

## IN RE CARDIZEM & VALLEY DRUG CO.: THE HATCH-WAXMAN ACT, ANTICOMPETITIVE ACTIONS, AND REGULATORY REFORM

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Congress has struggled to establish the proper equilibrium between maintaining appropriate incentives for the development of new drug products and controlling the escalating cost of pharmaceutical products.<sup>1</sup> In 1984, Congress attempted to balance these goals by enacting the Hatch-Waxman Act (the “Act”).<sup>2</sup> The Act established a regulatory framework that streamlines the procedures for bringing generic drug products to the market while compensating “pioneer” companies for enduring the lengthy drug approval process.<sup>3</sup>

While the Hatch-Waxman Act increased generic drug entry, it has also been vulnerable to abuse.<sup>4</sup> Moreover, although the Act alleviated high drug costs for products reaching the end of their patent terms, it also created incentives for anticompetitive behavior.<sup>5</sup> It became increasingly apparent that some of the original Hatch-Waxman Act provisions could be manipulated to achieve unintended market control, and that loopholes in the Act created perverse incentives for collusive agreements. Pioneer drug manufacturers could abuse the original Act by filing inconsequential patents just before their original patents expired in order to prevent competition from generics. Pioneer manufacturers also frequently entered into competition-stifling agreements, paying the first generic manufacturer to

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1. See *Competition in the Pharmaceutical Industry: Findings and Recommendation in the July 2002 FTC Study of Generic Drug Entry Prior to Patent Expiration: Hearing Before the Senate Comm. on the Judiciary*, 108th Cong. (June 17, 2003) [hereinafter *2003 Hearings*] (statement of Timothy J. Muris, Chairman, FTC), <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

2. Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 15, 21, 28, and 35 U.S.C.). This Act is typically referred to as the Hatch-Waxman Act because of the congressional sponsors, Senator Orrin Hatch and Representative Henry Waxman.

3. See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4* (2002) [hereinafter *FTC GENERIC DRUG STUDY*], <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

4. See *id.* at i-ii.

5. See *2003 Hearings*, *supra* note 1, paras. 3-4.

exploit a loophole under the Hatch-Waxman Act and effectively keep generic manufacturers off the market.

Recently, in private antitrust lawsuits, the Sixth Circuit and the Eleventh Circuit reached conflicting resolutions on similar cases involving pharmaceutical patent settlements and alleged pharmaceutical antitrust violations. The courts disagreed on whether Hatch-Waxman abuse is presumptively illegal. Private antitrust lawsuits and Federal Trade Commission (FTC) proceedings afford some means for combating potential antitrust violations stemming from Hatch-Waxman abuse and punishing anti-competitive behavior. If an alleged violation has a predictable anti-competitive effect and offers little in the way of procompetitive benefits, a court can deem the action presumptively illegal.

While courts must play an important role in enforcing antitrust regulations, anti-competitive behavior may be difficult to analyze because of the complex interplay of antitrust law, patent law, and the Hatch-Waxman provisions. Such difficulty stems from the fact that the Hatch-Waxman Act and patent law shield a certain level of anti-competitive behavior from antitrust prosecution.<sup>6</sup> While pharmaceutical patent settlements can be a valuable means of reducing the risk, costs, and burdens of litigation and clarifying intellectual property rights,<sup>7</sup> the incentives, goals and policies of antitrust law and patent protection must be balanced to find the socially optimal equilibrium that protects both competition and innovation. Therefore, the exclusionary patent rights necessary to encourage innovation must be continuously monitored to prevent unjustifiable exploitation of competition barriers. However, increasing antitrust liability and diminishing patent protection could undermine the profitability of pharmaceutical research and development.<sup>8</sup> When determining antitrust liability, private

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6. Kevin J. Arquit, *Patent-Antitrust: Dead or Alive? Patent Abuse and the Antitrust Laws*, 59 ANTITRUST L.J. 739, 740 (1990) (stating that "patents share one common attribute with economic regulation: they may allow firms to avoid the competitive process," but noting that the "Supreme Court has observed that the granting of patents 'is an exception to the general rule against monopolies and the right to access to a free and open market'").

7. David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 336-37 (2000).

8. See Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18, ¶ 24 (2003) (stating that it is important to recognize that research and development costs are extremely high and that lessening patent protection could lead to lower incentives for innovation). Eurek contends that "[c]onsumers must decide if they are willing to exchange the potential for future development of new life-saving drugs for smaller bills at the pharmacy in the short-term." *Id.*

proceedings must carefully analyze allegedly anticompetitive agreements in light of patent law and the Hatch-Waxman policy goals. Courts may not be adequately equipped to balance all of the competing policy goals. Therefore, problematic loopholes inherent in the Hatch-Waxman Act may ultimately require legislative and regulatory correction.

Recent regulatory measures may alleviate the risk of Hatch-Waxman abuse. The FTC has more aggressively pursued antitrust enforcement actions against pharmaceutical companies. In addition, the FTC studied the effects of the Hatch-Waxman Act and recommended legislative reform. Accordingly, Congress passed the Greater Access to Affordable Pharmaceuticals Act (“GAAP”) in an effort to close the loopholes of the Hatch-Waxman Act.<sup>9</sup>

While the Hatch-Waxman Act has been subject to some abuse, overall the Act has been considered remarkably successful<sup>10</sup> and is unlikely to be repealed. The Act must be vigilantly evaluated to insure a proper balance—weighing the need to spur new drug research against the need to increase the market entry of generic drugs, which help alleviate rising drug and health care costs.<sup>11</sup> Given the overall success of the Hatch-Waxman Act and the complexities of the underlying policy, courts should be reluctant to simplify private antitrust lawsuits by using a *per se* analysis for Hatch-Waxman-based settlements. Legislative reform that closes the loopholes of the Act and harmonizes the complex policy goals is a preferable way to reduce or eliminate the need for courts to evaluate private pharmaceutical antitrust cases.

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9. See *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: Hearing Before the Senate Comm. on the Judiciary, 108th Cong. (Aug. 1, 2003) [hereinafter *Greater Access to Affordable Pharmaceuticals Act Hearing*] (statement of Timothy J. Muris, Chairman, FTC), <http://www.ftc.gov/os/2003/08/030801pharmtest.htm>.

10. 2003 *Hearings*, *supra* note 1, para. 3 (“Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved \$8-10 billion on retail purchases of prescription drugs in 1994 alone.”).

11. See generally Sheila F. Anthony, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Remarks at the ABA “Antitrust & Intellectual Property: The Crossroads” Program para. 3 (June 1, 2000), <http://www.ftc.gov/speeches/anthony/sfip000601.htm> (arguing that striking a balance between the exclusionary rights necessary for innovation and those that dampen competition is an ongoing challenge).

## I. BACKGROUND

The Hatch-Waxman Act increased generic drug market entry by reducing the filing requirements for Food and Drug Administration (FDA) approval of drug products that are bioequivalent to previously approved patented drugs.<sup>12</sup> Generic drug manufacturers need only file an Abbreviated New Drug Application ("ANDA") rather than the lengthy New Drug Application ("NDA"), which requires extensive safety and efficacy data.<sup>13</sup> The ANDA allows generic drug manufacturers to submit less extensive data by allowing the generic manufacturer to use the pioneer drug's safety and efficiency data.<sup>14</sup> The generic manufacturer must simply demonstrate that the generic version is "bioequivalent" to the pioneer drug.<sup>15</sup>

In order to protect the patent interests of pioneer drugs and shield new drug innovation incentives, the Hatch-Waxman Act allows pioneer patent holders to obtain an automatic thirty-month stay against ANDA approval.<sup>16</sup> The Act requires a generic drug applicant to file a "paragraph IV certification" stating that "in the opinion of the applicant and to the best of his knowledge," the generic drug does not infringe on any drug patent listed in the FDA Orange Book.<sup>17</sup> The generic applicant must also give notice to the pioneer patent holder.<sup>18</sup> The patent holder then has forty-five days to file a patent infringement action.<sup>19</sup> If an infringement action is filed, a thirty-month stay automatically goes into effect, and the FDA cannot approve any generic drug related to the pioneer patent, regardless of the merits of the infringement claim.<sup>20</sup> If the court hearing the infringement action declares the patent invalid or not infringed, the automatic thirty-month delay in the FDA approval process terminates and approval is made effective on the date of the court's decision.<sup>21</sup> If the court finds the patent valid and infringed, the approval date for the generic drug is set for

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

13. 21 U.S.C. § 355(j) (2000).

14. *Id.* § 355(j)(2)(A).

15. *Id.* § 355(j)(2)(A)(iv); FTC GENERIC DRUG STUDY, *supra* note 3, at 5. To be a bioequivalent the generic drug product must have the same active ingredient, route of administration, dosage strength, and proposed labeling as the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv).

16. FTC GENERIC DRUG STUDY, *supra* note 3, at 39.

17. *Id.* § 355(j)(2)(A)(vii). The FDA publishes drug information and patent information in what is known as the Orange Book.

18. *Id.* § 355(j)(2)(B).

19. *Id.* § 355(j)(5)(B)(iii).

20. *Id.* § 355(j).

21. *Id.* § 355(j)(5)(B)(iii)(I).

the date of the patent's expiration.<sup>22</sup> The court may grant the patent holder a preliminary injunction prior to the expiration of the thirty-month stay, thereby extending the delay in FDA approval until the court holds the patent invalid or not infringed.<sup>23</sup> Finally, in order to compensate the generic manufacturer for the thirty-month stay, the first generic drug manufacturer receives a 180-day period of exclusive marketing rights.<sup>24</sup> This 180-day period of exclusivity rewards the first generic manufacturer burdened with challenging the pioneer patent by granting the it a temporary monopoly in the generic market.

Soon after passage, it became evident that the original Hatch-Waxman Act provisions could be manipulated for the purpose of creating economic benefits exceeding those intended by Congress.<sup>25</sup> The thirty-month automatic stay provision, intended to allow patent holders to sue potential infringers before they received FDA approval, proved manipulable by pioneer companies who listed multiple, meritless patents solely for their ability to trigger the automatic stay.<sup>26</sup> The 180-day exclusivity provision was a reward created to encourage generic companies to challenge weak patents held by pioneer companies.<sup>27</sup> Nevertheless, the provision was often used to keep all generic companies from receiving FDA approval; pioneer companies often collaborated with the first generic company and paid them not to trigger the 180-day exclusivity period, thus indefinitely preventing all subsequent ANDA approval.<sup>28</sup> FTC and private antitrust violation proceedings have sought to punish pharmaceutical companies that abuse these provisions of the Hatch-Waxman Act. In addition, legislative action has attempted to close the loopholes in the Hatch-Waxman Act.<sup>29</sup>

## II. ANTITRUST LAW

In recent years, the need for antitrust enforcement in the pharmaceutical industry has increased.<sup>30</sup> Antitrust evaluation of patent settlements—identification of antitrust risks and potentially offsetting efficiency bene-

22. *Id.* § 355(j)(5)(B)(iii)(II).

23. *Id.* § 355(j)(5)(B)(iii)(III).

24. *Id.* § 335(j)(5)(B)(iv).

25. See FTC GENERIC DRUG STUDY, *supra* note 3, at i-xi (summarizing the effects of the Hatch-Waxman Act provisions on pharmaceutical companies' behavior).

26. See *id.*

27. See *id.*

28. *Id.* at vii.

29. See *Greater Access to Affordable Pharmaceuticals Act Hearing*, *supra* note 9, paras. 1-2.

30. Balto, *supra* note 7, at 322.

fits—is increasingly important.<sup>31</sup> The FTC regulates potential antitrust behavior and has the power to prosecute anticompetitive conduct such as collusion, monopolization, and unlawful restraint of trade.<sup>32</sup> The Federal Trade Commission Act of 1914 empowers the FTC to investigate and, where necessary, prohibit unfair methods of competition affecting commerce—thereby protecting consumers against unfair practices.<sup>33</sup> The agency issues a cease and desist letter if, after issuing a complaint, it determines the FTC Act has been violated.<sup>34</sup>

Private parties may also bring actions to enforce antitrust laws<sup>35</sup> under the Sherman Antitrust Act, which prohibits unreasonable restraints of trade.<sup>36</sup> Restraints of trade are generally analyzed under a “rule of reason” approach in which the finder of fact decides reasonableness based on a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.<sup>37</sup>

Courts can forego a factual rule of reason approach and declare the restraint illegal *per se* if the anticompetitive effect is “predictable and pernicious” and has “limited potential for procompetitive benefit.”<sup>38</sup> The court must believe that the practice facially appears to almost always restrict competition and decrease output, thus enabling the court “to predict with confidence that the rule of reason will condemn it.”<sup>39</sup> The *per se* label should not be assigned without careful consideration. A departure from the rule of reason standard must be based upon demonstrable economic effect rather than formalistic line drawing.<sup>40</sup>

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31. See generally Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, 16 ANTITRUST 53 (2002).

32. Balto, *supra* note 7, at 323.

33. 15 U.S.C. § 45 (2000).

34. *Id.* § 45(b).

35. *Id.* § 15. The FTC may bring specific charges against agreements found to be of an anticompetitive nature based on Section 5 of the FTC Act which states that “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful” and that “the Commission is hereby empowered and directed to prevent” such actions. *Id.* § 45(a).

36. *Id.* § 1.

37. *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 343 & n.13 (1982) (quoting *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918)).

38. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

39. *Maricopa*, 457 U.S. at 344.

40. *Id.* at 364-67 (Powell, J., dissenting).

### III. RECENT PRIVATE PHARMACEUTICAL PATENT ANTITRUST CASES

In cases with similar facts, the Sixth Circuit and the Eleventh Circuit have ruled differently on issues of alleged pharmaceutical antitrust violations. In *Valley Drug Co. v. Geneva Pharmaceuticals*,<sup>41</sup> the Eleventh Circuit split with the Sixth Circuit's holding in *In re Cardizem CD Antitrust Litigation*.<sup>42</sup> The Eleventh Circuit disagreed with the Sixth Circuit's rule that an agreement between a pioneer manufacturer and a generic company (to delay marketing until resolution of the patent infringement case in exchange for exit payments) was a classical restraint of trade and *per se* illegal.<sup>43</sup> The Eleventh Circuit rejected the presumptive illegality of the settlement, stating that the "potential exclusionary power of the patent" in relation to the exclusionary power of the agreement must be considered.<sup>44</sup>

#### A. *In re Cardizem CD Antitrust Litigation*

*Cardizem* focused on the allegedly anticompetitive nature of a contract between Hoescht Maison Roussel, Inc. ("HMR") and Andrx Pharmaceuticals, Inc. ("Andrx").<sup>45</sup> HMR manufactures the prescription drug Cardizem, a pioneer prescription drug used to treat angina and hypertension and to help prevent heart attacks and strokes.<sup>46</sup> HMR entered into an agreement ("Agreement") with Andrx, whereby Andrx was paid to refrain from marketing its generic version of Cardizem.<sup>47</sup> Purchasers of Cardizem ("plaintiffs") filed a complaint against HMR and Andrx claiming that the Agreement violated federal and state antitrust laws by preventing a generic version of Cardizem from entering the market, resulting in artificially high prices. The plaintiffs labeled the Agreement a horizontal restraint of trade and brought federal antitrust claims under section 1 of the Sherman Act.<sup>48</sup> The district court granted partial summary judgment to the plaintiffs on the grounds that the Agreement was a horizontal restraint of trade and therefore *per se* illegal.<sup>49</sup>

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41. 344 F.3d 1294 (11th Cir. 2003).

42. 332 F.3d 896 (6th Cir. 2003).

43. *Valley Drug*, 344 F.3d at 1311 n.26.

44. *Id.* at 1311.

45. 332 F.3d at 896.

46. *Id.* at 901.

47. *Id.*

48. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 691 (E.D. Mich. 2000).

49. *Id.*

The parties did not dispute the events leading up to the Agreement.<sup>50</sup> HMR's original patent for Cardizem expired, and Andrx, the first potential generic manufacturer of Cardizem, filed an ANDA with the FDA.<sup>51</sup> Two months later, HMR obtained a new patent (the '584 patent) for a version of Cardizem with a dissolution profile that released the drug over eighteen hours.<sup>52</sup> Andrx filed a "Paragraph IV Certification" that claimed its ANDA did not infringe the '584 patent.<sup>53</sup> HMR filed a patent infringement suit against Andrx, alleging Andrx's generic infringed the new '584 patent.<sup>54</sup> Though the complaint sought neither damages nor a preliminary injunction, the infringement suit automatically triggered a thirty-month stay.<sup>55</sup> During the thirty-month stay, the FDA could not officially approve Andrx's ANDA unless the patent court ruled the patent invalid or not infringed.<sup>56</sup> The FDA tentatively approved Andrx's ANDA, indicating that final approval would be granted upon eligibility.<sup>57</sup>

Just nine days after the FDA announced tentative approval, HMR and Andrx entered into the Agreement.<sup>58</sup> The Agreement required HMR to pay Andrx \$40 million each year that Andrx did not enter the market after the thirty-month stay.<sup>59</sup> In addition, Andrx agreed to not resolve the underlying patent dispute, which would have terminated the thirty-month stay.<sup>60</sup> Andrx was required to dismiss its antitrust and unfair competition counterclaims against HMR, to diligently prosecute its ANDA, and to not relinquish or compromise its 180-day period of exclusivity.<sup>61</sup> Under the Agreement, Andrx could only market the generic version of Cardizem in the United States if (1) Andrx obtained a favorable, final court ruling in the patent infringement case; (2) HMR and Andrx entered into a licensing agreement; or (3) HMR entered into a license agreement with a third party.<sup>62</sup>

The Sixth Circuit found the Agreement a horizontal restraint of trade eliminating competition in the market for Cardizem throughout the entire

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50. *Cardizem*, 332 F.3d at 901.

51. *Id.* at 902.

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

United States, and thus presumptively illegal.<sup>63</sup> Moreover, the court found the Agreement, by preventing the end of the underlying patent litigation, effectively precluded or seriously delayed the patent court decision, which would have ended the thirty-month stay.<sup>64</sup> In addition, payments to prevent the marketing of the generic drug deferred the trigger of the 180-day exclusive period.<sup>65</sup> Utilizing provisions of the Hatch-Waxman Act, the Agreement effectively kept future third-party filers from entering the generic market.<sup>66</sup> The Sixth Circuit found that the Agreement could not “be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation.”<sup>67</sup> Rather, the defendants sought to “bolster the patent’s effectiveness” at inhibiting competition.<sup>68</sup> The Sixth Circuit declared that “the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justification in a particular case” and therefore “once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or presence of procompetitive effects is irrelevant.”<sup>69</sup> The Sixth Circuit found presumptive illegality because the exclusion payment was a classical example of a horizontal agreement to eliminate competition.<sup>70</sup> Therefore, the court concluded, the motion for summary judgment was properly granted because the defendants committed a *per se* violation of the antitrust laws.<sup>71</sup>

## B. *Valley Drug Co. v. Geneva Pharmaceuticals*

Valley Drug Co. sued Abbott Laboratories (“Abbott”), Geneva Pharmaceuticals (“Geneva”), and Zenith Goldline Pharmaceuticals (“Zenith”), alleging restraint of trade in violation of section 1 of the Sherman Antitrust Act.<sup>72</sup> Abbott manufactures terazosin hydrochloride and markets it under the name Hytrin.<sup>73</sup> Hytrin is a pioneer prescription drug used for the treatment of hypertension and enlarged prostate.<sup>74</sup> Abbott entered into separate

63. *Id.* at 908.

64. *Id.* at 908 n.12.

65. *Id.*

66. HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 33.9 (Supp. 2003).

67. *Cardizem*, 332 F.3d at 908.

68. *Id.*

69. *Id.* at 909.

70. *Id.*

71. *Id.* at 915.

72. *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1294 (11th Cir. 2003).

73. *Id.*

74. *Id.* at 1298.

agreements ("Agreements") with generic manufacturers Zenith and Geneva.<sup>75</sup> The Agreements were signed while the parties were engaged in patent litigation and the generics were pursuing FDA approval.<sup>76</sup> An interesting twist on this case is that Abbott mistakenly failed to file an infringement suit based on the Geneva's submission of the capsule ANDA, and the FDA subsequently approved Geneva's capsule form of terazosin hydrochloride.<sup>77</sup> The district court hearing the case held that the Agreements were *per se* violations of section 1 of the Sherman Act and granted summary judgment for the plaintiffs.<sup>78</sup>

Geneva and Zenith agreed not to sell or distribute either the capsule or tablet version of terazosin hydrochloride until a third party introduced a generic product or Abbott's patent expired.<sup>79</sup> In exchange, Abbott agreed to pay Zenith an initial \$3 million, then \$3 million after 3 months, and \$6 million every three months thereafter.<sup>80</sup> Abbott also agreed to pay Geneva \$4.5 million each month.<sup>81</sup> The generic companies agreed to retain their ANDA rights, including the 180-day period of exclusive marketing, and to refrain from aiding any other person in opposing or invalidating any of Abbott's terazosin patents.<sup>82</sup>

The defendants appealed the district court's conclusion that the Agreements were *per se* violations.<sup>83</sup> The appellants argued that the rule of reason analysis should be used because (1) courts lacked sufficient experience with the kind of agreements at issue to find liability under a *per se* analysis; (2) there were procompetitive justifications requiring a full rule of reason analysis; and (3) all patent settlements must be analyzed under the rule of reason.

The Eleventh Circuit agreed with the defendants and reversed the grant of summary judgment, concluding that because a patent dispute was central to the case, a *per se* characterization was "premature without further analysis."<sup>84</sup> The court emphasized that a patent grants its owner the lawful

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75. *Id.*

76. *Id.* at 1296.

77. *Id.*

78. *Id.* at 1299.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.* at 1300. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. *Id.* Abbott also agreed not to sue Zenith for infringement if it entered the market consistent with the Agreements. *Id.* at 1299.

83. *Id.* at 1303.

84. *Id.* at 1304.

right to exclude others, and therefore a “patentee’s allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability.”<sup>85</sup> The court specified that “when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal.”<sup>86</sup> The court went on to find that the Agreements appeared to be no broader than the potential exclusionary power of the patents, and that the subsequent invalidity of the patent did not render the patent irrelevant.<sup>87</sup>

The court also indicated that the exclusionary payments under the settlement did not necessarily demonstrate that the patent was invalid or that the Agreements had anticompetitive effects beyond those lawfully granted under the patent.<sup>88</sup> The Eleventh Circuit declared that payments themselves do not imply that an infringement suit lacks merit.<sup>89</sup> Other factors that must be weighed are lost profits from generic competition or profits from entry, the risk of the defendants’ inability to satisfy judgment, and the litigation costs each side expected to save from a settlement.<sup>90</sup> Explicitly disagreeing with the Sixth Circuit, the Eleventh Circuit determined that “antitrust analysis cannot ignore the scope of the patent exclusion” and that payment from the patentee to the alleged infringer should not be automatically condemned under antitrust law because “patent laws and the coverage of the antitrust laws are not separate issues.”<sup>91</sup>

#### IV. ANALYSIS

The Sixth and the Eleventh Circuit Courts of Appeal came to contradictory conclusions on cases involving similar facts—patent settlement agreements with exclusionary payments by the pioneer drug manufacturer to the generic drug company made in exchange for the generic’s delayed entry into the market. The Sixth Circuit affirmed the presumptive illegality of the exclusion payment, characterizing it as a horizontal agreement to eliminate competition. The Eleventh Circuit explicitly disagreed with the Sixth Circuit, asserting that an agreement is not presumptively invalid if it involves an exclusionary payment because the “antitrust implications of . . . exclusionary effects requires an analysis of the effects of antitrust li-

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85. *Id.* at 1305.

86. *Id.* at 1306 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003)).

87. *Id.* at 1307.

88. *Id.* at 1309-10.

89. *Id.*

90. *Id.*

91. *Id.* at 1310.

ability on the innovation and disclosure incentives created by the patent regime.”<sup>92</sup>

The Eleventh Circuit correctly ruled that *per se* analysis was inappropriate. Antitrust issues have become increasingly complex in patent antitrust cases,<sup>93</sup> and particularly with respect to exclusion payments. *Per se* analysis may save litigation expenses, but the method may over-simplify antitrust injury. The economic incentives to settle patent cases are well-documented.<sup>94</sup> A legal regime prohibiting such settlements imposes substantial direct costs on the court system and the taxpayers who fund it.<sup>95</sup> Direct, comprehensive, and well-rounded legislative reform of the Hatch-Waxman Act should be pursued to correct the root of the problem.

In *Cardizem*, the Sixth Circuit placed emphasis on the exclusionary aspect of the agreement.<sup>96</sup> The FTC has voiced concerns about exclusionary payments, sometimes called “exit payments” or “payments with wrong way directional flow.”<sup>97</sup> The concern regarding these payments is that the pioneer manufacturer pays the generic manufacturer to stay off the market, thus restricting competition.<sup>98</sup> An exit payment to the alleged infringer by the patentee “is designed to keep the alleged infringer off the market” but is “not necessarily determinative of whether prohibiting the practice is socially optimal.”<sup>99</sup> While consumers benefit from generic drugs, “merely focusing on the social benefits of competition after the creation of the patented item ignores the very foundation of the patent system—the expected monopoly rents that provide the ex ante incentives to engage in inventive

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92. *Id.* at 1311.

93. See Joseph Scott Miller, *This Bitter Has Some Sweet: Potential Antitrust Enforcement Benefits from Patent Law's Procedural Rules*, 70 ANTITRUST L.J. 875, ¶¶ 1-2 (2003).

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

95. See *id.*

96. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (stating that “it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent’s effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market”).

97. *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the Senate Comm. on Commerce, Sci., and Transp.*, 108th Cong. paras. 16-21 (Apr. 23, 2002) [hereinafter *2002 Hearings*] (statement of Timothy J. Muris, Chairman, FTC), <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>.

98. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1757 (2003) [hereinafter Hovenkamp et al. 2003] (arguing that “[e]xclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments”).

99. Crane, *supra* note 94, at 771.

activity.”<sup>100</sup> Determining what is socially optimal is a practice best left to the legislature.

In a forthcoming article, Hovenkamp, Janis, and Lemley argue that the rule of presumptive illegality is ultimately socially optimal because it decreases litigation costs as compared to the rule of reason approach.<sup>101</sup> It has also been argued, however, that balancing the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime may require in-depth analysis that extends beyond simply looking at the directional flow of the payments.<sup>102</sup> Therefore, cases should not be condemned as *per se* illegal, but should be assessed under a rule of reason if there are plausible efficiency reasons for such agreements, particularly in the context of the Hatch-Waxman Act.<sup>103</sup> While the Hatch-Waxman Act may have created incentives for anticompetitive behavior, an agreement should not be considered a *per se* violation simply because it involves the Hatch-Waxman provisions.

The rule of reason analysis may not be required, and a *per se* illegality can be used, depending on the size of the exit payment. Some dispute exists as to what size of exit payment should be considered too high. While some believe the size of the payment should be “no more than the expected value of litigation and collateral costs attending the lawsuit,”<sup>104</sup> others believe a litigation expense ceiling is “unnecessarily narrow.”<sup>105</sup> Still others have argued that inclusion of the “collateral costs” presents too many uncertainties and therefore payments should be limited solely to the litigation costs.<sup>106</sup> Although exit payments can achieve efficiencies in reducing litigation expenses,<sup>107</sup> large exclusion payments often entail market power of a degree likely to stifle free competition.<sup>108</sup> Exit payment settle-

100. *Id.*

101. Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. (forthcoming 2004) [hereinafter Hovenkamp et al. 2004].

102. *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1311 (11th Cir. 2003).

103. See James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777 (2003).

104. Hovenkamp et al. 2003, *supra* note 98, at 1759.

105. Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: a Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1802 (2003).

106. Maureen A. O’Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: a Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1782 (2003).

107. See Brodley & O’Rourke, *supra* note 31, 53.

108. Hovenkamp et al. 2003, *supra* note 98, at 1757.

ments should be allowed when the likelihood of success of the patentee's infringement suit is high and payment is not excessive.<sup>109</sup> While the size of an exit payment may eliminate the need for the rule of reason analysis, many courts, like the Eleventh Circuit, may not feel comfortable making this determination because of the complex economic implications and competing social policies.

In *Cardizem*, a portion of the Andrx agreement was *per se* unlawful even in the absence of a patent dispute.<sup>110</sup> Even so, the Sixth Circuit did not articulate this point to justify its *per se* approach and did not differentiate between provisions that fell within the scope of the patent's protection and those that did not. Furthermore, a provision of an agreement which may be *per se* unlawful in isolation may not be enough, when part of a larger agreement, to make the whole agreement unlawful. In *Valley Drug*, for example, the Geneva Agreement provision that prevented Geneva from manufacturing its capsule form of the drug, if viewed in isolation, would be an obvious *per se* illegal restraint of trade. Abbott failed to file an infringement suit for the capsule form, and thus had no intellectual property claim; this gave Geneva an undisputed legal right to market the drug. The Eleventh Circuit did not directly address this capsule issue, but stated that "it may also be helpful to identify with specificity which provisions or combinations of provisions are illegal" while cautioning that these provisions should not be viewed in isolation.<sup>111</sup> Instead, the Eleventh Circuit contends that such an agreement should be legal when it "will have the overall effect of enhancing competition," even if parts of it restrain trade.<sup>112</sup>

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109. See Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

110. Hovenkamp et al. 2003, *supra* note 98, at 1765. Hovenkamp et al. further explained that:

The settlement agreement also "restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending . . . patent case." While the language of this opinion is a little opaque, if it meant that Andrx promised not to sell products that Cardizem did not claim in its patent to begin with, then that portion of the agreement was *per se* unlawful notwithstanding a patent dispute. The agreement was a naked horizontal market division agreement, and the only justification for such agreements is that market division such as territorial and field-of-use restrictions are lawful when they are contained in patent licenses.

*Id.*

111. *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1313 & n.31 (11th Cir. 2003).

112. *Id.*

Viewing the specific provisions of the agreement, however, may not be necessary. There has been some debate about using antitrust law and the rule of reason method to solve intellectual property disputes. It has been argued that rule of reason analysis is appropriate because it has the ability to take into account information assessing the validity of the patent, which is important because a valid patent holder is given a right to preclude competition.<sup>113</sup> Using the *per se* analysis for exit payments might therefore limit the patent holder's ability to protect its intellectual property rights.<sup>114</sup> However, this argument has been attacked on the grounds that an antitrust inquiry cannot help with intellectual property issues such as the "likely validity and scope of the claimed IP rights, and the reasonableness of the settlement as one among many outcomes of the IP dispute."<sup>115</sup> Therefore, an agreement that is pro-competitive only if the patent is valid and is being infringed does not need any detailed rule of reason antitrust analysis because the antitrust issue depends solely on an intellectual property analysis of the patent. Granted, some Hatch-Waxman agreements may only depend on an intellectual property analysis. Overall, however, the Act sets out a regulatory framework meant to balance competing antitrust and patent policies in order to promote drug innovation while controlling the cost of pharmaceutical drug products. Therefore, when these concerns are in fact far from balanced, pharmaceutical companies repeatedly create agreements that abuse the provisions of the Act, fine-tuning the doctrine through the courts is unwise. Legislative action is necessary to reestablish the proper equilibrium.

## V. REGULATORY REACTIONS

In order to regulate Hatch-Waxman abuse, the FTC has pursued numerous antitrust enforcement actions, studied generic drug entry prior to patent expiration, and recommended legislative reform. Embracing the FTC recommendations, the GAAP reforms (1) the thirty-month stay provision, (2) the FDA Orange Book listing procedures, and (3) the 180-day exclusivity provision of the Hatch-Waxman Act. While these regulatory reactions will undoubtedly correct some perverse incentives of the Act, the enormous financial incentive to find and exploit the Act's loopholes necessitates continuous monitoring and reform of abused provisions.

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113. See Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 ANTITRUST 68 (2003).

114. See Langenfeld & Li, *supra* note 103, 786.

115. Hovenkamp et al. 2003, *supra* note 98, at 1725.

## A. Federal Trade Commission Enforcement

The FTC has pursued numerous antitrust enforcement actions against both pioneer and generic drug manufacturers.<sup>116</sup> The first generation of FTC litigation focused on potentially collusive settlements between brand name and generic manufacturers.<sup>117</sup> The FTC focused on agreements that provided for reverse payments, restricted the generic's ability to enter with noninfringing products, or restricted the generic's ability to assign or waive its 180-day marketing exclusivity rights.<sup>118</sup> The two leading cases in this generation of litigation, *Abbott/Geneva* and *Hoechst/Andrx*, were each resolved by consent orders.<sup>119</sup>

The second generation of FTC litigation targeted improper Orange Book listings.<sup>120</sup> The FTC's first enforcement action to remedy an allegedly improper and anticompetitive Orange Book listing was initiated in 2002, when it issued a consent order against Biovail Corporation.<sup>121</sup> Finally, the FTC has focused on settlements between generic manufacturers.<sup>122</sup> The FTC's consent order against Biovail Corporation and Elan Corporation required them to terminate their agreement not to compete in the generic market and barred them from engaging in similar conduct in the future.<sup>123</sup>

### 1. *Bristol-Meyers Squibb*

The most recent FTC action concerning Hatch-Waxman abuse involved Bristol-Meyers Squibb. The FTC filed a complaint against Bristol for (1) paying a generic competitor millions of dollars to refrain from marketing its generic drug until the brand-name patent expired, and requiring the generic company to abandon its patent challenge;<sup>124</sup> (2) misleading the FDA about the scope, validity, and enforceability of its patents;<sup>125</sup> (3) abusing FDA regulations to block generic entry and thereby breaching its

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116. See 2003 Hearings, *supra* note 1.

117. See 2002 Hearings, *supra* note 97, paras. 16-21.

118. See *id.*

119. 2003 Hearings, *supra* note 1, para. 17. For more information about recent examples of objectionable settlements, see Janet A. Gongola, Prescriptions for Change: *The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787 (2003).

120. 2002 Hearings, *supra* note 97, paras. 22-37.

121. 2003 Hearings, *supra* note 1, paras. 26-30.

122. 2002 Hearings, *supra* note 97, paras. 38-41.

123. 2003 Hearings, *supra* note 1, paras. 32.

124. This charge is representative of the first generation of Hatch-Waxman Act charges.

125. This claim is a form of the second generation of FTC litigation.

duty of candor and good faith before the Patent and Trademark Office (PTO); and (4) filing an objectively baseless patent infringement lawsuit in federal court.<sup>126</sup> The FTC alleged a decade-long pattern of anticompetitive acts by Bristol to obstruct the entry of generic competition for two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar, allegedly protecting nearly \$2 billion in annual sales.<sup>127</sup> Bristol settled charges with the FTC, which issued a consent order barring Bristol from obtaining a thirty-month stay on later listed patents and from engaging in inequitable conduct before the PTO or the FDA.<sup>128</sup>

## B. Legislative Reform

The combination of private law suits and regulatory action has been insufficient to curb Hatch-Waxman abuse. It became apparent that provisions of the Act needed to be reformed because they inadvertently created opportunities for market control and collusive agreements. The Act created enormous financial incentives to engage in anticompetitive behavior. Loopholes allowed pharmaceutical companies to exploit the automatic thirty-month stay, the unchallengeable Orange Book listing, and the 180-day period of exclusivity.<sup>129</sup> The Senate and House both recently passed versions of GAAP, which reforms the Hatch-Waxman generic drug approval process.<sup>130</sup> These reforms are nearly identical to the recommendations that the FTC developed after intensive study of the Hatch-Waxman Act.<sup>131</sup> The GAAP will help reduce Hatch-Waxman abuse.

### 1. *Thirty-Month Stay and FDA Orange Book Listing*

The problem with the thirty-month stay stems from the fact that the FDA does not regulate the listing of patents in the Orange Book.<sup>132</sup> The FDA assumed that patent holders would list patents in good faith, and so did not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the

126. Complaint, *In re Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (Apr. 14, 2003).

127. 2003 Hearings, *supra* note 1, para. 29.

128. *In re Bristol-Myers Squibb Co.*, 68 Fed. Reg. 12,080 (Fed. Trade Comm'n Mar. 13, 2003) (proposed consent order).

129. Julia Rosenthal, Note, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 334 (2002).

130. *Greater Access to Affordable Pharmaceuticals Act Hearing*, *supra* note 9, para. 2.

131. *Id.*

132. See FTC DRUG ENTRY STUDY, *supra* note 3.

relevant NDA.<sup>133</sup> In fact, after a generic filed an ANDA, pioneer companies could list additional patents in the Orange Book and then file an infringement suit.<sup>134</sup> In *Cardizem*, for example, HMR listed the '584 patent after Andrx filed its ANDA and *then* filed an infringement suit.<sup>135</sup> The pioneer manufacturer could list patents at any time and then file an infringement suit to trigger an automatic thirty-month stay. Since the FDA cannot approve any ANDA during the thirty-month stay, the pioneer manufacturer prevented any generics from entering the market and competing against them for thirty months.

Furthermore, the automatic thirty-month stay provision created an incentive to list every patent related to a drug product and permitted a patent owner to prevent competition irrespective of the patent merits and without any significant penalty for a wrongful assertion.<sup>136</sup> For example, in *Valley Drug*, Abbott was granted multiple automatic thirty-month stays preventing generic competition on a patent later determined to be invalid. This ability to extend market exclusivity by simply listing a patent in the Orange Book encouraged pioneer drug companies to look for, attain, and list a variety of patents of little merit except for their ability to delay legitimate competition.<sup>137</sup> Improper listing of patents in the FDA's Orange Book enabled anticompetitive outcomes because companies holding weak or invalid patents could automatically trigger the thirty-month stay of ANDA approval, delaying generic entry into the market.<sup>138</sup>

The FTC recommended that only one thirty-month stay be permitted per drug per ANDA.<sup>139</sup> On June 12, 2003, new FDA regulations, effective August 19, 2003, were announced that limit drug companies to only one

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133. 2003 Hearings, *supra* note 1, paras. 12-13, 18, 26-30.

134. Comments of the Fed. Trade Comm'n, In the Matter of Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will Not Be Infringed, FDA Dkt. No. 02N-0417 (Dec. 23, 2002), <http://www.ftc.gov/be/v030002.pdf>.

135. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902 (6th Cir. 2003).

136. Engelberg, *supra* note 12 (“[T]he automatic thirty-month injunction inadvertently created a powerful incentive for the holder of an NDA to list any and every patent related to a drug product irrespective of whether such patent was a significant barrier to legitimate competition.”).

137. *Id.*

138. Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks at the Sixth Annual Health Care Antitrust Forum (Nov 3, 2000), at <http://www.ftc.gov/speeches/leary/learypharma.htm>.

139. 2003 Hearings, *supra* note 1, at § D.

thirty-month stay.<sup>140</sup> Both the Senate and the House versions of GAAP were passed codifying the FDA regulations and amending the Hatch-Waxman Act to allow only one thirty-month stay per drug product, per ANDA, for patents listed in the Orange Book prior to the generic ANDA filing.<sup>141</sup> A district court decision of patent invalidity or noninfringement terminates the thirty-month stay.<sup>142</sup>

Permitting only one thirty-month stay will prevent pioneers from making consecutive patent challenges to prevent generic entry. Requiring the patent holder to have listed the patent in the Orange Book prior to the generic ANDA filing prevents actions like the one seen in *Cardizem* where HMR allegedly listed its '584 patent after Andrx filed its ANDA just to trigger the thirty-month stay. Under this new rule, pioneer pharmaceuticals will still be able to prevent competitors from marketing generic drugs, based on a patent that is listed after an ANDA, by seeking a traditional preliminary injunction.

The GAAP bill provides generic applicants with the ability to challenge incorrect patent information listed in the Orange Book.<sup>143</sup> As recommended by the FTC study, the new regulations aim to resolve the uncertainty regarding the type of patents that may be listed in the Orange Book.<sup>144</sup> If these new regulations had been in place before *Valley Drug*, Geneva, Zenith and other generic manufacturers would have been able to challenge Abbott's listing of patents in the Orange Book before Abbott had the chance to sue for infringement and trigger the automatic thirty-month stay provision.

## 2. 180-Day Exclusivity Provision

Unexpectedly, the 180-day exclusivity provision had become an obstruction to generic competition rather than an inducement to generic entry. The 180-day exclusivity period became a problem because it prohibited subsequent FDA approval of generics until the first generic applicant either entered the market or a judgment declared the challenged patent invalid or not infringed.<sup>145</sup> Therefore, there was an incentive—perverse from

140. Press Release, United States Department of Health and Human Services, HHS Revises Regulations and Procedures to Speed Access to Generic Drugs (June 12, 2003) [hereinafter HHS Press Release], <http://www.hhs.gov/news/press/2003pres/20030612.html>.

141. *Greater Access to Affordable Pharmaceuticals Act Hearing*, *supra* note 9, paras. 2-4.

142. *Id.* para. 4.

143. *Id.* paras. 5-6.

144. HHS Press Release, *supra* note 140.

145. *2003 Hearings*, *supra* note 1, § E.

the standpoint of encouraging generic drug entry—for the pioneer manufacturer to make a collusive agreement that paid the first generic to not trigger the 180-day exclusivity period. Even if the underlying patent is not enforceable, the companies have large incentives to enter into collusive settlements.<sup>146</sup> For example, in *Cardizem*, HMR paid Andrx to not trigger the 180-day exclusivity period, thereby preventing the FDA from approving any other ANDA.<sup>147</sup>

The GAAP Act addresses abuses of the 180-day exclusivity period by terminating it under certain conditions. The new 180-day provision of market exclusivity is forfeited if (1) there is a failure to market within a reasonable time period; (2) the ANDA application is withdrawn; (3) the certification is changed from a paragraph IV to a paragraph III;<sup>148</sup> (4) there is a failure to obtain tentative approval within 30 months; or (5) the generic enters into an agreement with the brand-name company or another generic applicant that the FTC or a court finds in violation of the antitrust laws.<sup>149</sup> In *Cardizem*, Andrx would have forfeited their right to the 180-day exclusivity period by failing to market the drug within the prescribed time period.

## VI. CONCLUSION

The Hatch-Waxman Act has been effective in ameliorating the high cost of prescription drugs by encouraging the entry of less expensive generic drugs.<sup>150</sup> However, pharmaceutical companies have found ways to frustrate the Congressional intentions of the Hatch-Waxman Act by entering into collusive agreements that exploit certain provisions of the Act. Accommodating both antitrust laws and patent goals is a complex process. Patent law and the Hatch-Waxman Act confer a level of market power that is protected from antitrust law. Antitrust violations, patent law, and the Hatch-Waxman provisions all intersect, making anticompetitive behavior difficult to analyze.

The incentives, goals, and policies of antitrust law and patent protection must be balanced to determine the socially optimal equilibrium between competition and innovation. The exclusionary patent rights neces-

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146. See HERBERT HOVENKAMP ET AL., *supra* note 66.

147. *In re Cardizem Antitrust Litig.*, 332 F.3d 896, 802 (6th Cir. 2003).

148. A paragraph III certification states that the patent has not expired but will expire on a particular date and the FDA may approve the ANDA on the date that the patent expires. See FTC GENERIC DRUG STUDY, *supra* note 3.

149. *Greater Access to Affordable Pharmaceuticals Act Hearing*, *supra* note 9, para. 13.

150. FTC GENERIC DRUG STUDY, *supra* note 3, at i-ii.

sary to encourage innovation must be continuously monitored to prevent unjustifiable exploitation of competition barriers. Yet, increasing antitrust risk and lessening patent protection could make it unprofitable for pharmaceutical companies to develop new drugs. The short-term consumer benefits of decreased drug prices from generic competition must be weighed against the long-term health benefits that arise from the discovery of new drugs by pharmaceutical companies. Courts and legislatures must cautiously analyze complex antitrust liability, considering the public health benefits of promoting new drug innovation by monopolistic patent protection.

The GAAP regulatory reform of the Hatch-Waxman Act may create a stable equilibrium by closing loopholes prone to abuse in the existing law without drastically weakening pioneer pharmaceutical companies' patent protection. Nevertheless, pharmaceutical antitrust violations may continue to plague courts. Pharmaceutical companies should not be allowed to manipulate the system, but punishing them for exploiting loopholes leads to complicated policy dilemmas. Courts may not be adequately equipped to balance all of the competing policy goals. Problems innate in the Hatch-Waxman Act need to be corrected at the legislative level. Hopefully, the recent legislative reform will attain the proper balance.

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