

## HATCH-WAXMAN USE OR ABUSE? COLLUSIVE SETTLEMENTS BETWEEN BRAND-NAME AND GENERIC DRUG MANUFACTURERS

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In 1984, Congress passed the Hatch-Waxman Act,<sup>1</sup> amending the Federal Food, Drug and Cosmetic Act.<sup>2</sup> Also known as The Drug Price Competition and Patent Term Restoration Act of 1984, the Act was a far-reaching attempt to meet two mutually exclusive goals: to reward innovative new drug research, while simultaneously speeding the entry of inexpensive generic versions of drugs into the market.<sup>3</sup>

These apparently incompatible goals were achieved by rewarding research-based drug development with extra patent protection and modifying parts of the regulatory approval process for generic drugs.<sup>4</sup> Although the Hatch-Waxman Act has largely met the goal of stimulating new drug development and increasing the availability of generics,<sup>5</sup> provisions of the Act may have unwittingly created perverse incentives for anticompetitive activity. Several recent agreements between brand-name and generic pharmaceutical companies have attracted significant attention for their antitrust ramifications. These arrangements between supposed competitors have acted to stall the introduction of lower-priced generic drugs, rather than speeding their entry as intended. This Note begins with a description of the Act's main provisions and goals, followed by summaries of the cases and a discussion of proposed legislative reforms. This Note concludes that proposed legislation modifying two provisions of the Act, rather than increased antitrust surveillance, should be adopted in order to fulfill the Act's goals.

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1. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

2. 21 U.S.C. § 355 (1994).

3. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389 (1999).

4. *Id.* at 390-91.

5. See CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 1 (1998) [hereinafter CONGRESSIONAL BUDGET OFFICE STUDY].

## I. STATUTORY BACKGROUND

The Hatch-Waxman Act ("HWA") contained two separate titles, the first of which is the subject of this Note.<sup>6</sup> Both titles are currently the subject of considerable debate.<sup>7</sup>

### A. The Reduced Filing Requirements for Generic Drugs

The first provision of Title I concerns regulatory changes for federal Food and Drug Administration ("FDA") approval of generic drugs. The HWA established reduced approval requirements for generic drugs.<sup>8</sup> While new ("pioneer") drug approval requires the submission of extensive and lengthy documents in a New Drug Application ("NDA") to the FDA,<sup>9</sup> generic versions of these drugs can bypass part of this process, by filing an Abbreviated New Drug Application ("ANDA") for the generic versions of previously approved drugs. An ANDA incorporates data that the brand-name or pioneer manufacturer had already submitted to the FDA regarding the pioneer drug's safety and efficacy. The generic manufacturer must simply include data demonstrating that its generic version is "bioequivalent"<sup>10</sup> to the pioneer drug.<sup>11</sup>

To protect the patent rights of the pioneer drug maker, the applicant generic manufacturer must also certify that the generic drug will not infringe any patent that claims the pioneer drug.<sup>12</sup> One type of certification,

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6. Title II contained additional provisions for pharmaceutical development, including patent term restoration for term lost to FDA regulatory approval delay and freedom from patent infringement liability for testing during regulatory approval periods.

7. For example, Title II reform is urged by the biotechnology industry to give greater patent term restoration for biotechnology pharmaceuticals in recognition of the extended time required for their testing and approval. *See, e.g.,* William Holtz, *Reassessing Hatch-Waxman Incentives*, FOOD & DRUG L. INST. UPDATE, Issue 2, at 47 (2001), available at <http://www.fdpi.org/pubs/Update/2001/Issue2/Holtz/article.html>; David Schmickel, *The Biotechnology Industry Organization's View on Hatch-Waxman Reform*, 54 FOOD & DRUG L. J. 241, 242 (1999).

8. 21 U.S.C. § 355(j) (1994).

9. *Id.* § 355(a) (1994).

10. A "bioequivalent" drug has an equivalent rate and extent of absorption in the body as the original listed (pioneer) drug. Bioavailability and Bioequivalence Requirements, 21 C.F.R. § 320.1(e) (1982).

11. 21 U.S.C. § 355(j)(2)(A)(iv) (1994).

12. Manufacturers of the previously approved pioneer drug must list all patents related to their products in the FDA's "Orange Book" (officially known as the "Approved Drug Products with Therapeutic Equivalence Evaluations") as part of their initial NDA process. 21 U.S.C. § 355(b)(1) (1994). Generic manufacturers must then cite all Orange Book patents related to their ANDA drug.

a Paragraph IV certification, allows the generic manufacturer to allege that the pioneer drug patent is either invalid or would not be infringed by the marketing of the generic drug.<sup>13</sup>

As an incentive to file Paragraph IV certifications, the first generic manufacturer to file an ANDA containing a Paragraph IV certification regarding a particular patent receives a one hundred and eighty day period of exclusivity in which to market the generic drug, thereby preventing any other generic versions of the product from receiving ANDA approval during that time.<sup>14</sup> This period of exclusivity is one of the subjects of this Note. Although designed to encourage generic manufacturers to pursue the market, it has in fact been an inducement for generic and pioneer drug producers of a given drug to collaborate, rather than compete, with each other by stalling the entry of the less expensive generic into the marketplace.

### **B. The Thirty Month Stay of ANDA Approval**

Paragraph IV filing also requires that the generic manufacturer give notice to the pioneer drug manufacturer. On receipt of notice of a Paragraph IV filing, the patentee (usually, but not always, the pioneer drug manufacturer)<sup>15</sup> has forty-five days in which to file suit against the generic manufacturer for patent infringement.<sup>16</sup> The FDA cannot approve the generic ANDA for thirty months if such an action is brought. If the court hearing the infringement suit rules the patent at issue is either invalid or not infringed before the thirty months period expires, the generic is granted approval on the date of the court's decision.<sup>17</sup> This automatic thirty month stay is the other problematic aspect of the Act currently under discussion.

### **C. Impact of the HWA on the Drug Marketplace**

There is little disagreement that the HWA has profoundly increased consumer access to lower priced generic drugs. According to a 1998 Congressional Budget Office Study,<sup>18</sup> the generic drug share of United States prescription drug volume has increased from 19% in 1984 (the year before

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13. *Id.* § 355(j)(2)(A)(vii)(IV).

14. *Id.*

15. This Note will treat the terms patentee and brand-name manufacturer interchangeably; in some cases, of course, they will be separate companies.

16. *Id.* § 355(b)(1).

17. If there is no decision before the thirty month expiration, the generic is granted ANDA approval at the end of the thirty month period.

18. CONGRESSIONAL BUDGET OFFICE STUDY, *supra* note 5, at 1.

HWA enactment) to over 40% in 1996.<sup>19</sup> The percent of top-selling branded drugs that have a generic competitor on the market has increased from 36% in 1983 to nearly 100% in 1998 for brand-name drugs with expired patents.<sup>20</sup> The generic share of prescription drug volume has increased nearly 150% overall since HWA enactment.<sup>21</sup> In 1994 alone, consumers saved between \$8 and \$10 billion through the purchase of generic drugs.<sup>22</sup>

Additionally, there is evidence that the HWA expanded the number of generic manufacturers producing the same drug, which further lowers costs.<sup>23</sup> For example, the entry of a second generic version usually doubles the price decrease initiated by the first generic; three or more companies offering a generic version can lower the price by at least fifty percent or more from the branded price.<sup>24</sup>

These results indicate that the sooner more companies offer the same generic product, the greater the price competition, and the lower the price consumers pay for a generic version of a drug.<sup>25</sup> This demonstrates both that the rationale underlying the HWA was correct and that maneuvers that undercut these goals keep lower priced drugs away from the consumer.<sup>26</sup>

## II. CASES

Three recent cases illustrate the potential for anti-competitive agreements between generic and brand-name manufacturers. The first two—*Abbott-Geneva*<sup>27</sup> and *HMRI-Andrx*<sup>28</sup>—have settled by consent agreement,

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19. *Id.* at 27.

20. *Id.* at xii.

21. *Id.* at 27.

22. *Id.* at xiii.

23. *Id.* at 32.

24. David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 326 (2001).

25. CONGRESSIONAL BUDGET OFFICE STUDY, *supra* note 5, at 27.

26. FEDERAL TRADE COMMISSION, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE 206 (1999), available at <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

27. Complaint, *Abbott Labs. and Geneva Pharm.*, FTC Dkt. No. C-3945 (May 22, 2000) [hereinafter *Abbott-Geneva* Complaint].

28. Complaint, *Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corp.*, FTC Dkt. No. 9293 (Mar. 16, 2000).

while the third, *Schering Plough-ESI/Upsher-Smith*, is currently under Federal Trade Commission ("FTC") investigation.<sup>29</sup>

**A. *In re Abbott Laboratories and Geneva Pharmaceuticals***

The first case the FTC addressed regarding potential HWA abuses concerned Hytrin,<sup>30</sup> a brand-name for terazosin HCL. Terazosin HCL is a drug used to treat hypertension and enlarged prostate, and is produced by Abbott Laboratories.<sup>31</sup> In January 1993, Geneva filed an ANDA for FDA approval of its generic version of terazosin, in both capsule and tablet form. In April 1996, Geneva filed Paragraph IV certification, representing that its drug would not infringe the Abbott patent because the patent was invalid.<sup>32</sup>

Abbott sued Geneva within the stipulated forty-five day period, triggering the thirty month stay on FDA approval for Geneva's generic drug.<sup>33</sup> Abbott failed, however, to file infringement action against the capsule version of Geneva's product, although both capsule and tablet forms were involved.<sup>34</sup> Thus, the FDA approval process for the capsule form continued.

As first filer for the generic form, Geneva would have exclusivity for the first one hundred and eighty days after FDA approval, which it obtained in March 1998.<sup>35</sup> Geneva informed Abbott that it would launch its product unless Abbott paid it not to enter the market.<sup>36</sup> Abbott agreed to make payments of \$4.5 million per month into an escrow account in exchange for Geneva's promise not to release the generic product (in either capsule or tablet form) until the resolution of their litigation or the entry of another generic into the market, whichever came first.<sup>37</sup> These payments to Geneva continued until July 1999, even after Geneva won the patent suit in September 1998,<sup>38</sup> as Geneva calculated that it was more profitable to have Abbott pay into the escrow account and stay out of the market than

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29. Complaint, *Schering-Plough Corp.*, FTC Dkt. No. 9297 (Mar. 30, 2001) [hereinafter *Schering-Plough Complaint*].

30. *Abbott-Geneva Complaint*, *supra* note 27, at ¶ 11.

31. *Id.*

32. *Id.* ¶ 17.

33. *Id.* ¶ 18.

34. *Id.*

35. *Id.* ¶ 22.

36. *Id.* ¶ 36.

37. *Id.* ¶ 26.

38. *Id.* ¶ 31.

to enter with the generic.<sup>39</sup> Geneva cancelled the agreement in August 1999, pending an FTC investigation into the arrangement.<sup>40</sup>

The antitrust case was settled by FTC consent decree prior to litigation.<sup>41</sup> The agreement sharply limited similar arrangements between the competitors in the future. First, it established that future agreements between the brand-name and generic drug companies which cause relinquishment of the one hundred and eighty day exclusivity period to the brand-name company are prohibited.<sup>42</sup> Second, agreements in which the generic manufacturer is paid to stay off the market are barred in the context of ongoing patent litigation, unless approved by a court after the FTC is given time to present its views to the court.<sup>43</sup> Third, respondents are required to give the FTC thirty days notice before entering into such agreements in other contexts.<sup>44</sup>

The absence of financial penalties is noteworthy. However, the FTC implied that future instances of similar conduct would lead it to seek monetary recovery from the defendants, including disgorgement of illegal profits.<sup>45</sup>

## B. *In re Cardizem Litigation*

In contrast to the *Abbott-Geneva* case, the second publicized case of potential HWA collusion involved a generic manufacturer actively trying to avoid infringing the brand-name company's patents.<sup>46</sup>

### 1. *Contractual and Patent Relationships Between Defendants Andrx, Carderm, and Hoechst Marion Roussel*<sup>47</sup>

United States Patent No. 5,470,584 ("the '584 patent") issued to defendant Carderm on November 28, 1995. The '584 patent claims a delayed-release diltiazem hydrochloride formulation with a specific in-vitro dissolution profile.<sup>48</sup> This heart medication formulation is manufactured

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39. *Id.* ¶ 29.

40. *Id.* ¶ 33.

41. Consent Order, *Abbott Labs. and Geneva Pharm.*, FTC Dkt. No. C-3945 (May 22, 2000).

42. *Id.* at II.

43. *Id.* at III.

44. *Id.* at IV.

45. Statement of FTC Chairman Robert Pitofsky & Commissioners Sheila Anthony, Mozelle Thompson, Orson Swindle, and Thomas Leary, *Abbott Labs. and Geneva Pharm.*, FTC Dkt. No. C-3945-46 (May 22, 2000).

46. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 695 (E.D. Mich. 2000).

47. Hoechst Marion Roussel is now Aventis Corp.

48. *Cardizem*, 105 F. Supp. 2d at 686.

and sold under the name Cardizem CD by defendant Hoechst Marion Roussel ("HMRI") through a license from Carderm.<sup>49</sup>

Two months prior to the issuance of the '584 patent, defendant Andrx filed an ANDA for its controlled-release generic version of Cardizem.<sup>50</sup> On December 31, 1995, Andrx filed for Paragraph IV certification for all unexpired patents claiming Cardizem CD, and certified to HMRI that its generic formulation did not infringe patents belonging to HMRI, including the '584 patent.<sup>51</sup> HMRI and Carderm filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida on January 31, 1996, thereby triggering the thirty month HWA waiting period.<sup>52</sup> Andrx could neither gain final approval for its ANDA, nor commercially market its generic version of Cardizem, until either the thirty months expired or the court found the patent invalid or not infringed.<sup>53</sup>

On September 24, 1997, less than ten days after receiving tentative FDA approval for its ANDA, Andrx entered into an agreement with HMRI in which it promised not sell its generic version of Cardizem.<sup>54</sup> This agreement acknowledged that Andrx had created a bioequivalent version of Cardizem CD, had filed an ANDA on this product with the right to amend it, and that this generic product was the subject of infringement litigation between Andrx and HMRI.<sup>55</sup> The agreement also stated that HMRI intended to prevent the marketing or distribution of Andrx's product prior to a final judgment in the patent infringement case. To reduce the costs of litigation, Andrx agreed it would not commence the commercial sale of its generic version until: (1) a final judgment in the infringement litigation, (2) the licensing of Cardizem CD to Andrx by HMRI under this agreement, or (3) notice from HMRI that it was authorizing for itself or a third party the right to begin commercial sale of a generic version.<sup>56</sup> Andrx's ANDA received final FDA approval when the thirty month Hatch-Waxman period expired on July 8, 1998. HMRI began payments to Andrx for its nonmarketing of the generic July 9, 1998.<sup>57</sup> Andrx mean-

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49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 687.

53. *Id.*

54. *Id.*

55. *Id.* at 696.

56. *Id.*

57. *Id.* at 687.

while altered its formula in order to get around the '584 patent and submitted the changes to the FDA for supplemental approval.<sup>58</sup>

The FDA gave final approval to Andrx's supplemental ANDA on June 9, 1999, and on that same day, Andrx and HMRI agreed to settle their litigation and terminate their agreement.<sup>59</sup> This agreement contained several provisions, one of which was the continued assertion by HMRI that Andrx's product infringed the '584 patent, while Andrx asserted that it did not. Second, Andrx stated its intent to market its reformulated product following FDA approval, but agreed not to market it in the U.S. without a license from HMRI.<sup>60</sup>

Andrx began commercial marketing of its Cartia XT generic on June 23, 1999, triggering the one hundred and eighty day period of Hatch-Waxman exclusivity and blocking the entry of generic versions from any other manufacturer into the market.<sup>61</sup> By this point, HMRI had paid Andrx almost \$90 million under the terms of the agreement.<sup>62</sup>

## 2. *Private Litigation*

In addition to federal antitrust enforcement, private and state plaintiffs also sought to enforce Section 1 of the Sherman Act against HMRI, Carderm, and Andrx.<sup>63</sup> Class action and individual suits commenced in the United States District Court for the Eastern District of Michigan under the Sherman Act and corresponding state law provisions, alleging that the agreement between Andrx and HMRI/Carderm was illegal as a horizontal market allocation.<sup>64</sup> These suits were consolidated by plaintiffs into a single motion for partial summary judgment on the issue of whether the agreement between manufacturers was a per se violation of antitrust regulations.<sup>65</sup>

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58. *Id.* In fact, in an effort to avoid infringement action from HMRI, Andrx twice filed prior approval supplements to its ANDA. The second supplement was filed on September 11, 1998, adding a small amount of a new ingredient to its generic formula and further modifying the dissolution profile for its generic version away from that of the '584 patent. In a Second Supplemental Certification (a Paragraph IV Certification), Andrx argued that its generic product, Cartia XT, did not infringe the '584 patent due to these differences. In spite of these efforts, HMRI pursued its attempts to keep Andrx's product off the market. *Id.* at 687-89.

59. *Id.* at 689.

60. *Id.*

61. *Id.* at 690.

62. *Id.* at 689.

63. *Id.* at 682.

64. *Id.*

65. *Id.*

Judge Edmunds found that the agreement was unlawful on its face and constituted a per se violation of Section 1 of the Sherman Antitrust Act.<sup>66</sup> The Court determined that the HMRI/Andrx agreement was an agreement between horizontal competitors which allocated the entire U.S. market for the drug at issue and its bioequivalents. The court also found that the agreement was not ancillary to any pro-competitive purpose.<sup>67</sup> Partial summary judgment was granted for claimants.<sup>68</sup>

### 3. *Antitrust Analysis in Private Litigation*

The essential elements of a Sherman Act Section 1 violation are: (1) a contract, combination, or conspiracy; (2) affecting interstate commerce; (3) which imposes an unreasonable restraint on trade.<sup>69</sup> Horizontal agreements, that is, agreements between competitors, “pose the most significant dangers of competitive harm,”<sup>70</sup> and are antitrust’s most “suspect classification,”<sup>71</sup> as they preclude competition between firms that would be competitors but for the accused arrangement.<sup>72</sup> Two modes of analysis are used by the court, the per se analysis and the rule of reason. A per se analysis implies that certain market actions, such as horizontal price fixing and market allocation, are so inherently anticompetitive that each is illegal per se without inquiry into the actual harm done. Such violations are usually only found when prior cases have established the anticompetitive effects of a sufficiently similar business practice.<sup>73</sup>

HMRI and Andrx argued that the per se rule was inapplicable to their agreement because they were never actual horizontal competitors; Andrx had not yet entered the market with its generic version of Cardizem when the agreement was formed.<sup>74</sup> The Court dismissed the defendants’ argu-

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66. *Id.* at 706.

67. *Id.*

68. *Id.*

69. 15 U.S.C. § 1 (1994).

70. 11 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1902(a) (1998).

71. *Id.*

72. *Id.*

73. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

74. Rule of reason analysis is used for less presumptively illegal actions, requiring the factfinder to find that under all circumstances of the case, the practice in question imposes an unreasonable restraint on trade. Which of these analyses to use on the restraint of trade at issue is a question of law for the court. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 691 (E.D. Mich. 2001). The District court’s finding of a per se agreement was dramatic, as it can be argued that no “sufficiently similar” business practice had ever occurred before with which to compare the manufacturers’ alleged behavior. Patent settlements, in general, are analyzed under the rule of reason. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY § 5.5(c) (2d ed. 1999).

ment, noting that “an arrangement is said to be ‘horizontal’ when (1) its participants are either (a) actual rivals at the time the agreement is made or (b) potential rivals at the time the agreement is made, and (2) the agreement eliminates some avenue of rivalry among participants.”<sup>75</sup>

#### 4. *Federal Trade Commission Action*

The Federal Trade Commission also instigated its own investigation in 1999. This action culminated in a consent decree in April 2001,<sup>76</sup> with limitations on future agreements similar to those placed on Abbott and Geneva.<sup>77</sup>

### C. **Schering Plough Agreements with ESI and Upsher-Smith Concerning the Drug K-Dur 20**

The third instance of an alleged anticompetitive agreement under the HWA is currently under investigation.<sup>78</sup> Both the government and private plaintiffs have filed actions against Schering Plough for separate agreements with Upsher-Smith<sup>79</sup> and ESI.<sup>80</sup> These firms manufacture generic versions of Schering’s K-Dur 20, an extended-release potassium chloride formulation used for the treatment of depleted potassium levels.<sup>81</sup>

Upsher-Smith filed a Paragraph IV certification for generic K-Dur 20 and notified Schering Plough on November 3, 1993.<sup>82</sup> Schering promptly sued Upsher-Smith for patent infringement.<sup>83</sup> On the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the agreement, Schering paid \$60 million to Upsher-Smith to keep Upsher from entering the market with any version of K-Dur 20, whether it infringed Schering’s patent or not.<sup>84</sup> Ostensibly, the payment was in exchange for licenses to market five Upsher-Smith products, but these li-

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75. *Cardizem*, 105 F. Supp. 2d at 700 (citing 11 HOVENKAMP, *supra* note 70, ¶ 1901b).

76. Consent Order, *Hoechst Marion Roussel, Inc., Carderm Capital L.P. & Andrx Corp.*, FTC Dkt. No. 9293 (Nov. 27, 2000).

77. *Id.* at II.

78. This case is currently in administrative trial.

79. *Schering-Plough* Complaint, *supra* note 29.

80. ESI Lederle, Inc. is a division of American Home Products Corporation, primarily engaged in generic drug research and manufacture. *Schering-Plough* Complaint, *supra* note 29, ¶ 6.

81. *Schering-Plough* Complaint, *supra* note 29, ¶ 31.

82. *Id.* ¶ 38.

83. *Id.* ¶ 39.

84. *Id.* ¶ 44.

censes had minimal value to Schering Plough, which has made little or no use of them.<sup>85</sup>

In November 1998, Upsher-Smith received FDA approval to market Klor Con M20, its generic version of K-Dur 20.<sup>86</sup> In accordance with its agreement with Schering however, Upsher withheld the generic from the market.<sup>87</sup>

Similarly, Schering paid \$20 million to ESI, a generic manufacturer that planned to launch its generic K-Dur 20 formulation after Upsher-Smith's one hundred and eighty days of exclusivity had run.<sup>88</sup> Once again, the payments were in exchange for licenses for two ESI products that Schering has not marketed to date.<sup>89</sup>

Although ESI received tentative approval of its ANDA from the FDA on May 11, 1999, it will not be able to obtain final approval until Upsher-Smith's one hundred and eighty day period of exclusivity has run.<sup>90</sup> But because Upsher has never introduced its generic into the market, this one hundred and eighty days has never begun, and thus cannot expire.<sup>91</sup>

### III. FEDERAL RESPONSES

The HWA has unwittingly created opportunities for the formation of horizontal agreements between competitors in the pharmaceutical industry. By providing pioneer drug manufacturers with the thirty month stay of ANDA approval for generic competitors, the HWA provides an opportunity for "sham" or delaying litigation, because approval for the generic ANDA cannot proceed while the patent litigation takes place. This litigation may have little to do with the underlying value of the patent(s) at issue, and amounts, in some cases, to a stipulated preliminary injunction without judicial review.<sup>92</sup>

Second, the reward of one hundred eighty days of exclusivity for the first generic challenger has essentially functioned as a plum to reward the

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85. *Id.* ¶ 45-46.

86. *Id.* ¶ 48.

87. *Id.* ¶ 49.

88. *Id.* ¶ 59.

89. *Id.* ¶ 56.

90. *Id.* ¶ 60.

91. *Id.*

92. See Sheila Anthony, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implication of Certain Types of Agreements Involving Intellectual Property, Prepared Remarks Before the Am. Bar Assoc. Antitrust and Intellectual Property: The Crossroads Program (June 1, 2000), available at [www.ftc.gov/speeches/anthony/sfip000601.htm](http://www.ftc.gov/speeches/anthony/sfip000601.htm).

formation of a collusive agreement or settlement. As written, the HWA contains no requirement that the one hundred and eighty days actually ever be triggered in order to act as blockade against subsequent generic challengers who might have competing products.<sup>93</sup> As long as the patent infringement litigation between the pioneer manufacturer and the first generic challenger is ongoing, or even if it has settled and the generic challenger has not yet launched its product, the generic market is essentially held closed. The drug is kept at the original on-patent price until the patent expires, regardless of the validity of the patent itself.<sup>94</sup> This issue will only intensify in importance, as it is estimated that in the next five years, some two hundred drugs, with combined sales of \$30 billion, will go off-patent.<sup>95</sup>

Responses to these loopholes in the HWA fall into two main categories: calls for structural modification of the HWA itself, or increases in antitrust surveillance of agreements between brand-name and generic drug companies. There are currently a number of issues related to pharmaceuticals under Congressional review, and this will likely increase as pressure from industry groups like Pharmaceutical Research and Manufacturer of America ("PhRMA")<sup>96</sup> and the numbers of drugs going off-patent increase over the next several years.<sup>97</sup>

#### A. Structural Reform

The McCain-Schumer "Greater Access to Affordable Pharmaceuticals Act" undertakes broad structural reform of the HWA itself.<sup>98</sup> This bill has four major modifications, two of which are discussed below.<sup>99</sup>

First, the McCain-Schumer bill would alter the automatic thirty month stay provision for challenged generic ANDAs. Instead, the pioneer manufacturer could seek a preliminary injunction in the courts to stop the first generic challenge to its patent(s), eliminating, in theory, the possibility of "sham" or delaying litigation by the pioneer company. Since the stay would not be triggered without judicial review of the validity of the under-

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93. *Id.*

94. *Id.*

95. Peter Stone, *PhRMA Fights Back*, NAT'L J., July 21, 2001.

96. For further information on PhRMA, see <http://www.phrma.org>.

97. See William Waller, *Pharmaceutical Legislative Update*, 5 FOOD & DRUG L. INST. UPDATE 4, available at <http://www.fdpi.org/Update/2001/Issue5/waller/html>; Stone, *supra* note 95.

98. S. 812, 107th Cong. (2001).

99. The bill would also increase federal investigation of the citizen petition process, and relax the bioequivalence standards used to compare original and generic drugs. S. 812, 107th Cong. § 2 (2001).

lying patents, the main goal of Paragraph IV filing—to encourage generic challenge of weak or invalid patents—would be met. Critics have argued that this solution would not be successful in the pharmaceutical industry, where courts are reluctant to grant preliminary injunctions in cases where technical expertise requirements are high and monetary compensation would seem suitable.<sup>100</sup>

Second, the McCain-Schumer bill would establish a “use it or lose it” trigger for the one hundred and eighty day first-to-file generic exclusivity. If a successful generic challenger failed to launch its product within a specified number of days<sup>101</sup> after winning the infringement suit, the one hundred and eighty day exclusivity would roll over to a second generic manufacturer.<sup>102</sup> This would eliminate the incentive for the pioneer manufacturer to pay the first generic challenger to simply stay out of the market indefinitely.

This bill also included a budget for a FTC study within five years of enactment to assess effectiveness of the changes.<sup>103</sup> Senate Bill 812, the McCain-Schumer bill, was introduced in May 2001 and was referred to the Committee on Health, Education, Labor, and Pensions.<sup>104</sup>

## B. Antitrust Surveillance

Increased antitrust surveillance procedures have also been advocated to forestall anticompetitive collusion between drug manufacturers.

### 1. *The Leahy Notification Bill*

Rather than changing the HWA itself, Senator Leahy’s “Drug Competition Act of 2001”<sup>105</sup> would increase FTC scrutiny of patent infringement settlements between innovator and generic drug companies. Any agreement between brand-name and generic manufacturers that could have the effect of limiting the appearance of a generic version of the brand-name company’s product on the market would require notice to the FTC within ten days of the agreement’s execution,<sup>106</sup> subject to a \$20,000 per day

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100. See e.g., Anthony, *supra* note 92, at 2.

101. The McCain-Schumer bill provides for a ninety day limit. S. 812, 107th Cong. § 3(a)(3) (2001). A previous attempt at reforming HWA suggested a one hundred and eighty day limit. 64 Fed. Reg. at 42,873.

102. S. 812, 107th Cong. § 3(a)(3) (2001).

103. *Id.* § 8.

104. At the time of publication, the McCain-Schumer bill was still in Committee. See <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN00812:>

105. S. 754, 107th Cong. (2001)

106. *Id.* § 6.

penalty for each day of violation.<sup>107</sup> This bill left the Judiciary Committee in October with a favorable recommendation.<sup>108</sup>

## 2. *The Response of the FTC: Assessing the Scope of the Problem*

In response to the rising tide of concern, Representative Waxman, one of the original co-sponsors of the HWA, asked that the FTC “investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that might delay generic drug competition throughout the U.S.”<sup>109</sup> In October 2000, the FTC announced that it would undertake such a study and initiated a period of public comment. The study was aimed at examining the extent to which agreements between brand-name pharmaceuticals and generic drug firms may have delayed generic competition and the operation of the one hundred and eighty day exclusivity provision. In addition, the study would look at the impact of provisions in the Act on listing of patents by brand-name pharmaceutical companies in the FDA “Orange Book” and of provisions that trigger a stay on FDA approval of a proposed generic drug.<sup>110</sup>

According to the testimony of Molly Boast, then Director of the FTC Bureau of Competition, to Congress in May 2001, the Commission hoped that the study “would provide valuable information to Congress as it considers possible reform of the Hatch-Waxman Act.”<sup>111</sup>

Responses to the FTC’s requests for information were collected from brand-name and generic manufacturers in June 2001, and the Commission hopes to have the study completed by the end of 2001.<sup>112</sup> Upon completion of this study, the FTC will issue its recommendations for federal responses to the current HWA dilemma.<sup>113</sup> An accurate assessment of the number of companies involved in potentially anticompetitive abuses of the Act will provide guidance in the push for reform.

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107. *Id.* § 7.

108. *Bill Summary & Status for the 107th Congress*, at [http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN00754:\(last visited Feb. 19, 2002\)](http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN00754:(last visited Feb. 19, 2002)).

109. Press release, Federal Trade Comm’n, FTC Testifies on Competition in the U.S. Pharmaceutical Industry (May 24, 2001), available at <http://www.ftc.gov/opa/2001/05/drugtest.htm> [hereinafter FTC Press Release].

110. *Id.*

111. Molly Boast, Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Prepared Statement of the Federal Trade Commission Before the Senate Judiciary Committee (May 24, 2001), available at <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

112. *Id.*

113. *Id.*

#### IV. DISCUSSION

Revisions to the HWA have been proposed repeatedly through the years.<sup>114</sup> However, modification of a highly complicated piece of legislation like the Act is fraught with both difficulties and pitfalls. Unquestionably, the Act has been successful at achieving its stated goals. Tinkering with the “balancing act”<sup>115</sup> and demonstrated value of HWA raises concerns.<sup>116</sup>

The alternative, simply increasing enforcement of the antitrust laws and surveillance of potential anticompetitive agreements, raises its own set of problems. The Department of Justice and the FTC have finite resources. If they are called upon to study every proposed agreement or patent settlement in the pharmaceutical field, delays in approval time would undoubtedly increase even with substantial investment in personnel and resources to support this increased scrutiny.<sup>117</sup>

Several commentators have suggested ways to look at the relationship between the legislation itself and intellectual property in general. A discussion of these is helpful in analyzing the value of proposed solutions.

##### A. Basic Conflict between Intellectual Property and Antitrust

Patents provide one of the few exceptions to the general rule against monopolies. As incentives for innovation, they drive the market for new inventions and goods forward.<sup>118</sup> The HWA was enacted with the intent to maintain and increase the drive for new pharmaceutical development.<sup>119</sup>

Additionally, public policy favors the efficient resolution of disputes, including patent litigation,<sup>120</sup> to conserve judicial resources and lower

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114. David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2001). See, e.g., Drug Patent Term Restoration Review Procedure Act of 1999, S. 1172, 106th Cong. (1999).

115. See, e.g., *Pharmaceutical Intellectual Property Issues: Hearing Before the Senate Comm. on the Judiciary*, 107th Cong. (2001) (statement of Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America).

116. See, e.g., *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Health Subcomm. of the House Energy and Commerce Comm.*, 107th Cong. (2001) (written testimony of Greg Glover, of Ropes and Gray).

117. Balto, *supra* note 114.

118. *Id.*

119. Pub. L. No. 98-417, 98 Stat. 1585 (codified as 15 U.S.C. §§ 68(b)-68(c), 70(b) (1994)).

120. U.S. Dep't of Justice & FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 5.5 (1995), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> (Apr. 1995).

transaction costs.<sup>121</sup> Settlements between litigants in patent cases can facilitate cooperation and further innovation. The Intellectual Property Guidelines jointly issued by the Department of Justice and the FTC adopt this view, stating that “settlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements.”<sup>122</sup> Settlements between horizontal competitors, however, raise special concerns. Where settlements could involve such agreements, the Guidelines advise that the government should “consider whether the effect of the settlement is to diminish competition among entities that would have been actual or likely competitors.”<sup>123</sup>

### 1. *Azcuenaga’s Test*

Former FTC Commissioner Mary Azcuenaga has proposed a simple test for evaluating the relationship between antitrust law and intellectual property.<sup>124</sup> First, one determines whether the intellectual property right was obtained in a proper manner. If there was no fraud or inequitable conduct in acquiring the patent, then antitrust laws may apply. Next, one considers whether the holder of the patent right improperly expanded the scope of the right. If the intellectual property right was properly obtained, and the patentee has not improperly extended it, there is no need to apply antitrust law.<sup>125</sup>

The *Cardizem*, *Abbott/Geneva*, and *Schering-Plough* cases would all appear to involve the second instance. There is no evidence of the patents being improperly obtained, but there is evidence that the HWA loopholes were used to improperly expand the scope (in this case, duration) of the brand-name drug’s patent monopoly. Applying this test would weigh in favor of adopting the McCain-Schumer revisions—closing the loopholes in the Amendment itself, rather than intensifying antitrust law.

### 2. *Leary’s Test for Reverse Payments*

FTC Commissioner Thomas Leary has recently suggested that the most straightforward test of the legitimacy of patent settlements between potential competitors is the presence of payments from the patent holder to

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121. *Id.*

122. *Id.*

123. *Id.*

124. Mary Azcuenaga, Recent Issues in Antitrust and Intellectual Property, Address at the Boston University School of Law (Oct. 23, 2000), in *B.U. J. SCI. & TECH. L.* (2001).

125. *Id.* at Part V.

the potential challenger.<sup>126</sup> Since these payments flow in the opposite direction of an expected license agreement for the intellectual property right in question,<sup>127</sup> they can be considered evidence of a presumptively anti-competitive agreement.<sup>128</sup> All three of the above HWA cases meet this simple test. In each situation the holder of the patent was paying the competitor, rather than the competitor paying the patent owner, for the right to use the intellectual property at issue.

Efficiency would weigh in favor of modifying HWA provisions themselves rather than simply increasing antitrust scrutiny. Judge Edmund's finding of a *per se* Section 1 violation in the Cardizem litigation demonstrates that these collusive agreements would be quickly invalidated as facially anticompetitive in court. However, the HWA, as currently written, provides an arguably legitimate way to use the thirty month stay and the one hundred and eighty day exclusivity period to forestall generic entry. Thus brand-name and generic companies can have their cake and eat it too—brand-name manufacturers get longer market exclusivity, and their generic partners make greater profit by not entering the market at all. Preventing these collusive agreements from occurring in the first place by closing the HWA loopholes prevents the consumer from losing early access to generics, rather than waiting for antitrust enforcement to catch up.<sup>129</sup>

## B. Industry and Consumer Group Responses

Not surprisingly, PhRMA, the largest lobbying group for research-based pharmaceutical companies, is vigorously opposed to modification of the HWA.<sup>130</sup> Fearing strengthened generic access to the drug market, PhRMA has intensified public comment against McCain-Schumer passage and is donating significant sums of money to Congressional members with influence on its passage.<sup>131</sup>

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126. Thomas Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes*, Part II, Speech Before the American Bar Association's Antitrust Healthcare Program (May 17, 2001), available at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm>.

127. *Id.* at Part IV.

128. *Id.*

129. Balto, *supra* note 114, at 340 (“[C]onsumers will have paid millions of dollars in unlawfully high prices before such a determination (of an antitrust violation) is made, and the Commission will be put in the position of seeking disgorgement and restitution, which, while serving the ends of justice, are imperfect tools for making consumers whole.”)

130. Stone, *supra* note 95.

131. *Id.*

Generic manufacturers' groups are strongly in favor of adoption of the McCain-Schumer bill. In spite of smaller budgets, efforts by the Generic Pharmaceutical Association include hiring successful outside lobbyists as part of their plan to "correct the imbalance in the marketplace that favors brand-name companies."<sup>132</sup>

Consumer and managed healthcare groups such as Public Citizen,<sup>133</sup> Consumer's Union,<sup>134</sup> the U.S. Public Interest Research Groups,<sup>135</sup> and the Academy of Managed Care Pharmacy<sup>136</sup> all support the bill's passage. The Consumer's Union asserts that it "eliminates some of the delay tactics that have allowed the brand-name companies to hold up the process [of generic entry] and deny consumers the chance to buy generic alternatives."<sup>137</sup>

## V. CONCLUSION

Agreements that make anticompetitive use of the automatic thirty month stay of approval for generic challengers and the one hundred and eighty day generic exclusivity period are unintended side effects of the Hatch-Waxman Act. While the HWA has clearly improved access to lower-priced generic alternatives for the consumer,<sup>138</sup> three recent cases illustrate the ease with which manufacturers can use the Act's provisions to illegitimately extend their patent rights, to the consumer's cost rather than benefit.<sup>139</sup> The financial incentives to exploit these provisions will only increase over the next several years, as a large number of high-selling pharmaceuticals go off-patent and motivation increases for their manufacturers to extend the period of monopoly pricing.<sup>140</sup>

The results of the FTC's current study of the pervasiveness of anti-competitive agreements in the pharmaceutical field will generate further

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132. *Id.*

133. Press Release, Public Citizen, Public Citizen Applauds Introduction of Schumer-McCain Bill to Make Less Costly Generic Drugs More Widely Available (May 1, 2001) (on file with author).

134. Press Release, Consumers Union, CU Praises McCain-Schumer Drug Bill, (May 1, 2001) (on file with author) [hereinafter CU Press Release].

135. Press Release, Academy of Managed Care Pharmacy, AMCP Endorses the 'Greater Access to Affordable Pharmaceuticals Act' (Jun. 7, 2001) (on file with author).

136. Stone, *supra* note 95.

137. CU Press Release, *supra* note 134.

138. CONGRESSIONAL BUDGET OFFICE STUDY, *supra* note 5, at 1.

139. *Id.*

140. For example, heart-burn drug Prilosec, the top-selling prescription drug, earned \$4.62 billion in U.S. sales in 2000. Its patent expired April 1, 2001. Dana S Elfin, *As Patent Controversies Engulf Prilosec, Generics Call for Hatch-Waxman Reform*, 9 HEALTH-CARE POLICY REP. (BNA) 12 (Mar. 26, 2001).

grounds for reform when complete.<sup>141</sup> Even in the absence of this data, the magnitude of the Abbott-Geneva, HMRI-Andrx and Schering-Plough agreements, and the numbers of pharmaceuticals soon to go off-patent,<sup>142</sup> demonstrate the need for closing the loopholes in the HWA. By eliminating the automatic thirty month stay following Paragraph IV filing, the Schumer-McCain bill will eliminate the ability of a brand-name manufacturer to stall generic approval and marketing based on a possibly valueless patent. It will also remove the one hundred and eighty day exclusivity period as an incentive to hold off the entry of generic drugs into the market. In the interest of fulfilling the Act's original goals of increasing consumer access to both new drugs and lower priced generics, the Bill should be adopted.

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141. FTC Press Release, *supra* note 109.

142. Elfin, *supra* note 140, at 475.

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