

# THE LEGALITY OF HATCH-WAXMAN PHARMACEUTICAL SETTLEMENTS: IS THE TERAZOSIN TEST THE PROPER PRESCRIPTION?

## I. INTRODUCTION

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act,<sup>1</sup> commonly known as the Hatch-Waxman Act,<sup>2</sup> in order to increase the availability of low-cost generic drugs by creating a less costly generic drug approval process.<sup>3</sup> By most accounts, the Hatch-Waxman Act has been successful.<sup>4</sup> As of 1983, merely thirty-five percent of the best-selling drugs with expired patents had generic counterparts, whereas now nearly all do.<sup>5</sup> Moreover, it is estimated that in 1994 alone, Americans saved between eight and ten billion dollars by switching from brand-name to generic drugs.<sup>6</sup> The Hatch-Waxman Act has succeeded because it combines an expedited Food and Drug Administration (FDA) approval process for generic drugs with additional intellectual property protections for brand-name, or pioneer, drugs, thereby satisfying the desires of both the generic and pioneer pharmaceutical industries.<sup>7</sup>

Notwithstanding the Hatch-Waxman Act's apparent success, the high cost of pharmaceuticals continues to be a source of concern.<sup>8</sup> A recent University of Connecticut poll found that seventy-seven percent of

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). This law is codified "in scattered sections of 15, 21, 28, and 35 U.S.C." Larissa Burford, Note, *In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 BERKELEY TECH. L.J. 365, 365 n.2 (2004).

2. See Burford, *supra* note 1, at 365 n.2 ("This Act is typically referred to as the Hatch-Waxman Act because of the congressional sponsors, Senator Orrin Hatch and Representative Henry Waxman.").

3. H.R. REP. NO. 98-857, at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647 ("The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.").

4. See, e.g., Timothy J. Muris, Chairman of Federal Trade Commission, Prepared Statement Before the Senate Judiciary Committee (June 17, 2003), <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

5. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at xii (July 1998), <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.

6. *Id.* at xiii.

7. See, e.g., Muris, *supra* note 4.

8. See, e.g., Howard Fine, *Drugmakers Under Fire: The Pharmaceutical Industry is on the Defensive as Government Officials and Consumers Decry Rising Costs Amid a Furor Over Safety*, L.A. BUS. J., Sept. 5, 2005, at 21 (addressing attempts in California to pass a measure requiring drug companies "to negotiate with the state to lower prices for the uninsured or be barred from lucrative Medi-Cal contracts").

respondents believed that prescription drugs cost too much, and seventy percent believed that drug company profits were too high.<sup>9</sup> Additionally, the presence of cheaper drugs in other nations has fueled the perception that Americans are being gouged<sup>10</sup> and has spurred calls for legislation allowing the importation of pharmaceuticals from abroad.<sup>11</sup>

Although no single factor accounts for high drug costs, one problem is that the complex Hatch-Waxman Act contains loopholes that give pioneer drug manufacturers and their generic counterparts incentives to enter into allegedly collusive settlements.<sup>12</sup> Specifically, “pioneer brand-name drug companies are paying generic drug companies, which challenge the brand-name drug patents, not to compete or to delay litigation.”<sup>13</sup> Settlement payments of this type are often referred to as “reverse,” “exit,” or “exclusion” payments.<sup>14</sup> At first glance, exit payment settlements would seem to violate antitrust laws: agreements between competitors to divide the market and exclude other competitors are per se illegal under Section 1 of the Sherman Act.<sup>15</sup> However, most brand-name drugs are subject to one or more patents, and the presence of patents alters the antitrust analysis.<sup>16</sup>

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9. *Id.*

10. *Id.* According to the article, California Attorney General Bill Lockyer is “dragging these drug companies into the court of law because they’re gouging the public on basic life necessities.” *Id.*

11. See Pharmaceutical Market Access Act of 2005, S.109, 109th Cong. (2005). The need for a ready supply of low-cost drugs became a national security concern following the anthrax attacks in 2001. See, e.g., Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 126 (2002) (noting that in the wake of the anthrax threat, public attention focused on the fact that the patent rights to ciprofloxacin, the only antibiotic approved by the FDA to treat inhalation anthrax, were held by the German pharmaceutical company Bayer, who had the right to exclude all other companies from manufacturing or selling the drug in the United States). Similarly, fears of a “bird flu” epidemic have caused policymakers to pay even closer attention to the supply of cheap pharmaceuticals. Sabin Russel, *Flu Drug Maker Won’t Share Patent: Roche Rejects Calls to Allow Production of Generic Versions*, S.F. CHRON., Oct. 13, 2005, at A1, available at <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/10/13/MNG39F7MNG1.DTL&type=health> (discussing fears that Roche’s refusal to license generic versions of its antiviral drug Tamiflu could lead to shortages of the drug should a bird flu epidemic break out).

12. Burford, *supra* note 1, at 365.

13. Marcy L. Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as “Settlements” Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1338 (2001).

14. See Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 698–99 (2004). The term “exit payments” will be used throughout this Note.

15. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128 (E.D.N.Y. 2003), *aff’d*, 429 F.3d 370 (2d Cir. 2005) (“[A]n agreement between a monopolist and a potential competitor to divide between them and exclude other competition is per se illegal under Section 1 [of the Sherman Act].”).

16. See, e.g., *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1305 (11th Cir. 2003) (“A patent grants its owner the lawful right to exclude others.”).

Exit payments, therefore, lie at the thorny intersection of antitrust and patent law.<sup>17</sup>

Because pioneer-generic settlement agreements might not violate antitrust laws if the patents on the drugs are valid,<sup>18</sup> two important questions are raised when assessing the legality of such settlements.<sup>19</sup> The first is whether courts, when addressing the legality of exit payment settlements in antitrust cases, should inquire into the validity of the patents involved. Assuming that the answer to the first question is yes,<sup>20</sup> the second question is how courts should go about making such an inquiry.<sup>21</sup>

This Note will be limited to addressing the latter of the two questions. Part II begins with a discussion of the history and purpose behind the Hatch-Waxman Act and how drug companies have allegedly attempted to exploit its loopholes. I will also briefly outline relevant antitrust and patent law concepts. In Part III, I will first summarize the arguments supporting the idea that antitrust courts should undertake a limited inquiry into the merits of the patents involved in exit payment settlements. I will then argue that that the novel approach taken by the court in *In re Terazosin Hydrochloride Antitrust Litigation* (“*Terazosin*”), though flawed in some ways, balances the competing concerns of antitrust and patent law.<sup>22</sup>

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17. See Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, ANTITRUST, Summer 2003, at 70 (“[P]atent settlements between rivals have become an important battleground in the perennial tension between intellectual property and antitrust.”).

18. See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064 (11th Cir. 2005) (“In the context of patent litigation, . . . the anticompetitive effect [of excluding competitors] may be no more broad than the patent’s own exclusionary power.”).

19. It should be noted that courts do not find patents “valid.” Rather, the best a court can do is determine that the patent in question is “not invalid” based on the issues raised. For simplicity’s sake, however, in this paper the words “valid” and “not invalid” will be used interchangeably.

20. Several scholars have argued persuasively that as a theoretical matter, courts addressing the antitrust implications of Hatch-Waxman settlements should indeed look at the validity of the patents involved. See generally 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 (2003); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1735 (2003) (“Permitting ex post judicial queries into the validity and coverage of settled patents may sound onerous, and may sometimes even be a deal breaker. But it is necessary in our ‘middle set’ of cases in order to distinguish pro-from anticompetitive agreements.”); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); see also *infra* Part III.A. But see Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1 (2005).

21. See *infra* Part III.

22. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005), enforcing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003). This Note focuses

Finally, in Part IV, I will offer some suggestions for how the *Terazosin* approach can be improved—namely, that it should be applied only in certain limited situations and that it should be incorporated into antitrust law’s “rule of reason.”<sup>23</sup>

## II. HISTORY

### A. *The Hatch-Waxman Act*

#### 1. *Pre-Hatch-Waxman Regulation of the Pharmaceutical Industry*

Under federal law, no new drug can be marketed or sold in the United States without first having been approved by the FDA.<sup>24</sup> Between 1938 and 1962, FDA approval was relatively easy to achieve.<sup>25</sup> At that time, the law required pioneer drug manufacturers to submit to the FDA a New Drug Application (NDA) containing drug safety information.<sup>26</sup> Marketing of the drug could begin sixty days after the manufacturer submitted the NDA to the FDA, unless the FDA disapproved of the drug during this period.<sup>27</sup>

The FDA drug approval process became more complicated, however, with the passage of the Drug Amendments of 1962.<sup>28</sup> These amendments required that prior to marketing, all new drugs, generic and pioneer, must be approved as safe and effective.<sup>29</sup> Because testing the safety and efficacy of new drugs required manufacturers to conduct costly and time-consuming tests on human subjects,<sup>30</sup> the new NDA procedures contributed to a sharp increase in drug prices.<sup>31</sup> Similarly, the increased

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on the opinion of the district court on remand from the Eleventh Circuit in *Valley Drug Co.*, not on the previous opinion also called *In re Terazosin Hydrochloride Antitrust Litigation*, that the Eleventh Circuit reversed. See *infra* Part III.B.

23. See *infra* Part IV.

24. 21 U.S.C. § 355(a) (2000) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”).

25. See *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984).

26. *Id.* at 864.

27. See, e.g., Stephanie Greene, *A Prescription For Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 313 (2005).

28. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.).

29. H.R. REP. NO. 98-857, at 16 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2649. This is in contrast to the pre-1962 situation, where safety, but not efficacy, studies were required for FDA approval. *Id.*

30. *Id.*

31. Greene, *supra* note 27, at 314.

testing requirements led to a delay of over three years between the submission of a NDA and its approval.<sup>32</sup> As for generic drugs, the 1962 amendments required that generic drug manufacturers also submit safety and efficacy studies, “even if such studies had already been performed for identical drugs or drugs with identical active ingredients.”<sup>33</sup> Furthermore, generic drug manufacturers could not conduct safety and efficacy studies involving another’s patented drug without subjecting themselves to liability for patent infringement.<sup>34</sup>

Thus, by 1984 both pioneer drug manufacturers and their generic competitors were lobbying for FDA reform.<sup>35</sup> Generic drug manufacturers argued that because using patented drugs for research was considered infringing activity, no generic drugs could be produced until the patents in question expired, thus extending the patent holder’s monopoly position.<sup>36</sup> Moreover, redundant safety and efficacy studies were prohibitively expensive,<sup>37</sup> if not unethical.<sup>38</sup> Patent holders, on the other hand, argued that because they could not sell the patented drugs until after FDA approval, the drug testing regime effectively deprived them of years of patent protection.<sup>39</sup>

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32. See *id.* at 313–14. In addition, there is some evidence that by the early 1980s it could take from seven to ten years for a pharmaceutical company to satisfy regulatory requirements. *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984).

33. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003). However, the 1962 amendments did allow for expedited approval of generic drugs that were based on “new” drugs approved prior to 1962. H.R. REP. NO. 98-857, at 16, as reported in 1984 U.S.C.C.A.N. 2647, 2649. Specifically, as part of an Abbreviated New Drug Application (ANDA), “a manufacturer of a generic drug must conduct tests that show the generic drug is the same as the pioneer drug and that it will be properly manufactured and labeled.” *Id.* Still, there was “no ANDA procedure for approving generic equivalents of pioneer drugs approved after 1962.” *Id.* This ANDA procedure foreshadows the one that would later be created by the Hatch-Waxman Act. See *infra* text accompanying note 41.

34. *Valley Drug*, 344 F.3d at 1296. In *Roche Prod., Inc. v. Bolar Pharm. Co.*, the Federal Circuit held that the “limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements” by anyone other than the patentee was actionable patent infringement. *Roche Prod., Inc.*, 733 F.2d at 861.

35. See Greene, *supra* note 27, at 313.

36. *Id.*

37. See Lobanoff, *supra* note 13, at 1333 (“Relying on the clinical trials already approved by the FDA for the brand-name drugs . . . could have saved the generic manufacturers time, effort, and money.”).

38. H.R. REP. NO. 98-857, at 16 (1984), as reprinted in U.S.C.C.A.N. 3647, 2649 (“[R]etesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.”).

39. See Greene, *supra* note 27, at 313.

## 2. *The Hatch-Waxman Act*

To solve the problems associated with the FDA approval process, Congress enacted the Hatch-Waxman Act in 1984.<sup>40</sup> The law created an Abbreviated New Drug Application (ANDA) that allowed generic drug manufacturers to “piggyback” on a pioneer drug’s safety and efficacy studies.<sup>41</sup> Moreover, the Hatch-Waxman Act modified the definition of patent infringement so that conducting safety and efficacy studies for FDA approval was no longer considered an infringing activity.<sup>42</sup> In order to placate pioneer drug manufacturers, the Hatch-Waxman Act also extended the term of a patent to compensate for the time when a patented drug was undergoing the FDA approval process and could not be marketed.<sup>43</sup> By enacting the Hatch-Waxman Act, Congress attempted to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”<sup>44</sup>

Under the original Hatch-Waxman Act, an NDA applicant was required to submit with his or her NDA the number and expiration date of any patent(s) that claimed the drug for which the applicant sought FDA approval.<sup>45</sup> The FDA then published this patent information, along with other drug information, in what is popularly known as the “Orange Book.”<sup>46</sup> Essentially, NDA applicants have to list information on patents that a generic manufacturer might infringe when copying the pioneer drug.<sup>47</sup>

In order for a generic manufacturer to piggyback off a drug listed in the Orange Book, the generic manufacturer first has to provide information showing that that the generic drug is the same as the brand-name drug to be copied.<sup>48</sup> Next, an ANDA applicant must make one of four

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40. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

41. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

42. *See, e.g., id.* at 1296.

43. *Id.*

44. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 192 (E.D.N.Y. 2003) (quoting *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000)).

45. *See* 21 U.S.C. § 355(b)(1) (2000).

46. *See Valley Drug*, 344 F.3d at 1297.

47. *Id.*

48. *See* 21 U.S.C.A. § 355(j)(2)(A)(i)-(v) (2003). To be considered the same as the FDA-approved drug it is copying, a generic drug must have the same active ingredients, route of administration, dosage form, strength, and labeling as the FDA-approved drug. 21 U.S.C. § 355(j)(2)(A)(i)-(v). Further, the two drugs must be bioequivalent. 21 U.S.C. § 355(j)(2)(A)(iv).

certifications for each of the pertinent patents listed in the Orange Book.<sup>49</sup> In what is known as a “paragraph IV” certification, the ANDA applicant certifies that the patent covering the approved drug “is invalid or will not be infringed by the manufacture, use, or sale” of the generic drug.<sup>50</sup> Making a paragraph IV certification has important legal ramifications. The ANDA applicant must notify the holder of the listed patent that an ANDA has been filed containing a paragraph IV certification.<sup>51</sup>

Because the filing of a paragraph IV ANDA is considered by statute to be constructive patent infringement,<sup>52</sup> the patent holder then has forty-five days after receipt of notice to file a patent infringement suit against the ANDA applicant.<sup>53</sup> If the patent holder does not bring suit within forty-five days, the FDA may approve the ANDA immediately.<sup>54</sup> Alternatively, if the patent holder does file a patent infringement suit within the forty-five-day window, an automatic thirty-month stay of FDA approval of the ANDA is granted.<sup>55</sup> The FDA cannot approve the ANDA until the end of the thirty-month stay, or until there is a court decision holding that the patent is invalid or not infringed.<sup>56</sup>

In addition to providing for an automatic thirty-month stay, the Hatch-Waxman Act awards the first paragraph IV filer a 180-day period free from other generic competition.<sup>57</sup> While the 180-day exclusivity period is in effect, the FDA is precluded from approving any other ANDA for the

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49. 21 U.S.C.A. § 355(j)(2)(A)(vii) (2003).

50. 21 U.S.C.A. § 355(j)(2)(A)(vii)(IV) (2003). Alternatively, the ANDA applicant could “certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; [or] (3) the patent will expire, identifying the expiration date . . .” *Valley Drug*, 344 F.3d at 1297. “If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, see 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, see 21 U.S.C. § 355(j)(5)(b)(ii).” *Valley Drug*, 344 F.3d at 1297.

51. See 21 U.S.C.A. § 355(j)(5)(B) (2003).

52. See Bruce R. Genderson, *Settlements in Hatch-Waxman Act Patent Litigation: Resolving Conflicting Intellectual Property and Antitrust Concerns*, 3 SEDONA CONF. J. 43, 45 (2002) (“The statute treats the filing of the ANDA-IV certification as a technical act of infringement, thereby creating jurisdiction.”).

53. 21 U.S.C.A. § 355(j)(5)(B)(iii) (2003).

54. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 193 (E.D.N.Y. 2003) (citing 21 U.S.C. § 355(j)(5)(B)(iii)). After FDA approval, the ANDA filer may begin to market its generic drug. *Id.* However, if the patent on the pioneer drug has not yet expired, “the ANDA filer assumes the risk it might be found liable for infringing the pioneer manufacturer’s patent.” *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 744 (E.D.N.Y. 2001).

55. 21 U.S.C.A. § 355(j)(5)(B)(iii) (2003). “The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) [the patent infringement statute] after the 45-day window expires. The 30-month stay of FDA approval, however, will not be triggered.” *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1298 n.5 (11th Cir. 2003).

56. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

57. See generally 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

drug in question.<sup>58</sup> Prior to the 2003 amendments to the Hatch-Waxman Act, the exclusivity period was triggered by either the marketing of the generic drug by the first ANDA filer or a court decision finding the patent on the pioneer drug invalid or not infringed.<sup>59</sup> The purpose of the exclusivity period is to serve as an incentive for generic manufacturers to challenge drug patents believed to be weak.<sup>60</sup>

### 3. *Manipulation of the Hatch-Waxman Act*

Even though the Hatch-Waxman Act has increased the availability of generic drugs,<sup>61</sup> the statute's complex provisions have rendered it vulnerable to manipulation.<sup>62</sup> Specifically, both the thirty-month stay provision and the 180-day exclusivity period may be used to subvert the aims of the Hatch-Waxman Act.<sup>63</sup> According to Congressman Henry Waxman, "The law has been turned on its head. We were trying to encourage more generics and through different business arrangements, the reverse has happened."<sup>64</sup>

The problem with the thirty-month stay of FDA approval is that pioneer drug companies have allegedly listed multiple patents of dubious merit in the Orange Book solely in order to make use of the automatic stay.<sup>65</sup> Those who filed an ANDA for a particular drug were forced to make paragraph IV certifications for every patent listed in the Orange Book for that drug.<sup>66</sup> With multiple patents, the patent-holding pioneer drug manufacturers could, and did, seek multiple thirty-month stays, delaying generic entry and the resulting lower prices.<sup>67</sup>

Although the multiple thirty-month stay tactic pits a pioneer drug manufacturer against its natural enemy, a generic drug manufacturer, the

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58. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d at 193.

59. *Id.* The triggering mechanism for the 180-day exclusivity period was amended by Title XI of Medicare Prescription Drug and Modernization Act of 2003. *See infra* Part II.A.4.

60. *See* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1298 (11th Cir. 2003).

61. *See supra* Part I.

62. *See* Lobanoff, *supra* note 13, at 1337–38.

63. Burford, *supra* note 1, at 370.

64. Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A1.

65. Burford, *supra* note 1, at 370 ("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.").

66. *See* Greene, *supra* note 27, at 319.

67. *Id.* at 313. Until the passage of the 2003 Amendments to the Hatch-Waxman Act, generic drug manufacturers were not able to challenge Orange Book listings. *Id.* at 318–19.



Hatch-Waxman Act may also cause collusion between the rivals.<sup>68</sup> This is accomplished when a pioneer and generic drug manufacturer settle their patent infringement suit via an exit payment settlement. Although the terms of exit payment settlements vary, most of them exhibit a similar pattern.<sup>69</sup>

First, the pioneer, patent-holding drug manufacturer files an infringement suit against a generic drug manufacturer who is about to make a generic version of the pioneer drug.<sup>70</sup> The two parties then settle the infringement suit, with the generic drug manufacturer agreeing not to enter the market for the drug in question and to not challenge the pioneer drug manufacturer's patent.<sup>71</sup> In return, the pioneer drug manufacturer agrees to pay the generic drug manufacturer a substantial amount of money.<sup>72</sup> As a result, "for a certain period of years [a] particular generic producer is disabled by the settlement agreement from entering the market."<sup>73</sup>

Furthermore, under the original Hatch-Waxman Act, if the generic drug manufacturer agrees to retain its 180-day exclusivity period,<sup>74</sup> the FDA will not be able to approve subsequent paragraph IV ANDAs filed by other generic competitors and an "approval bottleneck" will ensue.<sup>75</sup> Even when the 180-day exclusivity period is not an issue, exit payment settlements by their very terms delay the entry of low-cost generic drugs into the market.

#### 4. 2003 Hatch-Waxman Amendments

In response to the perceived problems with the Hatch-Waxman Act, President Bush signed into law the Access to Affordable Pharmaceuticals Act as Title XI of the Medicare Prescription Drug and Modernization Act of 2003 (Medicare Act).<sup>76</sup> Based in part on a Federal Trade Commission

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68. See Stolberg & Gerth, *supra* note 64.

69. Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 22–23 (2004).

70. *Id.* at 22.

71. *Id.*

72. *Id.*

73. *Id.*

74. See generally Lobanoff, *supra* note 13, at 1343 ("The first ANDA applicant to challenge a patented drug has the liberty to decline triggering the 180-day exclusivity period, which precludes the FDA from approving any subsequent generic challenger's application.")

75. Greene, *supra* note 27, at 319 ("Thus, the first ANDA IV filer, by deliberately delaying, or 'parking,' its 180 days of exclusivity, may create a bottleneck that prevents other generic competitors from getting FDA approval.")

76. Access to Affordable Pharmaceuticals Act, Pub. L. No. 108-173, Title XI, §§ 1101–1104,

study,<sup>77</sup> Title XI of the Medicare Act was designed to “prevent needless delays in getting more affordable generic drugs to market.”<sup>78</sup>

The Medicare Act contains several provisions amending the Orange Book listing procedures and the automatic thirty-month stay.<sup>79</sup> Most importantly, the Medicare Act allows for only one thirty-month stay per ANDA.<sup>80</sup> Also, when a generic manufacturer is sued for infringing a patent listed in the Orange Book, the generic manufacturer can counterclaim to correct or delete the patent information in the Orange Book.<sup>81</sup>

The Medicare Act also attempts to prevent abuse of the 180-day exclusivity period. First, the 180-day exclusivity period now operates on a “use it or lose it” basis wherein the first ANDA filer is required “to use the 180-day exclusivity period within certain time constraints or forfeit the period.”<sup>82</sup> Other circumstances that can lead to forfeiture include withdrawal of the application, amendment of the certification, and failure to obtain tentative marketing approval.<sup>83</sup> Second, if the first paragraph IV ANDA filer forfeits the 180-day exclusivity period, no subsequent ANDA filers are eligible for it;<sup>84</sup> there is only one exclusivity period.<sup>85</sup> Third, the

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1111–1123, 117 Stat. 2066 (2004); *see generally* Greene, *supra* note 27.

77. FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (last visited Jan. 28, 2006).

78. Greene, *supra* note 27, at 311.

79. Access to Affordable Pharmaceuticals Act, Pub. L. No. 108-173, Title XI, § 1101, 117 Stat. 2066 (to be codified at 21 U.S.C. § 355).

80. Greene, *supra* note 27, at 334 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). A patent holder can amend the Orange Book listing for the drug in question to add new patents, and can sue for infringement on these later patents, but no thirty-month stay would be triggered. *Id.* However, “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.” Burford, *supra* note 1, at 383.

81. Access to Affordable Pharmaceuticals Act, § 1101 (to be codified at 21 U.S.C. § 355(j)(C)(ii)). The patent information can be deleted if the generic manufacturer can show that the patent claims neither the pioneer drug nor an approved method of using the drug. The generic manufacturer cannot, however, recover damages for a patent holder’s erroneous listing of a patent in the Orange Book. Moreover, generic manufacturers can only challenge an Orange Book listing as a counterclaim, not an affirmative cause of action. *Id.*

82. Greene, *supra* note 27, at 349. The Medicare Act also eliminates the 180-day “court decision trigger,” choosing instead to focus on the first generic marketing of the generic product. *Id.*

83. H.R. 1, 108th Cong., BILL SUMMARY & STATUS, Library of Congress Thomas Website, <http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00001:@@D&summ2=m&> (last visited Jan. 28, 2006).

84. Access to Affordable Pharmaceuticals Act, § 1102(a)(2) (to be codified at 21 U.S.C. § 355(j)(5)(D)(iii)). *See also* H.R. 1, 108th Cong., *supra* note 83 (observing that the Medicare Act “[p]rohibits other subsequent ANDA applicants from being permitted the 180-day exclusivity period if all first ANDA applicants forfeit.”).

85. Greene, *supra* note 27, at 350.

Hatch-Waxman Act now requires that exit payment settlements involving pioneer and generic drugs be filed with the Assistant Attorney General and the Federal Trade Commission (FTC) for review.<sup>86</sup> Filing these agreements with the FTC should not only lead to fewer blatantly anticompetitive agreements, but it also should make it easier for the FTC to detect wrongdoing. Prior to the Medicare Act, settlements between drug makers and their generic rivals were usually kept confidential.<sup>87</sup>

The Medicare Act's revisions of the Hatch-Waxman Act should help deter pioneer and generic drug manufacturers from using the 180-day exclusivity period to delay generic entry into the market indefinitely.<sup>88</sup> On the other hand, "[t]he complexity of the Hatch-Waxman regulatory scheme will inevitably invite creative methods of advancing the different interests of brand-name and generic manufacturers."<sup>89</sup> Consequently, antitrust issues continue to be of vital importance with respect to exit payment settlements.<sup>90</sup>

### *B. Antitrust and Patent Law Overview*

Because the primary goal of antitrust law is to eliminate restraints on competition,<sup>91</sup> Section 1 of the Sherman Act makes illegal "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce . . . ."<sup>92</sup> Although on its terms the Sherman Act prohibits every agreement "in restraint of trade," the Supreme Court has long recognized that Congress intended to outlaw only unreasonable restraints,<sup>93</sup> i.e., those which suppress or destroy, rather than regulate, competition.<sup>94</sup>

Consequently, most antitrust claims are analyzed under the "rule of reason," wherein the reasonableness of a restraint is judged by looking at

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86. H.R. 1 (citing Pub. L. No. 108-173, Title XI, §§ 1112–13, 117 Stat. 2066 (2004)).

87. Stolberg & Gerth, *supra* note 64.

88. *See* Burford, *supra* note 1, at 385.

89. *See* Greene, *supra* note 27, at 354–55.

90. *See id.*

91. *See* PHILLIP AREEDA, LOUIS KAPLOW & AARON EDLIN, *ANTITRUST ANALYSIS* ¶ 130, at 37 (6th ed. 2004) (citing statement of Senator Sherman, 12 CONG. REC. 2455ff (1890) ("This bill [the Sherman Act] does not seek to cripple combinations of capital and labor, the formation of partnerships or of corporations, but only to prevent and control combinations made with a view to prevent competition, or for the restraint of trade, or to increase the profits of the producer at the cost of the consumer.")).

92. 15 U.S.C. § 1 (2000).

93. *See, e.g.,* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

94. *Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) ("The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition, or whether it is such as may suppress or even destroy competition.").

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>95</sup> Under rule of reason analysis, the plaintiff in an antitrust case must first demonstrate that the restriction in question has an anticompetitive effect.<sup>96</sup> Once an anticompetitive effect is demonstrated, the burden shifts to the defendant to offer a procompetitive justification for the restriction.<sup>97</sup>

Assuming this occurs, the plaintiff has the option of rebutting the defendant’s claim<sup>98</sup> or showing that the procompetitive justification is outweighed by the restraint’s anticompetitive effect.<sup>99</sup> In addition, a plaintiff in an antitrust case must prove that the injury was “of the kind that the antitrust laws were designed to prevent.”<sup>100</sup> Because a full-blown rule of reason analysis requires gathering detailed information,<sup>101</sup> proceeding under this theory often places a heavy evidentiary and financial burden on plaintiffs.

Fortunately for antitrust plaintiffs, the rule of reason is not required in all cases. Certain restraints “have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit, that they are deemed unlawful per se.”<sup>102</sup> Generally, restraints are

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95. *Khan*, 522 U.S. at 10.

96. See *Nat’l Soc. of Prof’l Eng’rs v. United States*, 435 U.S. 679, 693 (1978) (beginning rule of reason analysis by finding that the agreement was anticompetitive). See also *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 786 (1999) (Breyer, J., concurring in part and dissenting in part) (asking first whether the restrictions in question have the potential for genuine adverse effects on competition).

97. See *United States v. Microsoft*, 253 F.3d 34, 59 (D.C. Cir. 2001) (“[I]f a plaintiff successfully establishes a *prima facie* case under § 2 [of the Sherman Act] by demonstrating anticompetitive effect, then the monopolist may proffer a ‘procompetitive justification’ for its conduct.”). Although the framework used in the *Microsoft* case arose in a Sherman Act § 2 “monopolization” context, the court in *Microsoft* noted that its “balancing approach” was similar to the approach taken under the rule of reason. *Id.* In fact, “[i]t is clear . . . that the analysis under section 2 is similar to that under section 1 regardless whether the rule of reason label is applied . . . .” *Id.* (quoting *Mid-Texas Commc’ns Sys., Inc. v. Am. Tel. & Tel. Co.*, 615 F.2d 1372, 1389 n.13 (5th Cir.1980)).

98. See *Microsoft*, 253 F.3d at 59.

99. *Id.*

100. AREEDA, KAPLOW & EDLIN, *supra* note 91, ¶ 146, at 67–68. This is known as “antitrust injury,” and it requires that the plaintiff show “that it (1) suffers injury (or threatened injury) that is both (2) actually caused by the defendant’s illegal conduct and (3) of the kind that the antitrust laws were designed to prevent.” *Id.*

101. See *supra* text accompanying note 95.

102. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (citing *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)). Courts also apply what is known as the “quick look rule of reason.” See, e.g., *Cal. Dental Ass’n v. FTC*, 526 U.S. 756 (1999). However, the “categories of analysis of anticompetitive effect are less fixed than terms like ‘per se,’ ‘quick look,’ and ‘rule of reason . . . .’” *Cal. Dental Ass’n*, 526 U.S. at 779. Rather, the “object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one.” *Id.* at 781.

per se illegal when experience shows that the rule of reason, if applied, would condemn the restraint.<sup>103</sup> When the *per se* rule is applied, courts do not have to consider the intent behind the restraint, any procompetitive justifications for the restraint, or the actual competitive effect of the restraint.<sup>104</sup> Classic examples of conduct subject to the *per se* rule include price fixing, division of markets, group boycotts, and some tying arrangements.<sup>105</sup> Also subject to the *per se* rule are horizontal restraints on trade that involve agreements between competitors, which are generally regarded as the most anticompetitive form of restraint.<sup>106</sup>

Because exit payment settlements between pioneer drug manufacturers and their generic competitors are horizontal agreements, such settlements likely would be per se illegal in the absence of countervailing considerations.<sup>107</sup> The agreements are indisputably anticompetitive—one party exits or delays entering the market in exchange for a cash payment, decreasing the competition the remaining party faces.<sup>108</sup> In addition, exit payment settlements are analogous to horizontal market allocation agreements,<sup>109</sup> which are classic per se violations of the Sherman Act.<sup>110</sup>

The analogy between exit payment settlements and per se illegal horizontal restraints is not perfect, however. Settlements in the Hatch-Waxman Act context invariably involve patents, and their presence alters the antitrust analysis. Whereas the purpose of antitrust law is to foster competition, the intellectual property system attempts to stimulate invention by stifling competition via a government-sanctioned monopoly.<sup>111</sup> To that end, patent holders have a right to exclude others

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103. *Khan*, 522 U.S. at 10 (quoting *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 344 (1982)).

104. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906–07 (6th Cir. 2003) (citing *Nat'l Coll. Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 100 (1984)).

105. *E.g.*, *N. Pac. Ry. Co.*, 356 U.S. at 5 (listing conduct deemed *per se* illegal).

106. *See* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 *FOOD & DRUG L.J.* 321, 327 (2000) (“Agreements between or among competitors and/or potential competitors, so-called ‘horizontal’ restraints, are regarded as the most straightforwardly anticompetitive category in consumer welfare terms.”).

107. *See, e.g.*, *Lobanoff*, *supra* note 13, at 1339 (“Pharmaceutical companies engage in horizontal restraints of trade when they enter into agreements to abstain from competing in an important market area such as price, quality, or innovation, or in a specific product territory, or even refrain from all competition.”).

108. *See generally In re Cardizem CD Antitrust Litig.*, 332 F.3d at 896.

109. In the case of an exit payment settlement, the pioneer drug manufacturer has allocated the entire market.

110. *See United States v. Topco Assoc.*, 405 U.S. 596, 607–08 (1972).

111. *AREEDA, KAPLOW & EDLIN*, *supra* note 91, ¶ 282, at 343. If one takes a broader view, however, it is apparent that antitrust and intellectual property law both, “properly understood, seek to

from making, using, or selling the invention throughout the United States.<sup>112</sup> The right to exclude gives patent holders the freedom to engage in activity that would otherwise violate the antitrust laws.<sup>113</sup> For example, a patent holder “can grant exclusive territorial licenses carving up the United States among its licensees,” or “subdivide markets in ways other than territorial . . . .”<sup>114</sup>

The immunity patent holders enjoy is not, however, unlimited.<sup>115</sup> Patent law does not extend a patent holder’s monopoly beyond its statutory right to exclude.<sup>116</sup> Moreover, it is “well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”<sup>117</sup> The question in exit payment settlement cases, then, is determining where “the limits of the patent monopoly” lie.

Further complicating the analysis of exit payment settlements is that the legal system generally encourages settlements.<sup>118</sup> Not only are settlements beneficial to the litigants, but they also provide social benefits by reducing conflict and the burden on the courts.<sup>119</sup> When patents are involved, a settlement may be particularly valuable, as patent litigation is often complex and time-consuming.<sup>120</sup> Conversely, litigation regarding patent validity plays an important role in ensuring that “only truly worthy

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promote innovation and the general welfare, albeit through two somewhat different mechanisms—IP law by protecting the property rights and interests of (and thus financial returns to) inventors, antitrust law by combating restrictions on the competitive process that may harm consumers and slow innovation.” Abbott & Michel, *supra* note 20, at 2. It is also important to note that although it is common to speak of a patent as granting its holder a monopoly, one must distinguish between a patent “monopoly” and an economic monopoly. “A patent confers a monopoly in the sense of a right to exclude others from selling the patented product. But if there are close substitutes for the patented product, the patent “monopoly” is not a monopoly in a sense relevant to antitrust law.” Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003), *appeal dismissed*, 104 Fed. Appx. 178 (Fed. Cir. 2004).

112. 35 U.S.C. § 154(a)(1) (2000).

113. See *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304–05 (11th Cir. 2003); Genderson, *supra* note 52, at 44 (“[I]t is settled that a restraint that results from a patent, without more, is not a violation of the antitrust laws.”).

114. *Valley Drug*, 344 F.3d at 1305.

115. See, e.g., *Valley Drug*, 344 F.3d at 1304 (“The exclusionary right cannot be exploited in every way . . . .”).

116. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1067 (11th Cir. 2005).

117. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196–97 (1963) (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942)).

118. Genderson, *supra* note 52, at 46.

119. AREEDA, KAPLAN & EDLIN, *supra* note 91, ¶ 293, at 363.

120. Genderson, *supra* note 52, at 46. *But see* Joseph F. Brodley & Maureen A. O’Rourke, *Preliminary Views: Patent Settlement Agreements*, ANTITRUST, Summer 2002, at 53 (“It is important to note, however, that the policy reasons favoring settlement of litigation generally may not be as strong in patent cases as in others.”).

inventions are granted publicly protected monopolies.”<sup>121</sup> Therefore, courts must be wary of turning a blind eye to settlements that may sacrifice competitive values in the name of judicial efficiency.<sup>122</sup>

### III. ANALYSIS

#### A. Courts Assessing the Legality of Exit Payment Settlements Under the Antitrust Laws Should Undertake a Limited Inquiry Into the Merits of the Underlying Patents

Because patents immunize parties from antitrust scrutiny only up to the limits of the patent monopoly,<sup>123</sup> courts must determine where the limits of the patent monopoly lie. “It is well-settled that a patent holder’s protections are limited by the precise terms of the patent grant, and cannot be extended by agreement.”<sup>124</sup> The “precise terms of the patent grant” are referred to as the scope of the patent, and patent scope limits the exclusionary value of the patent. But scope is not the whole story. The exclusionary value of a pharmaceutical patent is a function of two variables—“the scope of the patent *and* its chance of being held valid.”<sup>125</sup> Consequently, when a plaintiff alleges that a patent settlement between pioneer and generic drug manufacturers violates antitrust laws, the court

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121. AREEDA, KAPLAN & EDLIN, *supra* note 91, ¶ 293, at 364. *See also* Abbott & Michel, *supra* note 20, at 3 (“Courts generally favor settlements as an efficient means to avoid litigation, but these public policy considerations do not mean that all settlements are presumptively efficient regardless of the cost.”).

122. *See* AREEDA, KAPLOW & EDLIN, *supra* note 91, ¶ 293, at 364 (“[W]e must think carefully about the competitive values that might be sacrificed by a settlement and how best to preserve them.”).

123. *See supra* Part II.B.

124. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1296 (S.D. Fla. 2005).

125. Hovenkamp et al., *supra* note 20, at 1761 (emphasis added). *See also* Shapiro, *Antitrust Limits to Patent Settlements*, *supra* note 20, at 395 (“[A] patent is best viewed as a probabilistic property right. What the patent grant actually gives the patent holder is the right to sue to prevent others from infringing the patent.”). Accordingly, “the patent holder’s rights are calibrated according to the likelihood that the patent holder would win the patent litigation and the extent of exclusion that such a victory would permit.” *Id.* For a critique of the notion of “probabilistic property rights,” see McDonald, *supra* note 20, at 68. McDonald argues that “this theory of probabilistic patent rights is simply an exercise in assuming one’s answer. Its premise is contrary to already existing principles of antitrust and patent law, and its conclusion would radically reform legal principles of causation that have been in place for centuries.” *Id.* at 69. It is important to note that both Shapiro and McDonald emphasize “patent strength, which certainly includes an assessment of validity.” Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *supra* note 17, at 70. In any event, this Note is predicated upon the idea that the exclusionary power of a patent is a function of its scope and probability of being found valid or not infringed.

must consider the probable validity of the patents that were the subject of the settlement.<sup>126</sup>

There is substantial agreement among commentators that as a theoretical matter an assessment of both patent scope and validity is necessary to determine the exclusionary value of a patent.<sup>127</sup> However, there is lively disagreement among scholars as to how courts should practically go about making this assessment in the context of patent settlements.<sup>128</sup> At one end of the spectrum, some authors believe that assessing patent validity and scope can be resolved only through patent litigation, and settlement precludes re-litigating infringement issues in a subsequent antitrust suit.<sup>129</sup> Conversely, others suggest that a “trial within a trial” is necessary; the court in an antitrust suit involving exit payments must as a threshold matter determine whether the patent is valid<sup>130</sup> or un infringed before addressing “normal” antitrust issues.<sup>131</sup> Herbert Hovenkamp, Mark Janis, and Mark Lemley argue that most patent settlements can be disposed of without an inquiry into the merits;<sup>132</sup> intellectual property issues are irrelevant if “(1) the agreement would be lawful under the antitrust laws even in the absence of any IP dispute, or (2) the agreement would be unlawful under the antitrust laws even if all the IP claims that are made were fully sustained.”<sup>133</sup> In the remaining cases, “where the settlement agreement would constitute lawful use of the claimed IP right if an infringement claim was valid, but not if there were not valid IP right,”<sup>134</sup> the authors advocate at least a limited inquiry into the merits of the underlying infringement suit, though it need not be a particularly searching inquiry.<sup>135</sup>

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126. See Hovenkamp et al., *supra* note 20, at 1765; Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *supra* note 17, at 70 (“With patent settlements, the outcome of the patent litigation itself is central to an evaluation of future competition in the absence of the agreement.”).

127. Brodley & O’Rourke, *supra* note 120, at 53 (“[A]ny precise identification of the antitrust risk would require assessment of patent validity and scope.”). *But cf.* Abbott & Michel, *supra* note 20, at 22 (“In sum, any analysis of whether a patentee’s exclusionary right includes the right to make exclusion payments and preempts antitrust scrutiny of those payments must taken into account all characteristics and features of patent policy, including the probabilistic nature of the patent right at the time of settlement.”).

128. See, e.g., *supra* note 20.

129. Brodley & O’Rourke, *supra* note 120, at 53.

130. See *supra* note 19.

131. See McDonald, *supra* note 20, at 70–71.

132. Hovenkamp et al., *supra* note 20, at 1725.

133. *Id.*

134. *Id.* at 1726.

135. See *id.* at 1759.



Besides further burdening the courts,<sup>136</sup> having a court hearing an antitrust suit engage in a “trial within a trial” on the infringement issues of the settled patent litigation may chill the incentive for pioneer and generic drug manufacturers to enter into legitimate settlements.<sup>137</sup> Parties settle in large part to save litigation costs, and there would be less incentive for settlement if the issues settled would have to be re-litigated as part of an antitrust suit.<sup>138</sup> The incentive for parties to settle is also decreased by the prospect of treble damages and criminal sanctions if the settlement is later found to violate antitrust laws.<sup>139</sup> Finally, if settlement options are stifled, pioneer drug manufacturers “may be less inclined to invest the research and development (R&D) costs associated with bringing new drugs to the market.”<sup>140</sup>

Assuming that some limited inquiry into the validity of the underlying patents is necessary, factors need to be developed to allow courts to engage in such an inquiry without re-litigating the underlying patent dispute. One method would be to have courts look at the existence of exit payments themselves as a proxy for conducting a hearing on the validity of the underlying patent, or at least considering the presence of exit payments as a highly significant factor in the analysis of likely validity.<sup>141</sup> This is attractive because the weaker the case for patent validity, the more a pioneer drug manufacturer would be willing to pay the generic manufacturer for delaying its entry into the market.<sup>142</sup> The sheer magnitude of exit payments suggests that the patents involved were weak and likely to be declared invalid or un infringed.<sup>143</sup> In addition, exit

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136. See *infra* note 203.

137. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (2005) (“Above all, making the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court’s assessment of the patent’s validity might chill patent settlements altogether.”).

138. Hovenkamp et al., *supra* note 20, at 1765 (noting that inquiry into the merits of IP disputes is time consuming and difficult, and “threatens to undo many of the benefits of settling the dispute in the first place”).

139. AREEDA, KAPLOW & EDLIN, *supra* note 91, ¶¶ 135–38, 143, at 45–50, 58–60.

140. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d at 206.

141. See, e.g., Hovenkamp et al., *supra* note 20, at 1759 (“In an antitrust challenge, a payment from a patentee to an infringement defendant for the latter’s exit from the market is presumptively unlawful, shifting the burden of proof to the infringement plaintiff.”); Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *supra* note 17, at 72 (“In short, large reverse payments create an inference of consumer harm and thus allow antitrust enforcers to avoid the complex task of showing directly that the patent in question was weak.”).

142. See Hovenkamp et al., *supra* note 20, at 1758 (“[T]he size of the expected exclusion payments are inversely related to the strength of the patentee’s case.”).

143. See, e.g., Abbott & Michel, *supra* note 20, at 14 (“A patentee would not make a substantial payment if it believed it could exclude the competition for that period solely on the basis of its patent.”); Hovenkamp et al., *supra* note 20, at 1758–59.

payment settlements in the context of Hatch-Waxman Act litigation are the “reverse” of normal patent settlements.<sup>144</sup> In a “normal” patent settlement the alleged infringer would pay the patentee-plaintiff, and the plaintiff would drop the suit or perhaps license its invention to the defendant.<sup>145</sup> Exit payment settlements, by reversing the flow of payments, suggest that the pioneer drug manufacturer is sharing its monopoly profits with its generic competitor in exchange for delayed market entry.<sup>146</sup>

Nevertheless, looking at the presence and magnitude of an exit payment is only a substitute for directly assessing the validity of the patent. Neither the directional flow of the settlement payment nor its magnitude are perfectly correlated with the likelihood that the underlying patent is invalid; both are affected by factors unrelated to the underlying merits of the patent litigation.<sup>147</sup> Furthermore, the Hatch-Waxman Act treats the mere filing of a paragraph IV ANDA as an act of patent infringement, meaning that the generic drug company can challenge the validity of the pioneer’s patent without subjecting itself to the risk of paying money damages that would be present if the generic manufacturer had “actually” infringed.<sup>148</sup> Accordingly, “there is only one way for payments to ‘flow’—from the party . . . with everything to lose (the patent) and nothing to gain (no prospect of damages) to the party . . . with everything to gain (free entry) and nothing to lose (no exposure to damages).”<sup>149</sup> Frameworks that focus solely on the exit payment may end up sacrificing accuracy in the name of ease. What is needed, then, is a test that allows a court to engage in a limited inquiry into the merits of a patent suit, but does so without unduly stifling Hatch-Waxman Act settlements. The court in *In re Terazosin Hydrochloride Antitrust*

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144. See, e.g., McDonald, *supra* note 20, at 68.

145. See Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, *supra* note 20, at 769 (“In an ordinary case of patent infringement, the patentee/plaintiff would usually collect from the infringer/defendant—not vice versa.”).

146. *Id.*

147. See Crane, *Ease Over Accuracy in Assessing Patent Settlements*, *supra* note 14, at 702 (“Standing alone, the directional flow of the settlement payment is a poor proxy for determining the ex ante likelihood that the plaintiff would prevail at trial and legally exclude the defendant.” *Id.* Moreover, “patentees look to settle patent infringement lawsuits for a variety of reasons, including out-of-pocket litigation costs, unrelated to ‘the value of eliminating competition that the patentee could not expect ex ante to exclude after trial.’” *Id.* at 705 (quoting Hovenkamp, Janis & Lemley, *supra* note 20, at 1758).

148. See McDonald, *supra* note 20, at 69–70.

149. *Id.* at 70.

*Litigation* (“*Terazosin*”) recently applied a test that in certain situations has the potential to satisfy both requirements.<sup>150</sup>

## B. Terazosin Background

### 1. Factual Background

*Terazosin* revolved around Abbott Laboratories’ (“Abbott’s”) attempt to protect Hytrin, its brand-name version of terazosin hydrochloride, from generic competition.<sup>151</sup> Hytrin is used to treat high blood pressure and certain other conditions,<sup>152</sup> and is covered by several patents, including the 5,504,207 patent (“the ’207 patent”).<sup>153</sup> This patent claimed a certain crystalline form of anhydrous terazosin hydrochloride.<sup>154</sup>

In 1996, Geneva Pharmaceuticals (“Geneva”) filed paragraph IV ANDAs based on Hytrin. One ANDA was filed for the capsule form of terazosin hydrochloride and a second ANDA was filed for the tablet form.<sup>155</sup> Abbott then filed an infringement suit alleging that Geneva’s tablet form of terazosin hydrochloride infringed the ’207 patent.<sup>156</sup> Geneva conceded that its terazosin hydrochloride tablet infringed this patent,<sup>157</sup> but it argued that the patent was invalid due to the “on-sale bar” doctrine.<sup>158</sup> In

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150. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005), enforcing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

151. *See id.* at 1286.

152. *Id.* at 1286. Hytrin is also used to treat benign prostatic hyperplasia, “an enlargement of the prostate gland that surrounds the urinary canal.” *Id.*

153. *Id.* at 1289.

154. *Id.* Specifically, the ’207 patent claimed “a crystalline polymorph of anhydrous terazosin hydrochloride with a certain X-ray diffraction pattern (Form IV) and a process for the preparation of terazosin hydrochloride . . .” *Id.*

155. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1298–99 (11th Cir. 2003).

156. *Id.* at 1299. Abbott failed, however, to file an infringement suit based on Geneva’s capsule form of the drug. *Id.* In addition, Zenith Goldline Pharmaceuticals also filed ANDAs for terazosin hydrochloride, settled with Abbott, and was a defendant in the subsequent antitrust suit. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1286 (S.D. Fla. 2005). Zenith, however, settled with the antitrust plaintiffs and is therefore not relevant to the antitrust analysis. *Id.* at 1286 n.3.

157. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. at 1289.

158. *Id.* at 1289–90. The “on-sale bar” is a defense to patent infringement based on the novelty requirement: if the claimed subject matter was “on sale in this country, more than one year prior to the date of the application for patent in the United States,” then the subject matter fails to meet the novelty requirement and the patent is invalid. 35 U.S.C. § 102(b) (2000). Here, Geneva claimed that sales of the patented form of terazosin hydrochloride were made in the early 1990s, more than one year before Abbott applied for the ’207 patent. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1290. In rebuttal, Abbott argued that although the sales occurred, the “on-sale bar” was not triggered because none of the purchasers knew that it was the patented form of terazosin hydrochloride that was

April 1998, Abbott and Geneva entered into the settlement agreement that gave rise to the subsequent antitrust suit.<sup>159</sup>

The settlement agreement provided that Geneva was not to sell or distribute any pharmaceutical product containing a form of terazosin hydrochloride until the occurrence of any one of several conditions.<sup>160</sup> The settlement agreement also required Abbott to pay Geneva \$4.5 million each month starting on April 30, 1998, and ending when, and if, the district court entered a final appealable judgment that Geneva did not infringe the '207 patent or that it was invalid. If there was a final appealable judgment in Geneva's favor, Geneva would continue to abstain from producing a generic copy and Abbott would pay into an escrow account until the resolution of the appeal.<sup>161</sup>

On September 1, 1998, after Abbott and Geneva entered into their settlement agreement, the district court granted summary judgment in Geneva's favor in the patent infringement suit, holding that the '207 patent was invalid due to the on-sale bar.<sup>162</sup> Pursuant to the settlement agreement, Abbott then began to make its payments directly into the escrow account.<sup>163</sup> Although the settlement agreement was designed to terminate automatically, Abbott and Geneva terminated it early, on August 13, 1999, in response to an FTC investigation.<sup>164</sup> Geneva began marketing the

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being sold. That is, the early 1990s purchasers knew they were taking terazosin hydrochloride, but they did not know which form. *Id.*

159. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1290.

160. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1300 (11th Cir. 2003). The conditions included the expiring of Abbott's '532 patent, someone else introducing a generic terazosin hydrochloride drug, or Geneva obtaining a court judgment that its terazosin tablets and capsules did not infringe the '207 patent. *Id.* This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. *Id.* Geneva also agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. *Id.*

161. *See In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1291.

162. *See id.* at 1290.

163. *See id.* By the time the settlement agreement was terminated, Abbott had placed \$49.5 million into escrow. *Id.*

164. Absent FTC involvement, the settlement agreement would have terminated on January 10, 2000, the date that the U.S. Supreme Court denied certiorari. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1290. Instead, Abbott and Geneva entered into consent decrees with the FTC. *See In re Abbott Labs.*, <http://www.ftc.gov/os/2000/05/c3945.do.htm>.

The orders prohibited Abbott and Geneva from entering into NDA/ANDA (brand-generic) Agreements in which: (1) the ANDA First Filer (generic) producer is prohibited from relinquishing its 180-day marketing exclusivity rights, or (2) the ANDA First Filer (generic) producer agrees to refrain from developing any drug product that has potential for FDA approval and that is not the subject of a patent infringement court action. The companies were also required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action that provided for payments to the ANDA First Filer (generic) in order to stay off the market, with advance notice to the Commission to allow it

capsule form of terazosin hydrochloride the same month and its tablet form of the drug approximately one year later.<sup>165</sup>

## 2. Procedural Background of Antitrust Suit

Almost two years after the settlement agreement was executed, a class of plaintiffs consisting of generic drug manufacturers, pharmacies/retailers, and interest groups<sup>166</sup> sued Abbott and Geneva alleging that the settlement agreement was illegal under Section 1 of the Sherman Act.<sup>167</sup> The district court agreed and held that the settlement agreement was per se illegal.<sup>168</sup> On interlocutory appeal, the Eleventh Circuit reversed, primarily because the district court failed to take the exclusionary power of the patent into account in its decision.<sup>169</sup> To guide the district court on remand, the appellate court stated that certain provisions of the settlement agreement were to be compared to the protections provided by a preliminary injunction and considered in light of

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time to present its views to the Court. Finally, the companies were ordered to give advance notice to the Commission before reaching a similar agreement in non-litigation contexts.

Uche Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 261 (2005).

165. See Melissa R. Leuenberger-Fisher, Note, *In re Terazosin Hydrochloride Antitrust Litigation: An Argument for the Rule of Reason*, 24 BIOTECH. L. REP. 417, 419 (2005).

166. See *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1294 (11th Cir. 2003). The Lexis versions of the *Valley Drug* opinion list the counsel for the plaintiffs. The generic drug manufacturers mentioned were Louisiana Wholesale Drug Company and Valley Drug Company. Also suing Abbott and Geneva were Walgreens Co., Inc., Kroger Co., the Eckerd Corporation, and Albertson's Inc., all of which are pharmacies and would presumably benefit from the lower drug prices that generic terazosin hydrochloride would bring. The AARP and the National Association of Chain Drug Stores also acted as amici in the case. *Id.*

167. See *Valley Drug*, 344 F.3d at 1301.

168. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000), *rev'd sub nom.* *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003). The district court characterized the settlement agreement as a horizontal market allocation between competitors, allocating the entire U.S. market for terazosin drugs to Abbott, who shared its profits with other "cartel" members during the duration of the settlement agreement. *Valley Drug*, 344 F.3d at 1304. Moreover, the district court found that the purpose of the settlement agreement was to "dissuade[] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period, eliminate[] the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim, and enlist[] their potential cooperation in opposing or refusing to support other drug makers' ANDAs." *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d at 1349.

169. *Valley Drug*, 344 F.3d at 1304. Similarly, the Eleventh Circuit held that "the appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the [settlement] Agreements reflect a reasonable implementation of these." *Id.* at 1312. Also of significance, the Eleventh Circuit found that the '207 patent may have allowed Abbott to obtain a preliminary injunction or stay pending appeal. *Id.* at 1305.

the likelihood of Abbott's obtaining such protections.<sup>170</sup> In addition, the Eleventh Circuit held that "[a]ny provisions of the [settlement] Agreement[] found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis . . . ."<sup>171</sup>

On remand, the district court concluded that at the time the settlement agreement was entered into, Abbott would not have been able to receive a preliminary injunction, and had litigation proceeded on the '207 patent, it would have been found invalid due to the on-sale bar.<sup>172</sup> Having established that the provision of the settlement agreement in question exceeded the exclusionary scope of the '207 patent,<sup>173</sup> the court applied "normal" antitrust principles and again found the provision to be per se illegal.<sup>174</sup>

### *C. Framework Developed in In re Terazosin Hydrochloride Antitrust Litigation*

The district court reached its conclusion by applying a test based on the Eleventh Circuit's instructions and the writings of Professor Hovenkamp.<sup>175</sup> Hovenkamp was read as urging a limited inquiry into the merits of the infringement suit, and the district court created a multi-factor test to determine whether the challenged provision of the settlement agreement was "a reasonable implementation of the exclusionary potential of the '207 patent."<sup>176</sup> First, the district court examined the exclusionary scope of the patent and the extent of the protections afforded by it.<sup>177</sup> The

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170. *Id.* at 1312.

171. *Id.* The court found application of the rule of reason inappropriate, "as the anticompetitive effects of exclusion cannot be seriously debated." *Id.* at 1311. Rather, "what is required here is an analysis of the extent to which antitrust liability might undermine" the incentives of the patent system. *Id.* Interestingly, the court also rejected the view that exit payments alone are sufficient for a finding of antitrust liability: "it is difficult to infer from the size of the payments alone that the infringement suits lacked merit." *Id.*

172. *See In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1306 (S.D. Fla. 2005).

173. *Id.* at 1310.

174. *See id.* at 1314. At this point in the litigation, the plaintiffs had "narrowed their Section One claims to a single provision of the Agreement—the prohibition of Geneva's marketing its generic terazosin products between the September 1, 1998, district court judgment in the '207 patent litigation and the Federal Circuit's mandate on August 12, 1999 . . . ." *Id.* at 1294.

175. *See id.* at 1295.

176. *Id.* Specifically, the district court found itself obligated to engage in "at least a limited inquiry into the merits of the parties' respective positions regarding the application of the 'on-sale' bar and the validity of the '207 patent, viewed as of the date on which the Agreement was entered into." *Id.*

177. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1299 (S.D. Fla. 2005)

second step was to evaluate the likely outcome of the patent litigation, looking specifically at the likelihood that Abbott would have been able to receive injunctive relief on the date the settlement was entered into.<sup>178</sup> Third, the district court looked at whether, in light of applicable law and policy considerations, the settlement agreement “represented a reasonable implementation” of the patent’s protections.<sup>179</sup> Any provision that failed to meet the three-part test was subjected to traditional antitrust analysis.<sup>180</sup>

### 1. *Exclusionary Scope of the Patent*

Under the first part of the *Terazosin* test, a court must consider the exclusionary value of the patent, which is a function of “the scope of the patent and its chance of being held valid.”<sup>181</sup> In practice, however, the focus, at least in *Terazosin*, is on the “legal scope” of the patent, which is delineated by its claims.<sup>182</sup> The analysis of the likely validity of the patent is reserved for the second step of the *Terazosin* test.<sup>183</sup> In essence, the first part of the *Terazosin* test acts as a screening mechanism that weeds out settlement provisions that are immediately subject to antitrust scrutiny because the patent is irrelevant.<sup>184</sup> For example, a provision in a settlement agreement that prevents a generic drug manufacturer from marketing drugs that the pioneer drug manufacturer has not patented would fail to pass muster under this first prong of the *Terazosin* test.<sup>185</sup> In *Terazosin*, the

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(“The starting point for the Court’s analysis on remand is to define the exclusionary scope of the ’207 patent.”).

178. *Id.*

179. *Id.* at 1295–96 (“[T]he Court next must determine whether the settlement represented a reasonable implementation of the protections afforded by the ’207 patent, in light of the applicable law, the then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes.”).

180. *Id.* at 1296.

181. *Id.* (quoting *Hovenkamp et al.*, *supra* note 20, at 1761).

182. *Id.* at 1297. In patent law, the extent of exclusion is governed by the claims set out in the patents specification. As Judge Giles Rich famously stated, “[T]he name of the game is the claim.” DONALD S. CHISUM ET AL., *PRINCIPLES OF PATENT LAW* 73 (3d ed. 2004).

183. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1299 (“[A]ny definitive construction of the exclusionary scope of the patent requires at least a limited assessment of the underlying patent infringement case. Therefore, the *second step* of the . . . analysis focuses on the likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement.” (emphasis added)).

184. The “exclusionary scope” prong of the *Terazosin* test is functionally similar to the threshold step in the *Hovenkamp et al.* framework, *supra* note 20, which places exit payment settlement cases into three categories, only one of which requires “special” analysis due to the presence of intellectual property. *Hovenkamp et al.*, *supra* note 20, at 1724–25.

185. For example, the district court noted that “the restriction on Geneva’s marketing of *any* terazosin hydrochloride product appears to extend well beyond the protections of the patent . . . .” *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1297. The district court never reached this

district court did not find it necessary to analyze the terms of the patent's claims, primarily because they were not at issue in the case.<sup>186</sup>

## 2. *Likely Outcome of the Underlying Patent Litigation*

The second prong of the *Terazosin* test “focuses on the likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement.”<sup>187</sup> The provision of the settlement agreement at issue delayed market entry by Geneva until appellate determination of patent validity, and was therefore similar to a preliminary injunction or appellate stay.<sup>188</sup> In order to obtain a preliminary injunction, the party seeking such relief must demonstrate “a reasonable likelihood of success on the merits.”<sup>189</sup> Moreover, the *Terazosin* test requires a court to look at the situation as of the date of the settlement.<sup>190</sup> Theoretically, this prevents a court from taking into account whether another court, subsequent to the settlement, had declared the patent invalid or not.<sup>191</sup> To avoid antitrust liability under the second prong of the *Terazosin* test, antitrust defendants must show that at the time of the settlement agreement, it was “more probable than not” that the patent would be declared not invalid.<sup>192</sup> In *Terazosin*, the district court found that at the time Geneva and Abbott entered into the settlement agreement, it was not probable that Abbott would win the infringement suit;<sup>193</sup> the on-sale bar would have rendered the '207 patent invalid.<sup>194</sup>

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issue, however, because the only provision of the settlement agreement challenged was “the prohibition of Geneva’s marketing its generic product until after appellate resolution of the '207 patent,” which implicated only “the temporal breadth of the patent’s provisions.” *Id.*

186. See *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1297.

187. See *id.* at 1299.

188. See *id.* Moreover, the Eleventh Circuit required such a comparison: “the '207 patent may have allowed Abbott to obtain preliminary injunctive relieve or a stay of an adverse judgment pending appeal . . . .” *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1305 (11th Cir. 2003).

189. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1302.

190. See *id.* at 1303.

191. See *id.* The impetus for assessing the legality of the settlement by looking at the time the agreement was entered into is explained by the Eleventh Circuit.

[E]xposing settling parties to antitrust liability for the exclusionary effects of a settlement [agreement] . . . merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcement of the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

*Id.* at 1308.

192. *Id.* at 1301. Abbott and Geneva had unsuccessfully argued that they only need prove a “reasonable possibility” of success in getting a preliminary injunction. *Id.* at 1300.

193. *Id.* (“Because the Court concludes that Abbott’s challenge to Geneva’s “on-sale bar”



### 3. Reasonable Implementation of the Patent's Protections

“Having concluded that Abbott was not likely to qualify for a preliminary injunction as of April 1, 1998,”<sup>195</sup> the district court determined that the challenged provision of the settlement agreement was not a reasonable implementation of the protections afforded by the '207 patent.<sup>196</sup> It is unclear from the district court's opinion exactly what applying the “reasonable implementation” prong of the *Terazosin* test entails; the district court merely looked at the proffered procompetitive justifications for the settlement agreement and found them wanting.<sup>197</sup> Functionally, the third prong of the *Terazosin* test is similar to the second step of the rule of reason where the defendant offers procompetitive justifications for the conduct shown to have anticompetitive effects.<sup>198</sup>

## IV. PROPOSAL

### A. Strengths and Weaknesses of the *Terazosin* Test

The major benefit of the *Terazosin* test is that it incorporates into its antitrust analysis an inquiry into the underlying validity of the patents involved.<sup>199</sup> This is important because, as discussed previously, a valid patent gives its holder the power to exclude others and may therefore save

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argument . . . was weak and unlikely to result in a District Court finding that the '207 patent was valid, it follows that Abbott was unlikely to obtain a preliminary injunction to keep Geneva off the market . . .”).

194. *Id.* Although the court in *Terazosin* stated that it ignored that the district court in the original patent infringement suit found the '207 patent invalid in September 1998, at least one scholar has found this claim dubious. “At the very least, the district court in the antitrust case appears to have failed to adhere to its own mandate that it ‘may not rely on the District Court’s analysis’ of the '207 patent . . . [in the infringement case] or on its ultimate conclusion that the patent was invalid under the on-sale bar.” Leuenberger-Fisher, *supra* note 165, at 423.

195. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d at 1307.

196. *See id.*

197. *See id.* at 1307–10. The district court rejected the arguments that the settlement agreement was reasonably necessary because: (1) the parties were operating against a backdrop of risk and uncertainty, and immediate launch of the generic product would have created legal and financial risks; (2) the challenged provision was ancillary to an agreement whose effect was to dispose of litigation and enhance competition; and (3) there was a high rate of reversal by the Federal Circuit of district court patent judgments. *Id.* at 1307–08. Most important to the district court was that the settlement agreement did not terminate the entire litigation but rather delayed entry while litigation proceeded. In the district court's view, this negated the efficiency and procompetitive justifications associated with settling disputes. *Id.* at 1308.

198. *See supra* Part II.B. Similarly, the first two prongs of the *Terazosin* test can be analogized to the initial inquiry under the rule of reason that seeks to ascertain whether the defendant's conduct has anticompetitive effects. *See supra* Part II.B.

199. *See supra* Part III.C.2.

an exit payment settlement from antitrust condemnation.<sup>200</sup> The court in *Terazosin* could have simply concluded that the size of the exit payments involved in the settlement agreement showed that Abbott had no faith in the validity of its patents, and therefore the patents likely were invalid and the settlement collusive.<sup>201</sup> Certainly this would have been easier on the court than looking into patent law issues in an antitrust suit.<sup>202</sup> Instead, the *Terazosin* test represented an attempt to take on a heavy administrative burden in order to get the most accurate result possible.

The *Terazosin* test does not, however, mean that a court must engage in a full patent trial during an antitrust case.<sup>203</sup> The *Terazosin* test only requires that a court determine whether it was more likely than not that the pioneer drug manufacturer would succeed in the infringement suit.<sup>204</sup> This preliminary injunction-like analysis is likely less burdensome on the courts than a full patent trial. Moreover, the less searching inquiry promulgated in *Terazosin* respects the idea that parties should be able to settle without undue interference by the courts.<sup>205</sup> It does this by requiring, not that the parties enter into the “best” settlement in terms of the public interest, but rather that they enter into a “reasonable” settlement—a settlement based on a patent more likely than not valid to begin with.<sup>206</sup>

In addition, the *Terazosin* test attempts to retain the incentive for pioneer and generic drug manufacturers to settle. This is accomplished by requiring that courts look at the likelihood of patent validity at the time of the settlement agreement.<sup>207</sup> This puts the court in the position that the parties were in when they settled, which is more fair to the settling parties than if a court scrutinized their behavior with the benefit of hindsight.<sup>208</sup>

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200. See *supra* Part III.A and note 137.

201. See *supra* Part III.A. See also Brodley & O'Rourke, *supra* note 120, at 55 (“The payment or giving of any other consideration to the generic manufacturer should be at least presumptively unlawful (if not per se unlawful), with the burden of proof on the parties to justify the payment.”).

202. See, e.g., Brodley & O'Rourke, *supra* note 120, at 53 (“The alternative of assessing probable validity and infringement in an antitrust proceeding fails to prove a tractable or predictive legal standard.”).

203. Of course, it is not unheard of for a court to engage in a trial within a trial. “Where a plaintiff alleges malpractice in litigation, the ‘but for’ test requires her to prove a ‘case within a case.’” STEPHEN GILLERS, REGULATION OF LAWYERS: PROBLEMS OF LAW AND ETHICS 638 (7th ed. 2005).

204. See *supra* Part III.C.2.

205. See *supra* Part II.B (discussing the legal system’s bias in favor of settlement).

206. An unreasonable settlement would be one where the exit payments are used to keep a weak patent from being invalidated. By engaging in preliminary injunction-like analysis, the *Terazosin* test is designed to prevent this from occurring.

207. See *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1303 n.21 (S.D. Fla. 2005) (“The Court, therefore, is not considering the subsequent invalidity of the patent, but rather is assessing the chances, gauged as of April 1, 1998, of Abbott succeeding in defending its patent.”).

208. See *supra* text accompanying note 191.

Under the *Terazosin* test, parties do not have to worry as much about a scenario wherein: (1) the parties settle a patent infringement suit; (2) a court subsequently declares the patent invalid; (3) smelling blood, antitrust plaintiffs sue, arguing that the settlement was anticompetitive because there was no valid patent involved; and (4) the antitrust court automatically agrees with the antitrust plaintiffs because the court in the patent case ultimately found the patent invalid.

This is not to say that the *Terazosin* test is without flaws.<sup>209</sup> There is the possibility that having antitrust courts revisit the merits of patent litigation could destroy the certainty and predictability that settlements are meant to provide.<sup>210</sup> The settling parties may have “simply traded the uncertainty of the outcome of the patent litigation, based on the patent merits, for the uncertainty of the outcome of the antitrust litigation, based again on the patent merits.”<sup>211</sup> The prospect of treble damages, a common remedy in antitrust cases, based on a later court’s assessment of a patent’s

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209. See *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005). The court implied that by looking into the validity of the '207 patent, the *Terazosin* court misinterpreted the Eleventh Circuit’s instructions in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1305 (11th Cir. 2003). *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d at 526 (“It is not certain that the district court correctly interpreted the Eleventh Circuit’s opinion, and indeed the Eleventh Circuit seems to have expressed some doubt on that point in an unrelated opinion.” (citing *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005))). While the court in *Valley Drug* did state that “good faith procurement [of a patent] furnishes a complete defense to an antitrust claim,” it did so only in the context of explaining the Supreme Court’s rationale in *Walker Process Equipment Co. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). *Valley Drug*, 344 F.3d at 1307. More importantly, the court mentioned time and again the “potential exclusionary power of the patent” and the “protection afforded by the patents.” *Valley Drug*, 344 F.3d at 1311–12. The Eleventh Circuit required the district court to compare the settlement agreement to a preliminary injunction; presumably, the Eleventh Circuit was aware that obtaining a preliminary injunction requires showing a likelihood of success on the merits, and therefore an inquiry into the validity of the '207 patent. Finally, the Eleventh Circuit, in *Schering-Plough Corp. v. FTC*, noted that the FTC “cavalierly dismissed our holding in *Valley Drug* . . . [by] stating that a determination of the merits of the underlying patent disputes was ‘not supported by law or logic.’” *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 n.18 (11th Cir. 2005). This strongly suggests that the Eleventh Circuit did approve some sort of inquiry into the validity of the patents involved in a Hatch-Waxman exit payment settlement, contrary to what the court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* implied.

210. See Abbott & Michel, *supra* note 20, at 33. For instance, there is the possibility that parties will settle, a later court then finds the patent valid, but during a subsequent antitrust suit the court applies the *Terazosin* test and finds that the patent likely was invalid based on the information available at the time of the settlement. The result would be that the settling parties would be liable for damages in the antitrust suit when the patent was not declared invalid. This would be highly unfair to the settling parties, and liability in such a case would almost certainly chill patent settlements. Of course, the likelihood of such a scenario occurring may not be high, as antitrust plaintiffs are unlikely to incur the litigation costs associated with challenging a settlement when one court has already refused to hold that the patent involved invalid.

211. *Id.* at 33–34.

validity may also make parties in patent suits wary of settling.<sup>212</sup> Moreover, patents are presumed valid, and inquiring into their validity in an antitrust suit may undermine this presumption.<sup>213</sup> Furthermore, “any antitrust rule must be sensitive to issues of administrability and uncertainty,” and the cost of inquiring into the validity of the patent may be high for an antitrust court even if the analysis is limited.<sup>214</sup>

*B. The Terazosin Test Should Be Applied Only in Limited Circumstances*

One way to solve some of the problems mentioned above is to carefully limit the situations where the *Terazosin* test is applied. A court in an antitrust case concerning the legality of exit payment settlements should only inquire into patent issues when absolutely necessary; effectively screening cases will get rid of cases where the settlement’s legality is independent of the patent’s validity or lack thereof.<sup>215</sup> Moreover, because the *Terazosin* test looks at whether a pioneer drug manufacturer could have obtained a preliminary injunction,<sup>216</sup> the test will be most useful when applied to settlements that are analogous to preliminary injunctions; settlements that delay, rather than completely prevent, generic entry into the market. In addition, the *Terazosin* test will be easier to apply when the antitrust court is faced with relatively simple patent law issues and facts.<sup>217</sup> As the complexity of the patent issues increases, so too will the administrative burden the *Terazosin* test places on antitrust courts, making the test less useful in those situations.

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212. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d at 530. Moreover, “[a]ntitrust remedies that unnecessarily deprive defendants of patent rights or that reduce the value of prospective patenting are likely to do more harm than good to the long run performance of the industry.” Hovenkamp, *supra* note 69, at 12.

213. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d at 529. *But see* Abbott & Michel, *supra* note 20, at 19 (characterizing the presumption of validity as “simply a procedural device for allocating the burden of proof to an accused infringer”). Accordingly, the presumption has “no separate evidentiary value’ in patent litigation and it should not be accorded that value in antitrust litigation.” *Id.*

214. Hovenkamp et al., *supra* note 20, at 1732.

215. See *supra* Part III.C.1 and accompanying notes.

216. See *supra* Part III.C.2.

217. For instance, the *Terazosin* case itself “presented none of the complicated claims construction issues that mark some patent infringement actions. The focus, instead, was on a single legal issue regarding the validity of the ’207 patent in light of Geneva’s challenge based on the ‘on-sale bar.’” *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1302 (S.D. Fla. 2005).

*C. The Terazosin Test Should Be Incorporated Into the Rule of Reason*

Another way to increase the utility of the *Terazosin* test would be to incorporate it into the rule of reason. Although the Eleventh Circuit suggested that application of the rule of reason would be inappropriate in exit payment settlement cases,<sup>218</sup> the *Terazosin* test is in some ways very similar to the rule of reason.<sup>219</sup> The first two prongs of the *Terazosin* test, which try to ascertain the exclusionary power of the patent, represent an attempt to determine if the exit payment settlement was anticompetitive.<sup>220</sup> Similarly, the first step of the rule of reason requires a plaintiff to show that the challenged conduct has an anticompetitive effect.<sup>221</sup>

If the *Terazosin* test were combined with the rule of reason, a plaintiff challenging the legality of an exit payment settlement in an antitrust suit first would have to prove that the pioneer drug manufacturer was unlikely to have succeeded on the merits of the patent infringement suit. A full patent trial would not be necessary; “the court could require the parties to submit affidavits and hold a hearing similar to a preliminary injunction hearing. If, based on a ‘quick look,’ the court concluded that the patent infringement claim was likely to succeed, the exit payment settlement should be approved without further inquiry.”<sup>222</sup> On the other hand, if the “quick look raised significant doubts regarding the validity of the patent,” a more thorough adjudication of the likely validity could be performed.<sup>223</sup> Assuming that the antitrust plaintiff provides sufficient proof of patent invalidity or non-infringement, the burden would shift to the antitrust defendants (the pioneer and generic drug manufacturers) to show that the exit payment settlement had procompetitive justification, as in the “second step” of the rule of reason,<sup>224</sup> or the third prong of the *Terazosin* test.<sup>225</sup>

Incorporating the *Terazosin* test into the rule of reason would produce several benefits. First, by giving antitrust defendants a chance to provide procompetitive justifications for the exit payment settlements, the *Terazosin* test/rule of reason combination will help prevent undue chilling of patent settlements. Parties engaging in exit payment settlements would

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218. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 n.27 (11th Cir. 2003).

219. *See supra* note 198 and accompanying text.

220. *See supra* Parts III.B.1–2 and note 198.

221. *See supra* Part II.B.

222. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, *supra* note 20, at 785.

223. *Id.*

224. *See supra* Part II.B.

225. *See supra* Part III.C.3.

not face the specter of being subjected to antitrust liability, and treble damages, solely because another court happened to find the patent invalid. The defendants would always have a chance to show that there were procompetitive justifications for the settlement, such as that it was ancillary to a legitimate agreement.<sup>226</sup> Second, placing the burden of proof on the antitrust plaintiffs acknowledges that patents are presumed valid;<sup>227</sup> patent-holding parties should not lose this presumption merely because they are being sued for an antitrust violation.<sup>228</sup> Finally, the courts have applied the rule of reason for decades and it is an entrenched part of antitrust law.<sup>229</sup> Although familiarity may often breed contempt, courts are accustomed to the rule of reason and may be more likely to apply the *Terazosin* test if it is incorporated therein.

## V. CONCLUSION

The test applied by the court in *In re Terazosin Hydrochloride Antitrust Litigation* goes a long way toward striking the proper balance between the goals of antitrust law and intellectual property law. It does so by recognizing that patent settlement agreements only harm consumers if it turns out that the underlying patent was invalid or unenforced, meaning that generic entry would have occurred absent settlement.<sup>230</sup> Therefore, a principled analysis of the legality of Hatch-Waxman settlements must inquire into the merits of the underlying patent infringement suit in some way.<sup>231</sup> The *Terazosin* test makes such an inquiry, and does so in a way designed to lessen the chilling effect that antitrust scrutiny may have on patent settlements.

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226. See *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282 (6th Cir. 1898) (“[N]o conventional restraint of trade can be enforced unless the covenant embodying it is merely ancillary to the main purpose of a lawful contract . . .”), *aff’d* 175 U.S. 211 (1899).

227. See *supra* note 213.

228. See, e.g., Crane, *Ease Over Accuracy in Assessing Patent Settlements*, *supra* note 14, at 709 (“One does not envy the patentee’s general counsel who has to inform senior management that by settling a patent infringement lawsuit they will presumptively become criminals and subject to fines and imprisonment unless they can persuade a jury that they likely would have won the patent infringement lawsuit anyway.”). Granted, the burden of proof is usually placed on the party in the best position to provide such proof, which in the case of antitrust challenges to Hatch-Waxman settlements would be the pioneer and generic drug manufacturers. *Id.* However, it makes sense to place the burden on the antitrust plaintiffs when they are the ones challenging the settlement and the validity of the patent.

229. See, e.g., *Standard Oil Co. v. United States*, 221 U.S. 1 (1911) (applying standard of reasonableness).

230. See *supra* Part III.A.

231. See *supra* Part III.A.

At first glance, however, it may seem that the *Terazosin* test is tilted too heavily in favor of the pioneer and generic drug manufacturers rather than consumers, especially in light of the suggestions provided for refining the test.<sup>232</sup> This tilt is especially worrisome given the high cost of drugs in this country.<sup>233</sup> Yet the *Terazosin* test gets at the worst kinds of settlements—those that simply mask weak patents and prevent generic entry into the market. Under the *Terazosin* test, drug companies that enter into exit payment settlements based on weak patents do so at the risk of treble damages. To go any further, though, may interfere with the incentives created by the patent system; pioneer drug manufacturers may be less likely to invest in new research if they feel that they will not be able to protect their investment by settling infringement cases.<sup>234</sup> Stringent antitrust scrutiny of Hatch-Waxman Act settlements could lead to more low-cost generic drugs now, but potentially decreased research into new drugs in the future. On the other hand, granting drug companies *carte blanche* when it comes to settling patent infringement suits may lead to revolutionary drugs in the future, but few affordable generic drugs now. To put it very broadly, the choice is between low-cost generic drugs now, or pricey innovative drugs in the future. The *Terazosin* test balances these concerns, allowing consumers to have the best of both worlds.

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232. See *supra* Part IV.

233. See *supra* Part I.

234. See, e.g., Shapiro, *Antitrust Limits to Patent Settlements*, *supra* note 20, at 392 (“The lion’s share of patent disputes are settled rather than litigated to a resolution in court. Lanjouw and Schankerman (2002) find that some 95% of patent lawsuits are settled prior to a court judgment.”) (citing J.O. Lanjouw & M. Schankerman, *Characteristics of Patent Litigation: A Window on Competition*, 32 RAND J. ECON 129, 129–51 (2001)).

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