2)(A)(iv).

50. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

51. *Id.* The first generic manufacturer is essentially granted a “mini-monopoly” from any generic competitors. Although the generic manufacturer will have to compete against the brand-name drug, because the cost of producing a generic is significantly lower, the generic manufacturer is highly likely to be able to undercut the brand-name price, while still making a large profit margin on the generic.

52. *See* 35 U.S.C. § 156(a)(4) & (c) (2000). This patent term extension, however, has not been as forthcoming as brand-name pharmaceutical manufacturers had hoped. For example, of the ninety applications for the extension of a pharmaceutical patent during 1998, only two were granted the full period of extension. *See* Miller, *supra* note 39, at 100.

53. *See* 21 U.S.C. § 355(j)(2)(A)(vii) (2000).

54. *See id.* § 355(j)(2)(A)(vii)(I).

55. *See id.* § 355(j)(2)(A)(vii)(II). If the generic manufacturer certifies under either of the first two certification options, the FDA may approve the ANDA immediately. *See id.* § 355(j)(5)(B)(i).

56. *See id.* § 355(j)(2)(A)(vii)(III). If this certification is filed, the FDA may approve the ANDA to be effective on the date the brand-name patent is certified to expire. *See id.* § 355(j)(5)(B)(ii).

57. *See id.* § 355(j)(2)(A)(vii)(IV). This certification is the source of much related litigation. *See* discussion *infra* Part I.C.

58. *See id.* § 355(j)(5)(B)(iii). If the brand-name manufacturer does not file such a lawsuit, the ANDA will be immediately approved after forty-five

FDA cannot approve the generic ANDA for thirty months.<sup>59</sup> This automatic stay may be supplemented by additional thirty-month stays.<sup>60</sup>

The Hatch-Waxman Act appears to have been successful in accomplishing at least some of its original objectives. Consumer access to lower-priced generic drugs has increased and the United States continues to be the world leader in pharmaceutical innovation and development.<sup>61</sup> For example, generic prescriptions now comprise over 47% of prescriptions.<sup>62</sup> This compares to only 19% in 1984 when the Hatch-Waxman Act was introduced.<sup>63</sup> Moreover, prior to the Hatch-Waxman Act, approximately 35% of pharmaceuticals no longer under patent protection had generic counterparts.<sup>64</sup> Today, virtually all do.<sup>65</sup> Although increased access to equivalent generic medications at a lower cost has been an unquestionable benefit to consumers, the Hatch-Waxman Act may also have a dark side. The very rules that purported to increase competition have perhaps not only increased incentives for brand-name and generic manufacturers to engage in collusive behavior, but may have also encouraged generic manufacturers to file frivolous lawsuits.<sup>66</sup> In addition, as reported by the Congressional Budget Office, the Hatch-Waxman Act may also have tilted the

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days. *See id.*

59. *See id.* If a court finds the brand-name patent invalid or not infringed by the generic drug, the FDA's approval of the ANDA will become effective on the date of such ruling. *See id.* § 355(j)(5)(B)(iii)(I). Furthermore, if the patent term was scheduled to expire prior to the end of the thirty-month extension, the ANDA would still be approved when the patent term was scheduled to end. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at ii. Thus, while the thirty-month extension does prevent generic entry into the market, it does not increase the length of the patent term. It simply prevents the generic manufacturer from marketing a competing product while the infringement litigation occurs.

60. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at iii. After the generic manufacturer files the ANDA, it is possible for the brand-name manufacturer to file an additional patent over the drug at issue. This forces the generic manufacturer to re-certify the ANDA, which gives the brand-name manufacturer another opportunity to file a suit and begin a new thirty-month stay. *See id.*

61. *See* Balto, *supra* note 43, at 324.

62. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at i.

63. *See id.*

64. *See* CBO, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 (July 1998) [hereinafter CBO DRUG STUDY].

65. *See id.*

66. *See* discussion *infra* Part III.

balance too far in favor of generic manufacturers at the expense of brand-name manufacturers.<sup>67</sup>

### 3. Antitrust Laws

A market economy operates on the assumption that competitive markets will invariably result in the most efficient allocation of resources, the largest variety of consumer choices, and the lowest prices possible.<sup>68</sup> Antitrust laws, which seek to encourage and preserve the competitive marketplace, target private conduct that disrupts market efficiency.<sup>69</sup> There are three main statutory antitrust provisions that define unlawful conduct: 1) Section 1 of the Sherman Act; 2) Section 2 of the Sherman Act; and 3) Section 7 of the Clayton Act.<sup>70</sup>

Section 1 of the Sherman Act provides that “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.”<sup>71</sup> In order to establish a violation of Section 1, a “contract, combination . . . or conspiracy” must be established.<sup>72</sup> Thus, bilateral conduct involving two or more entities is required. In the context of the Hatch-Waxman Act, this conduct might entail a generic manufacturer agreeing with a brand-name manufacturer that the generic manufacturer will not enter the market with a generic copy in return for payments from the brand-name manufacturer.

Section 2 of the Sherman Act states that, “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony . . . .”<sup>73</sup> Unlike Section 1, Section 2 of the Sherman Act can be applied to conduct by a single firm (monopolization) as well as conduct by two or more firms (combination or conspiracy).<sup>74</sup>

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67. See CBO DRUG STUDY, *supra* note 64, at ix.

68. See David A. Balto, *Intellectual Property: General Antitrust Principles*, in INTELLECTUAL PROPERTY ANTITRUST 2002, at 11 (Practising Law Institute Patents, Copyrights, Trademarks, and Literary Property Course, Handbook Series No. G0-0119, June - July 2002).

69. See *id.*

70. See *id.*

71. Sherman Act § 1, 15 U.S.C. § 1 (2000).

72. 15 U.S.C. § 1.

73. Sherman Act § 2, 15 U.S.C. § 2.

74. See Balto, *supra* note 68, at 12.

Section 7 of the Clayton Act proscribes stock and asset acquisitions that, “in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.”<sup>75</sup> Under this section, stock or asset mergers or acquisitions of one pharmaceutical company by another may be subject to scrutiny depending on the effect on the relevant product and geographic market.

These three antitrust statutes combine to create risks in the Hatch-Waxman-Act environment for violations by both brand-name and generic pharmaceutical manufacturers. One of the antitrust problems in the pharmaceutical industry results from exit payments by brand-name manufacturers to a potential generic competitor that either exits or never enters the relevant market.<sup>76</sup> This payment is a “horizontal market-division agreement” that antitrust laws find *per se* illegal.<sup>77</sup> Consumers end up paying more and buying less while the conspirators share in monopoly profits.<sup>78</sup> Another potential antitrust problem arises when a brand-name manufacturer and a generic manufacturer conspire to have the generic manufacturer withdraw a patent challenge in return for cash payments. This collusion fails to trigger the 180-day exclusivity for the first generic to file the ANDA and delays generic entry into the market indefinitely.<sup>79</sup>

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75. 15 U.S.C. § 18.

76. See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 748 (2002).

77. *Id.*

78. See *id.*

79. Essentially what occurs is as follows. The generic manufacturer files an ANDA with a Paragraph IV Certification as discussed *supra* Part I.A.2. The brand-name manufacturer then files an infringement lawsuit within forty-five days, which begins the automatic thirty-month stay. In addition, the filing of the ANDA by the generic manufacturer creates a 180-day period of market exclusivity for the generic manufacturer as specified in 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000). The key point is that the 180-day period does not begin until “the first commercial marketing of the drug” that was produced by the first generic manufacturer to file the ANDA. See *id.* § 355(j)(5)(B)(iv)(I). Therefore, if the first generic manufacturer withdraws its Paragraph IV patent challenge, it is essentially agreeing to not market the product. By not ever marketing the product, the start of the 180-day period is never triggered and all other generic competitors are prevented from having a competing ANDA approved by the FDA. Without an approved ANDA, no generic competitors can market their product to compete with the brand-name drug. The result is that the patent term extends beyond the statutory allowed period and results in the brand-name manufacturer earning higher returns than a

#### 4. Patent Laws

Patents are essentially legal monopolies that society tolerates in the belief that innovation would not otherwise occur in a free market.<sup>80</sup> The pharmaceutical industry presents a classic example of a free market failure. Without patent protection, anyone could copy a drug as soon as it was marketed. This realization is important because, unlike the cost of producing an automobile, for example, the ingredient and manufacturing cost of producing a pharmaceutical is generally quite small.<sup>81</sup> The majority of the costs of producing a pharmaceutical are incurred during the development, testing, and approval of the compound that will later be manufactured and sold.<sup>82</sup> If a generic manufacturer could simply copy the formulation immediately after it was developed or marketed, they could manufacture it and sell it for a significantly lower price than the brand-name manufacturer. The brand-name manufacturer, of course, would need to recover the costs of developing and testing the drug. Obviously, they would be unable to recover their costs and produce any profit, resulting in less incentive to develop new pharmaceuticals. Ultimately, innovation and the consumer would suffer. In the case of pharmaceuticals, although there may be altruistic motives, profit is the principal lure enticing drug manufacturers to invest large sums of time and money toward the discovery of new drugs.<sup>83</sup> Patent law offers the protection allowing this investment to occur.

All patent laws are enacted pursuant to Article I, Section 8, of the Constitution, which provides, "The Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

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competitive market would allow.

80. Society tolerates a firm having monopoly power due to the belief that, unless the firm is able to earn monopoly profits for some period of time, less innovation will occur. See Crane, *supra* note 76, at 754.

81. See Robert H. Balance, *Market and Industrial Structure*, in CONTESTED GROUND: PUBLIC PURPOSE AND PRIVATE INTEREST IN THE REGULATION OF PRESCRIPTION DRUGS 97 (Peter Davis ed., 1996) (Showing that the manufacturing [i.e. labor and material] costs for pharmaceuticals for brand-name manufacturers were approximately 25% of total costs during 1989).

82. See LEVY, *supra* note 22, at 175-78.

83. See F.M. SCHERER, *The Pharmaceutical Industry*, in HANDBOOK OF HEALTH ECONOMICS 1317 (A.J. Culyer & J.P. Newhouse eds., vol. 1B 2000).

Discoveries.”<sup>84</sup> Under this authority, Congress has enacted laws allowing the owner of a patent to exclude others from infringing that patent by making, using, or selling the patented invention.<sup>85</sup> The grant of a patent is intended to increase the perceived reward to inventors.<sup>86</sup> The philosophy is that the greater the potential reward, the more firms will be willing to invest in new technologies and innovation.<sup>87</sup> This goal is accomplished by granting the patent for a limited period of time. After the patent expires, the previously protected information is publicly available for all to use.

The patent term for all products is currently twenty years from the filing of the patent application.<sup>88</sup> Prior to the twentieth century, pharmaceutical manufacturers (like any other manufacturer) were able to use the entire patent term to market their product.<sup>89</sup> However, with the advent of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, pharmaceutical manufacturers were effectively prevented from utilizing the full length of the patent term for product marketing.<sup>90</sup> The FDCA required pharmaceutical manufacturers to spend time proving a drug is safe and effective *prior* to marketing the drug – time that is effectively taken away from the patent term during which they can recover their costs.<sup>91</sup> This process has been estimated to leave only ten years for pharmaceutical manufacturers to recoup their costs.<sup>92</sup>

## B. ANTITRUST RISKS

There are three main risks that the Hatch-Waxman Act appears to have created for anticompetitive behavior. First, as previously noted, FDA approval of an ANDA filed by a generic manufacturer cannot occur during the automatic thirty-month stay of approval.<sup>93</sup> This delay provides a significant enticement for litigation that may have little relationship to the underlying

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84. U.S. CONST. art. I, § 8.

85. These statutes have been codified in 35 U.S.C. §§ 1-351 (2000).

86. *See* Crane, *supra* note 76, at 754.

87. *See id.*

88. *See* 35 U.S.C.A. § 154(a)(2) (2000).

89. *See* Miller, *supra* note 39, at 95.

90. *See id.* at 95-6.

91. *See id.* at 96.

92. *See id.* at 98.

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

brand-name patent.<sup>94</sup> Essentially, the brand-name manufacturer is granted a preliminary injunction without any judicial review.<sup>95</sup> By filing litigation solely to protect its monopoly position, the brand-name manufacturer runs the risk entering into an illegal restraint of trade.

Second, the 180-day exclusivity period for the first generic challenger does not have any requirement that it ever be triggered.<sup>96</sup> Thus, if the infringement litigation is ongoing—or if the generic manufacturer has yet to launch its product—the generic market is essentially closed to other generic competitors.<sup>97</sup> The brand-name drug continues to have patent protection, regardless of its actual validity.<sup>98</sup> This fact is a significant enticement for a brand-name manufacturer and a generic manufacturer to enter into a collusive agreement.<sup>99</sup>

Third, because multiple thirty-month stays of approval are allowed,<sup>100</sup> there is an incentive for brand-name manufacturers to file either patent extensions or additional patents over pharmaceuticals when their original patent term is about to end.

### C. RECENT ANTITRUST LITIGATION

The FTC's recent activity has challenged alleged anticompetitive agreements between pioneer and generic manufacturers. These actions address agreements reached in the context of the Hatch-Waxman Act. The FTC has been concerned that some firms may be exploiting the regulatory scheme by forming agreements to delay or prevent the introduction of generic drugs into the pharmaceutical market. Actions have been initiated against Schering-Plough, Hoechst Marion Roussel, and Abbott-Geneva in the past several years.

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94. See Rosenthal, *supra* note 12, at 327.

95. See *id.*

96. See *supra* note 79 and accompanying text.

97. See *supra* note 79 and accompanying text.

98. See *supra* note 79 and accompanying text.

99. See Rosenthal, *supra* note 12, at 327-28. For example, the generic manufacturer could agree to never launch its product, effectively excluding other generics from entering the market. This practice is exactly what Barr Laboratories has often been accused of. See *infra* note 159 and accompanying text.

100. See GENERIC DRUG ENTRY STUDY, *supra* note 12, at iii.



## 1. Schering-Plough

The first action entails two agreements involving Schering-Plough.<sup>101</sup> Both agreements regard generic versions of a Schering-Plough medication called K-Dur 20.<sup>102</sup>

In the first agreement, Upsher-Smith filed an ANDA with a Paragraph IV Certification for its generic version of K-Dur 20.<sup>103</sup> Within forty-five days, Schering-Plough filed suit against Upsher-Smith for patent infringement.<sup>104</sup> However, immediately prior to the trial, the two companies settled and Schering-Plough agreed to pay \$60 million to Upsher-Smith.<sup>105</sup> In return, Upsher-Smith agreed not to enter the market with any version of K-Dur 20 prior to September 2001.<sup>106</sup>

The second agreement involved ESI Lederle.<sup>107</sup> ESI planned on releasing its generic version of K-Dur 20 after Upsher-Smith's 180-day exclusivity period ended.<sup>108</sup> However, since Upsher-Smith had yet to introduce its generic version of K-Dur 20 into the market, the 180-day period had not begun.<sup>109</sup> Furthermore, since Upsher-Smith agreed not to market the generic until September 2001, it would be almost six years until ESI would be able to market its generic product.<sup>110</sup> Schering-Plough then filed suit against ESI to trigger the thirty-month stay.<sup>111</sup> ESI then entered into an agreement with Schering-Plough for a payment of at least \$20 million.<sup>112</sup>

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101. See Complaint at ¶¶ 1, 38, & 51, *In re Schering-Plough Corp.*, FTC Docket No. 9297 (Mar. 30, 2001) [hereinafter Schering-Plough Complaint], available at <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>.

102. See *id.* at ¶ 1.

103. See *id.* at ¶ 38.

104. See *id.* at ¶ 39.

105. See *id.* at ¶ 44.

106. See *id.* Schering-Plough also received licenses for five of Upsher's products. See *id.* However, none of the licenses were ever used in any meaningful way. See *id.* at ¶ 46. This gave the impression that the licenses were simply included in an attempt to hide the true nature of the agreement. See *id.* at ¶¶ 45-46.

107. See *id.* at ¶ 51. ESI Lederle, Inc. is a division of American Home Products. See *id.* at ¶ 6.

108. See *id.* at ¶ 52.

109. See *id.* at ¶ 60.

110. See *id.* at ¶ 44 and compare with ¶¶ 51-60 (ESI had submitted its ANDA to the FDA on December 29, 1995).

111. See *id.* at ¶ 53.

112. See *id.* at ¶ 55. As with Upsher-Smith, Schering-Plough also "purchased" two licenses from ESI, but has yet to utilize either of them. See *id.* at ¶¶ 55-56.

In March 2001, in response to the agreement between ESI and Schering-Plough, the FTC charged Schering-Plough and Upsher-Smith with engaging in unfair methods of competition designed to delay the entry of a generic version of K-Dur 20 into the U.S. market.<sup>113</sup> Recently, this charge has been dismissed by one of the FTC's administrative law judges.<sup>114</sup> The FTC estimated the agreements Schering-Plough had with Upsher-Smith and ESI "cost consumers \$100 million."<sup>115</sup> The FTC is currently appealing this decision;<sup>116</sup> however, if they lose, the result could open a new pathway for similar agreements between brand-name and generic manufacturers.<sup>117</sup> The FTC is concerned that this ruling implies "the agreement between Schering-Plough and Upsher-Smith was a reasonable way to settle the patent infringement suit,"<sup>118</sup> which is contrary to the FTC's philosophy.<sup>119</sup>

## 2. Hoechst Marion Roussell, Inc.

Hoechst Marion Roussell, Inc. ("HMRI") manufactured and sold Cardizem CD, a heart medication.<sup>120</sup> In September 1995, Andrx filed an ANDA for its generic version of Cardizem and then claimed that its version did not infringe on the Cardizem CD patents.<sup>121</sup> HMRI then filed a timely patent infringement suit against Andrx, which triggered the thirty-month stay of FDA final approval of Andrx's ANDA.<sup>122</sup> In September 1997, prior to the expiration of the thirty-month stay, an agreement

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113. *See id.* at ¶¶ 63-67.

114. *See FTC to Appeal Schering, Upsher-Smith Dismissal*, 34 WASHINGTON DRUG LETTER, no. 27, July 8, 2002, at 2 ("Administrative Law Judge Michael Chappell cited [sic] a lack of evidence in the case and dismissed the charges involving Schering and Upsher-Smith, as well as similar charges against Schering related to an arrangement between the company and ESI Lederle.").

115. *Id.*

116. *See id.*

117. *See id.*

118. *Id.*

119. The FTC believes that as a result of the agreement between the companies, consumers were denied the benefit of competition between brand-name and generic manufacturers, leaving less choice in the marketplace and having to pay higher prices for pharmaceuticals. *See Schering-Plough Complaint*, at ¶ 67.

120. *See Complaint at ¶ 1, In re Hoechst Marion Roussell, Inc.*, FTC Docket No. 9293 (Mar. 16, 2000), available at <http://www.ftc.gov/os/2000/03/hoechstandrxcplaint.htm>.

121. *See id.* at ¶ 17.

122. *See id.* at ¶ 18.

was reached between Andrx and HMRI.<sup>123</sup> In this agreement, Andrx agreed to delay the marketing of its generic version of Cardizem CD and HMRI agreed to make large monetary payments to Andrx.<sup>124</sup> Soon thereafter, federal, state, and private plaintiffs brought class action and individual lawsuits for violations of Section 1 of the Sherman Act.<sup>125</sup> The suits were eventually consolidated and the trial judge granted summary judgment, stating that the agreement was unlawful on its face and was a *per se* violation of the Sherman Act.<sup>126</sup> The FTC also conducted a separate investigation that eventually resulted in a consent decree limiting future agreements between the two companies.<sup>127</sup>

### 3. Abbott – Geneva

Abbott is a major pharmaceutical company whose patented drug, Hytrin, accounted for over twenty percent of its \$7.7 billion in United States revenues in 1998.<sup>128</sup> Geneva is a leading manufacturer of generic pharmaceuticals in the United States.<sup>129</sup> Geneva was the first manufacturer to file an ANDA for a generic version of Hytrin, and, in April 1996, Geneva filed a Paragraph IV Certification with the FDA.<sup>130</sup> Abbott sued Geneva for patent infringement, which triggered the thirty-month stay of FDA approval of Geneva's generic version of Hytrin.<sup>131</sup> Abbott and Geneva then entered into an agreement

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123. See *id.* at ¶ 23.

124. See *id.* at ¶¶ 23-26. These payments amounted to over \$10 million per quarter. See *id.*

125. See *In re Cardizem CD Antitrust Litig.*, 105 F. Supp.2d 682, 684-85 (E.D. Mich. 2000).

126. See *id.* at 685, 689 (“[T]he HMRI/Andrx Agreement is an agreement between horizontal competitors that allocates the entire United States market for Cardizem CD and its bioequivalents to Defendant HMRI, and thus constitutes a restraint of trade that has long been held illegal *per se*. . .”).

127. *Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoescht Marion Roussel, Inc. and Andrx Corp.*, Fed. Trade Comm'n, Apr. 2, 2001, at <http://www.ftc.gov/opa/2001/04/hoechst.htm> (“Under terms of the agreement, the companies [are] barred from entering into arrangements in the future that have the purpose or effect of delaying the entry of generic pharmaceuticals.”).

128. Complaint at ¶ 1, *In re Abbott Labs.*, FTC Docket No. C-3946 (May 22, 2000), at <http://www.ftc.gov/os/2000/05/c3946complaint.htm>.

129. See *id.* at ¶ 3.

130. See *id.* at ¶ 17.

131. See *id.* at ¶¶ 18-19. Geneva had filed certifications for both a tablet and capsule form of its generic Hytrin. Through an oversight, Abbott neglected to file a patent infringement suit over the capsule form. As a result,

whereby Abbott agreed to pay Geneva \$4.5 million per month until a judgment in the patent dispute was issued.<sup>132</sup> This agreement did not settle the suit; it simply delayed generic entry into the market.<sup>133</sup> On the heels of a Federal Trade Commission investigation, the two companies terminated their agreement and Geneva finally brought their generic to market.<sup>134</sup> The antitrust case eventually settled due to a FTC consent decree.<sup>135</sup> This agreement limited similar arrangements between the two companies in the future and, while no financial penalties were levied, the FTC implied that similar conduct in the future might lead to them.<sup>136</sup>

Based upon these cases and their report, the FTC has apparently concluded that these types of agreements to resolve patent disputes are highly suspect and perhaps *per se* illegal. FTC staff commented further at various ABA programs that the commission “has great skepticism toward such agreements.”<sup>137</sup> This leads to their apparent conclusion that there is a violation of antitrust laws if the following two events occur:<sup>138</sup> first, a patent holder (i.e. brand-name manufacturer) “who occupies its market position in substantial part because of its patent rights pays an alleged infringer” (i.e. generic manufacture), and second, the “alleged infringer then withholds its product from the market.”<sup>139</sup>

The above mentioned litigation has led to discussion of how the Hatch-Waxman Act might be improved to mitigate these risks. In July 2002, the FTC released its proposed changes.<sup>140</sup>

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the thirty-month stay applied only to the tablet form. *See id.*

132. *See id.* at ¶¶ 26-27.

133. *See id.* at ¶ 29. Geneva’s CEO publicly remarked that the agreement gave Geneva “the best of all worlds’ because Geneva obtained a risk-free ‘monetary settlement on an ongoing basis until the litigation was resolved’ and could still market its product exclusively for 180 days after the litigation was over.” *Id.*

134. *See id.* at ¶ 33.

135. *See Balto, supra* note 43, at 338.

136. *See id.* at 338-39.

137. Yee Wah Chin & Thomas G. Krattenmaker, *Unilateral Technology Suppression: Appropriate Antitrust and Patent Law Remedies*, in 41ST ANNUAL ADVANCED ANTITRUST SEMINAR: DISTRIBUTION & MARKETING, at 1036 (Practising Law Institute Corporate Law and Practice Course Handbook Series No. B0-01C7, Jan. – Feb. 2002).

138. *See id.*

139. *Id.*

140. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at ii.

## II. FEDERAL TRADE COMMISSION RECOMMENDATIONS

The FTC study began in April 2001.<sup>141</sup> Its purpose was to provide a “more complete picture” of how well generic competition was working under the provisions of the Hatch-Waxman Act.<sup>142</sup> The report was intended to help determine whether, among other things, the types of agreements the FTC has challenged between branded and generic drug makers are isolated instances or typical of industry practices.<sup>143</sup> For example, the FTC wanted to know the frequency with which patent cases are settled as compared to litigated to a final court decision.<sup>144</sup> Since last May, the FTC has tracked patent listings in the Orange Book, the timeliness of the listings and the number of challenges by generics.<sup>145</sup> The FTC issued two recommendations aimed at correcting the deficiencies in the current statutory environment regulating pharmaceutical drug development.<sup>146</sup>

### A. RECOMMENDATION ONE

The first recommendation is to permit only one automatic 30-month stay per drug product in accordance with ANDA.<sup>147</sup> This recommendation is aimed at resolving infringement disputes over patents listed in the Orange Book subsequent to the filing date of the generic applicant’s ANDA.<sup>148</sup> Currently a brand-name manufacturer can list additional patents for brand-name drugs in the Orange Book after the generic applicant has already filed an ANDA.<sup>149</sup> This listing forces the generic manufacturer to submit a new Paragraph IV Certification, which would trigger an additional 30-month stay for the same drug (assuming the patent holder timely files

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141. *See id.* at 1.

142. *Id.* Specifically, the Study was to review “generic entry *prior to* expiration” of the corresponding brand-name patent. *Id.*

143. *See id.*

144. *See id.* at ii.

145. *See id.* After the United States Patent Office approves a brand-name pharmaceutical patent, it is then listed in the FDA’s Orange Book subsequent to FDA approval for use in humans. *See* 21 U.S.C. § 355(j)(7)(A)(i) (2000). Once a drug is listed in the Orange Book, any potential competitors must first resort to the ANDA process. *See supra* Part I.A.2.

146. *See* GENERIC DRUG ENTRY STUDY, *supra* note 12, at ii and vi.

147. *See id.* at ii.

148. *See id.* at iii.

149. *See id.*

suit).<sup>150</sup> The FTC study indicated that this situation occurred eight times and resulted in additional delays for generic drugs, ranging in duration from four to forty months beyond the original extension period.<sup>151</sup> In the four cases that eventually went to court, the later issued patents were found to be “invalid or not infringed by the ANDA.”<sup>152</sup>

#### B. SECOND RECOMMENDATION

The second recommendation relates to the 180-day exclusivity period and encourages Congress to pass legislation “to require brand name companies and first generic applicants to provide copies of certain agreements” to the FTC.<sup>153</sup> Since these agreements may be anticompetitive and raise antitrust issues, this recommendation is aimed at providing the FTC with copies to allow the FTC to perform more timely reviews of the agreements.<sup>154</sup> Since these agreements often involve the settlement of ANDA-related infringement suits, they result in a brand-name manufacturer paying a generic manufacturer to delay their market entry.<sup>155</sup> This practice effectively parks the 180-day exclusivity period and prevents subsequent generic competitors from entering the market.<sup>156</sup> As part of its study, the FTC examined twenty settlement agreements for ANDA-patent cases, and found that fourteen of them had the potential to delay the onset of the 180-day period.<sup>157</sup> Finally, the FTC said it should be made clear that the 180-day exclusivity period starts running under the following circumstances: a generic company begins to sell a brand-name drug; any court issues a decision as to the propriety of a patent; or a court dismisses a declaratory judgment action for lack of jurisdiction.<sup>158</sup>

### III. DISCUSSION

The FTC recommendations largely focus on the conduct of the brand-name manufacturers. This approach is appropriate to the extent that brand-name manufacturers are to blame for

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150. *See id.*

151. *See id.*

152. *Id.* at iv.

153. *Id.* at vi.

154. *See id.* at viii.

155. *See id.*

156. *See id.*

157. *See id.* at vii.

158. *See id.* at ix-x.

the problems in the pharmaceutical industry. However, there is evidence that at least some problems result from actions of generic manufacturers, and others result from the structure of the pharmaceutical regulatory environment.<sup>159</sup> Nonetheless, the FTC appears unable to extricate itself from the belief that competition in the pharmaceutical industry will improve if only generic manufacturers are given additional advantages.<sup>160</sup> Even if true at one time, this does not appear to be true anymore. There are several reasons to question the wisdom of further tilting the balance in favor of generic manufacturers at the expense of brand-name manufacturers.

However, when one looks at the FTC's report, it is possible for it to appear as though there is not a significant problem in the first place. Even in this litigation-rich environment the FTC could only find eight pharmaceuticals, where brand-name manufacturers may have received multiple 30-month stays.<sup>161</sup> However, even when an extra thirty months are granted, contrary to the popular perception, brand-name pharmaceutical companies are not getting an extra thirty months of patent life on top of twenty years of protection. In actuality, the average

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159. For an example of this result, one need look no further than the case of Barr Laboratories. Although it is technically a generic manufacturer, the company has earned over 65% of its revenues from "settlements" with brand-name companies and not from actually selling generic drugs. See Bethany McLean, *A Bitter Pill*, FORTUNE, August 13, 2001, at 122.

160. This thought pattern is certainly an easy trap to fall into since there is much to like about generic drugs: they are cheaper and they generally do the same thing that the more expensive brand-name drug does. However, it does ignore the fact that generic manufacturers are completely dependant on brand-name manufacturers to continue to innovate in order that the generic manufacturers will continue to have a stream of medications to copy. This fact speaks to the need for balance in any statutory adjustments. Just as generic manufacturers are dependant upon brand-name manufacturers for new products to copy, brand-name manufacturers are dependant upon innovation in order to survive. If they cannot profitably produce new and useful pharmaceuticals, when the generic competitor enters the market, the brand-name manufacturer will not survive.

161. See GENERIC DRUG ENTRY STUDY, *supra*, note 11, at 40. There have been a total of 8,259 generic applications since the Hatch-Waxman Act was passed. See *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing before the Senate Committee on the Judiciary*, 107<sup>th</sup> Cong. 4-5 (2001) (prepared statement of Molly Boast, Director, Bureau of Competition, Federal Trade Commission, Washington, DC). Considering that from this, there have only been fifty-eight related court decisions and eight "problem" cases identified by the FTC, it seems plausible that the Hatch-Waxman Act may actually be functioning relatively well. See *id.*

effective patent life for pharmaceuticals is ten years.<sup>162</sup> Even though 30-month stays may occasionally occur, the effective patent life is still far less than the nearly twenty years given to other industries. For example, in the FTC report, the brand-name drug, Paxil, was identified as having four 30-month stays.<sup>163</sup> However, even with the stays, Paxil will have far less than twenty years of effective patent life due to the length of time required for that product's development and approval.<sup>164</sup> All this indicates that, to the extent the study proposes to further harness brand-name manufacturers with statutory regulations, it may have been much ado about nothing.

Furthermore, the study fails to consider that generic manufacturers already enjoy a significant advantage from the Hatch-Waxman Act that competitors in other industries do not possess. For example, in no other industry is a competitor able to use its competition's product to develop its own product and rely on the innovator's safety data. These recommendations simply add to the arsenal of generic manufacturers. This fact can be demonstrated by the problem of frivolous ANDA filings by generic manufacturers claiming that a brand-name drug patent is invalid. This practice has increased recently, and generics are challenging patents earlier and earlier.<sup>165</sup> As the Hatch-Waxman Act stands now, brand-name drug manufacturers are given all the challenges they need to fend off frivolous filings. However, if the FTC's first recommendation became law, the brand-name manufacturer would be limited to just one 30-month challenge.

The FTC's second recommendation would appear to be appropriate to the extent that the FTC will use this

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162. See Miller, *supra* note 39, at 98.

163. See GENERIC DRUG ENTRY STUDY *supra*, note 12, at 51.

164. Paxil received FDA approval in December 1992. See *id.* However, it lost patent protection in August 2001. See Jeremy Shure, *Select Recent Court Decisions*, 28 AM. J.L. & MED. 136 (2002). As a result, Paxil only received approximately eight and a half years of effective patent life even after receiving four supposed 30-month extensions.

165. See Jayne O'Donnell, *Makers of Generic Drugs Take Some Legal Heat, Too*, USA TODAY, June 5, 2002, available at <http://www.usatoday.com/money/health/2002-06-06-generics-legal.htm> (last visited Feb. 27, 2003). Essentially, when a generic manufacturer files an ANDA with a Paragraph IV Certification, regardless of whether there is any merit to the generic manufacturer's claim, the brand-name manufacturer *must* initiate a lawsuit or the FDA will approve the generic competitor regardless of the claim's merit after forty-five days have expired. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000).



information on generic and brand-name agreements to stop anticompetitive actions similar to the ones described above.<sup>166</sup> However, this recommendation does nothing to prevent the filing of frivolous ANDA and Paragraph IV Certifications by a generic manufacturer. The generic manufacturer has a strong incentive to do so via the 180-day exclusivity period. This marketing exclusivity period is a considerable reward for the generic manufacturer, and there is virtually no consequence for a frivolous filing. Since the generic product is not on the market, there will be no infringement damages for the brand-name manufacturer to recover. What might be more effective to prevent this practice is to have the FDA review the ANDA filing to ensure the generic manufacturer has not filed a frivolous claim. Doing so would still allow generic manufacturers to have their 180-day period of market exclusivity, while providing some protection to the brand-name manufacturer against frivolous patent challenges during the ANDA process.

The original objective of the Hatch-Waxman Act was “to balance the interests” of generic manufactures with that of brand-name manufacturers.<sup>167</sup> However, according to a recent study by the Congressional Budget Office, this balance has not been achieved, tilting instead in favor of generic manufacturers.<sup>168</sup> This balance would become even more tilted if the FTC’s recommendations are accepted. This result is perhaps due to the FTC’s belief that generic drugs offer significant cost savings over brand-name products. However, this assertion may be suspect. Generics are certainly cheaper than brand-name drugs, but that statistic fails to take into account the total cost of care as well as the impact on patient health. Studies have indicated that generic drugs may actually raise the cost of total health care.<sup>169</sup> This is because, despite

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166. See discussion *infra* Part I.C.

167. CBO DRUG STUDY, *supra* note 64, at 3.

168. See *id.* at ix (stating that “the cost to producers of brand name drugs from faster generic entry has roughly offset the benefit they receive from extended patent terms” and “the greater competition from generic drugs has somewhat eroded [the brand-name producers’] expected returns from research and development”).

169. See Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, HEALTH AFF., Sept./Oct. 2001, at 241 (2001); Frank R. Lichtenberg, *Do (More and Better) Drugs Keep People Out of Hospitals?*, 86 AM. ECON. REV., 384 (1996). These studies show that patients who were restricted to older, generic asthma and anti-depressant drugs wound up being sicker and spending more on hospitals, doctors, and

the cost savings in the short-term, there is a great incentive to continue using these cheap generic medications rather than the new pharmaceuticals that are developed. This projected increase in cost is certainly not a reason to stop producing and encouraging generic medications; however, it does indicate a need for a balance that encourages a competitive marketplace for both generic and brand-name manufacturers. Generics are never new drugs or better treatments. They are cheaper for consumers, but their continued viability is entirely dependant on new drug innovation. Furthermore, if one must choose between favoring brand-name or generic manufacturers, brand-name manufacturers should be preferred. The profits a generic manufacturer realizes are unlikely to be used for research and development of new pharmaceuticals. Conversely, the very existence of brand-name manufacturers is dependent entirely on the development of a steady stream of new and innovative products for the market. As such, the marketplace is likely to demand that profits be invested back into the research and development pipeline. The resulting innovation is what reduces total healthcare costs and improves a consumer's quality of life.

#### IV. CONCLUSION

The Hatch-Waxman Act's primary purpose was to decrease the high cost of prescription drugs by increasing the availability of cheaper generic versions while still encouraging new drug development. In the beginning, the Hatch-Waxman Act achieved this objective, as the market realized an unprecedented increase in generic drug entry. However, this objective is becoming more difficult to achieve as some brand-name and generic manufacturers have found ways to thwart the Hatch-Waxman Act's intentions through collusive agreements. As the cost of drug research and development rises, the pharmaceutical industry will feel increasing pressure to capitalize as much as possible on drug patents. This pressure can lead to anticompetitive agreements that may violate antitrust laws.

However, many brand-name pharmaceutical manufacturers feel threatened by potential infringement through generic competitors' frivolous ANDA filings. As a result, there is incentive to engage in potentially collusive

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emergency rooms than those who used newer medicines.

behavior to maintain their patent rights or, alternatively, to file frivolous extension patents. When brand-name companies offer settlements to generic companies they are often too lucrative to ignore because they are usually more than the generic company could make during its 180-day exclusivity period. The end result of these agreements is that consumers pay higher prices for brand-name pharmaceuticals and generic entry is prevented or stalled.

To the extent that recent proposals by the FTC prevent this result, they will benefit consumers. However, the proposals appear to focus mainly on the perceived transgressions of brand-name manufacturers. The proposals do not offer any solution for the significant problem of generic companies filing frivolous ANDA claims against brand-name manufacturer patents. These frivolous claims often result in settlements because brand-name manufacturers feel that paying off the generic company is less expensive than fighting a frivolous patent suit. The FTC needs to remember that the overall goal is to improve competition and the welfare of the consumer and not simply to handicap brand-name manufacturers while favoring generic manufacturers.