

# THE HATCH-WAXMAN ACT AND THE CONFLICT BETWEEN ANTITRUST LAW & PATENT LAW

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## I. INTRODUCTION

On September 12, 2006, the chief executive officer of Bristol-Myers Squibb, Peter Dolan, was fired due to the patent dispute over Plavix, Bristol-Myers' best selling drug.<sup>1</sup> Apotex, a Canadian generic drug maker that had filed a Paragraph IV application with the Food and Drug Administration (FDA) under the Hatch-Waxman Act, was challenging Bristol-Myers' patent for Plavix.<sup>2</sup> In an effort to settle the patent infringement lawsuit, Bristol-Myers and Apotex reached two tentative settlements in the early half of 2006 that involved Bristol-Myers paying Apotex a certain sum of money to wait to market its generic version, and Bristol-Myers agreeing not to market its own authorized generic until Bristol-Myers' patent expired in 2011.<sup>3</sup> The Federal Trade Commission (FTC) and state attorneys general, however, rejected the first agreement, and Bristol-Myers made significant concessions in the second agreement allowing Apotex to market its generic version for a period of time before it could file for an injunction. This resulted in Bristol-Myers lowering its earnings forecast for the year by about twenty-five percent.<sup>4</sup> Because of the unintended results of Bristol-Myers' effort to defend its patent, Bristol-Myers lost money and Mr. Dolan lost his job.

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This article generally reflects the law as of 2007 and does not purport to discuss all of the cases in this area—there have been other cases that discuss related issues.

<sup>1</sup> Stephanie Saul, *Drug Maker Fires Chief of 5 Years*, N.Y. TIMES, Sept. 13, 2006, at C1.

<sup>2</sup> Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; Saul, *supra* note 1, at C1.

<sup>3</sup> Saul, *supra* note 1, at C1.

<sup>4</sup> *Id.*

Patent law and antitrust law are fundamentally in conflict with each other. The goal of antitrust law is to increase competition and to punish businesses for anticompetitive acts. In contrast, the goal of patent law is to encourage innovation by granting monopolies to innovators and allowing them to charge super-competitive prices in order to recoup money spent on research and development. As a result, there are often times—as illustrated by the Bristol-Myers story—when, by defending a patent, an innovator runs into problems with antitrust law.

When dealing with pharmaceutical patents, there is a further issue of wanting to encourage innovation, while also ensuring consumers can afford the drugs they need. To deal with this issue, Congress passed the Hatch-Waxman Act.<sup>5</sup> One of the goals of the Act is to lower the prices of drugs for consumers by getting generics to the market faster.<sup>6</sup> To do so, the Act allows generic manufacturers to file with the FDA before the innovator's patent expires.<sup>7</sup> In order to file with the FDA, however, the generic manufacturer must establish bioequivalency with the patented drug.<sup>8</sup> Because the generic manufacturer does so with the intent to market its generic version, it infringes the innovator's patent, thereby resulting in the innovator suing for patent infringement.<sup>9</sup> In order to settle the patent infringement suit, the innovator has, in the past, typically agreed to pay the generic manufacturer a sum of money to keep the generic version off the market until the patent expires. Unfortunately, agreements of this type have been viewed by the FTC and some courts as a violation of the Sherman Antitrust Act.<sup>10</sup> Thus, as demonstrated by the Bristol-Myers story, the Act has had severe impacts on drug makers and the drug industry far beyond its original purpose.

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<sup>5</sup> Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585 (2003).

<sup>6</sup> *Id.*

<sup>7</sup> 21 U.S.C. § 355 (2006).

<sup>8</sup> *Id.*

<sup>9</sup> It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (2006).

<sup>10</sup> 15 U.S.C. § 1 (2006).

To date, the FTC opposes almost all patent infringement settlements between innovators and generic manufacturers.<sup>11</sup> This raises the question of whether or not a patent infringement suit can be settled without running into antitrust issues. However, the Eleventh Circuit has developed a three-part test used to evaluate whether or not a settlement is anticompetitive and, therefore, in violation of the Sherman Act.<sup>12</sup> The United States Supreme Court has yet to rule on whether this test is valid.<sup>13</sup>

This paper will first describe the conflict between patent law and antitrust law. Then, it will describe why the Hatch-Waxman Act was passed, what it accomplished, and the developments since its enactment. Third, it will discuss how the patent infringement suits that develop due to the Act are typically settled, the antitrust issues that arise due to the settlements, and the resulting antitrust suits. Fourth, it will discuss possible solutions to the antitrust issues and the problems with the solutions. Finally, this paper will argue that, at the moment, the Eleventh Circuit's three-part test is the most viable way to allow companies to settle patent infringement suits.

## II. THE CONFLICT BETWEEN PATENT LAW AND ANTITRUST LAW

Patent law is inherently at odds with antitrust law. Patents grant potential monopolies to innovators in an effort to encourage innovation by allowing them to charge higher prices to recoup money spent on research and development. The goal of antitrust law, however, is to increase competition and punish businesses for anticompetitive acts, including monopolies.

The Sherman Antitrust Act (Sherman Act) governs antitrust law. The Sherman Act has two main sections. Section 1 deals with anticompetitive agreements.<sup>14</sup> Section 2 deals with monopolization.<sup>15</sup>

Section 1 of the Sherman Act outlaws certain anticompetitive agreements—agreements that involve more than one company.<sup>16</sup> The section says that “[e]very contract, combination . . . or conspiracy, in restraint of trade or

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<sup>11</sup> See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. filed Feb. 13, 2008) (FTC suing Cephalon for allegedly unlawfully blocking the sale of generic versions).

<sup>12</sup> *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309–12 (11th Cir. 2003).

<sup>13</sup> Certiorari has been denied to the Eleventh Circuit cases that have requested it. See, e.g., *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006); *Valley Drug Co. v. Geneva Pharm., Inc.*, 543 U.S. 939 (2004).

<sup>14</sup> 15 U.S.C. § 1 (2006).

<sup>15</sup> 15 U.S.C. § 2 (2006).

<sup>16</sup> 15 U.S.C. § 1.

commerce among the several States, . . . is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony.”<sup>17</sup> There are two types of restraints: horizontal and vertical. Horizontal restraints involve direct competitors.<sup>18</sup> Vertical restraints involve companies in the supply chain, for example, suppliers or manufacturers.<sup>19</sup>

Within horizontal and vertical restraints, there are several different types, and each one is treated differently by courts. Horizontal price fixing is typically viewed as per se illegal, although courts sometimes will apply the “rule of reason” to horizontal agreements, which influence price.<sup>20</sup> Some courts hold that anything that influences price is price fixing and per se illegal.<sup>21</sup> In rule of reason analysis, the court looks at the relevant market, substitutability and the actual effect the agreement has on competition.<sup>22</sup> In describing the rule of reason approach, the Supreme Court defined it as “[e]very agreement concerning trade, every regulation of trade, restrains. . . . 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.”<sup>23</sup> Horizontal boycotts were initially treated as per se illegal according to the Supreme Court,<sup>24</sup> but subsequent cases have suggested that the per se rule

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<sup>17</sup> *Id.*

<sup>18</sup> See *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 215 (D.C. Cir. 1986) (ruling on the existence of a horizontal restraint because the members were actual competitors).

<sup>19</sup> See *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705 (2007) (discussing vertical agreements between manufacturers and distributors).

<sup>20</sup> See generally, *Bd. of Trade v. United States*, 246 U.S. 231 (1918) (applying rule of reason); *United States v. Trans-Mo. Freight Ass’n*, 166 U.S. 290, 325 (1897) (ruling per se).

<sup>21</sup> See *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 218 (1940) (referring to the history of the Court’s decision rendering price fixing agreements unlawful per se under the Sherman Act).

<sup>22</sup> See *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 20–21, 24 (1979) (holding blanket licenses acceptable in copyright cases because they reduce theft and lower transaction costs).

<sup>23</sup> *Bd. of Trade*, 246 U.S. at 238.

<sup>24</sup> See, e.g., *Fashion Originators’ Guild of America, Inc. v. FTC*, 312 U.S. 457, 465 (1941) (a scheme developed by textile and garment manufacturers violated both the Clayton and Sherman Antitrust Acts).

only applies in certain cases.<sup>25</sup> Vertical price fixing—price fixing among suppliers and distributors—is also governed by the rule of reason approach.<sup>26</sup>

Section 2 of the Sherman Act addresses monopolization.<sup>27</sup> Monopolies involve the acts of a single firm. According to the Act, it is illegal to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, . . . shall be deemed guilty of a felony.”<sup>28</sup>

Patent law is potentially at odds with both sections of the Sherman Act. Often, a patent grants a monopoly and allows its owner to charge a higher price than the market would allow with competition. These acts would traditionally violate Section 2 of the Sherman Act, but patent law makes them lawful.<sup>29</sup> Patent law also allows a patent owner to defend its patent when that patent is infringed.<sup>30</sup> If the owner wishes to avoid long and costly litigation, however, and decides to settle with the infringer, section 1 of the Sherman Act is violated.<sup>31</sup> The violation occurs because the settlement is an agreement between competitors.<sup>32</sup>

One particular area where patent law and antitrust law collide is pharmaceuticals. Congress faces competing goals of encouraging innovation while, at the same time, lowering the cost of drugs to consumers. In an effort to accomplish these goals, Congress passed the Hatch-Waxman Act. Unfortunately, as discussed below, the Act has only served to increase the tension between patent law and antitrust law.<sup>33</sup>

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<sup>25</sup> *Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 297 & n9 (1985).

<sup>26</sup> *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705 (2007) (holding vertical price-fixing arrangements to be judged by rule of reason).

<sup>27</sup> 15 U.S.C. § 2 (2006).

<sup>28</sup> *Id.*

<sup>29</sup> 35 U.S.C. § 154(a)(1) (2006) (A patent grants “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”).

<sup>30</sup> 35 U.S.C. §§ 271, 281 (2006).

<sup>31</sup> *See* 15 U.S.C. § 1 (2006).

<sup>32</sup> *Id.*

<sup>33</sup> *See* discussion *infra* Part IV.

### III. THE HATCH-WAXMAN ACT

Congress enacted the Hatch-Waxman Act in 1984 as an amendment to the Federal Food, Drug, and Cosmetic Act and the Patent Act.<sup>34</sup> The goal of the Act was to encourage innovation in pharmaceuticals and to help put generic drugs on the market faster.<sup>35</sup> The Act extended patents and established a new way for generic drugs to obtain FDA approval.<sup>36</sup> This section will describe the background leading up to the passing of the Hatch-Waxman Act, the Act as it is now, and the developments since its enactment.

#### A. *Background and Congressional Intent*

Prior to 1984, Congress had a dual problem regarding patents and pharmaceuticals.<sup>37</sup> The first part dealt with innovators. When a pharmaceutical company is looking to manufacture and market a new drug, it must file a New Drug Application (NDA) with the FDA. Putting together an NDA “is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug’s safety and efficacy.”<sup>38</sup> However, the company must frequently file for the patent prior to conducting the clinical trials needed for FDA approval. Thus, the clock starts ticking on the patent immediately even though the company is unable to start marketing the drug until receiving FDA approval. Due to the time it takes to run all of the clinical trials required to receive FDA approval, the effective time for a patent was significantly reduced, sometimes by up to ten years.<sup>39</sup> This decreased the time an innovator had to recoup its expenses in research and development before generics

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<sup>34</sup> Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585.

<sup>35</sup> See H.R. REP. NO. 98-857, pt. 2, at 4–5 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2687–89.

<sup>36</sup> *Id.*

<sup>37</sup> *Examining the Interrelationship Between the Intellectual Property Provisions of the GATT Treaty Implementing Law and Food and Drug Law and Its Impact on the Creation of New Breakthrough Drugs and Production of Lower Generic Copies and S. 1277 a Bill to Provide Equitable Relief for the Generic Drug Industry, and for Other Purposes Before the S. Comm. on the Judiciary*, 104th Cong. 120 (1996) [hereinafter Mossinghoff] (statement of Gerald J. Mossinghoff, President, Pharmaceutical Research & Manufacturers of America).

<sup>38</sup> *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001).

<sup>39</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984) (“[I]t now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. . . . [T]he remaining effective life of patent protections assertedly may be as low as 7 years.”).

came to market. Thus, Congress attempted to “restor[e] . . . some of the time lost on patent life while the product is awaiting pre-market approval.”<sup>40</sup>

The second part of the problem dealt with putting generics on the market. In *Roche Prods., Inc. v. Bolar Pharm. Co.*,<sup>41</sup> the court held that performing the tests the FDA requires before a generic drug may be marketed is an act of patent infringement if executed during the patent period.<sup>42</sup> Bolar was developing a generic version of one of Roche’s drugs to market after Roche’s patent expired.<sup>43</sup> Because approval could take more than two years, Bolar began tests on its generic version before Roche’s patent expired.<sup>44</sup> Roche argued that “the use of a patented drug for federally mandated premarketing tests is a use in violation of the patent laws.”<sup>45</sup> At the time, the applicable law stated “[w]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.”<sup>46</sup> The court agreed with Roche that a patent owner “does not need to have any evidence of damage or lost sales to bring an infringement action.”<sup>47</sup> Bolar argued that, in the interest of public policy, it should be allowed to do tests in order to create a generic version and lower prices for consumers.<sup>48</sup> The court rejected that argument, however, and held that Bolar infringed Roche’s patent by performing tests during Roche’s patent’s life.<sup>49</sup> Thus, generic drug companies had to wait until the patent had expired before filing for FDA approval, thereby adding a considerable time lag between expiration of the patents and the marketing of the cheaper generics.

To solve this problem, Congress sought a means to restore the time lost due to regulatory review.<sup>50</sup> The goal was “to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously

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<sup>40</sup> H.R. REP. NO. 98-857, pt. 1, at 15 (1984).

<sup>41</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>42</sup> *Id.* at 863.

<sup>43</sup> *Id.* at 860.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at 861 (quoting 35 U.S.C. § 271(a)).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 862.

<sup>49</sup> *Id.* at 865.

<sup>50</sup> Mossinghoff, *supra* note 37, at 113.

enabling competitors to bring cheaper, generic copies of those drugs to market.”<sup>51</sup>

First, Congress wanted to encourage innovators by compensating for delays in drug approval with extensions in patents.<sup>52</sup> Second, Congress wanted to address the delays and uncertainties surrounding the drug approval process for innovators and generic manufacturers.<sup>53</sup> Finally, Congress wanted to make it possible for generics to reach the market faster.<sup>54</sup> Generics are significantly cheaper than brand names, and because they reach the market faster, the drugs cost less and are more available to consumers.

### B. The Act

To accomplish its goals, Congress passed the Hatch-Waxman Act.<sup>55</sup> In theory, the Act met all of Congress’ goals. It extended patents to compensate for time lost during FDA approval and allowed generics to be approved prior to the expiration of patents, thereby helping them to reach the market as soon as the patent expired.<sup>56</sup>

First, the Act encouraged innovators to continue to develop new drugs. Prior to the Act, innovators lost a large portion of their patent—sometimes up to ten years—due to the time it took to obtain FDA approval.<sup>57</sup> To solve this problem, the Act extended patents to compensate for some of the lost time and allow innovators to recoup their research and development costs.<sup>58</sup>

Second, the Act helped generics reach the market sooner. To accomplish this, it allowed generic drug manufacturers to file an Abbreviated New Drug Application (ANDA) that relied on data from innovators demonstrating safety and effectiveness of a particular drug.<sup>59</sup> In an ANDA, the generic manufacturer need only submit data “demonstrating the generic product’s bioequiva-

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<sup>51</sup> Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds)).

<sup>52</sup> Pharm. Research & Mfrs. of Am., *White Paper on Implementation of the Hatch-Waxman Act by the U.S. Food & Drug Administration*, January 18, 2002, at 4 [hereinafter *White Paper*].

<sup>53</sup> *Id.* at 3, 4.

<sup>54</sup> Mossinghoff, *supra* note 37, at 113.

<sup>55</sup> Mossinghoff, *supra* note 37, at 62; see Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585.

<sup>56</sup> Mossinghoff, *supra* note 37, at 62.

<sup>57</sup> Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864 (Fed. Cir. 1984).

<sup>58</sup> 35 U.S.C. § 156 (2006).

<sup>59</sup> Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001).

lence with the previously approved drug.”<sup>60</sup> As a result, generic drug manufacturers do not incur the same costs as brand name drug manufacturers, and can proceed through FDA approval faster.<sup>61</sup>

To further help generics enter the market, generic manufacturers were encouraged to challenge patents that might be invalid or unenforceable.<sup>62</sup> When filing an ANDA, a generic manufacturer must make one of four certifications:

- (I) the innovator has provided the FDA with no information about any patent claiming its drug;
- (II) the patent has already expired;
- (III) the date on which the patent will expire; or
- (IV) the patent will not be infringed by the ANDA or is invalid.<sup>63</sup>

In preparing an ANDA, “otherwise infringing acts necessary to prepare [the ANDA]” are not considered patent infringement for a generic manufacturer to conduct.<sup>64</sup> However, if a generic manufacturer “submit[s] . . . [an ANDA] . . . [and] if the purpose of such submission is to obtain [FDA] approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent,” it is considered infringement.<sup>65</sup>

If an ANDA asserts a Paragraph I or a Paragraph II certification—no patent claiming the drug has been filed with the FDA or the patent has already expired—the FDA may approve the application immediately.<sup>66</sup> If an ANDA contains a Paragraph III certification—stating the date the patent expires—then the FDA’s approval of the application will not be effective until the patent expires.<sup>67</sup>

Paragraph IV certifications pose a crucial problem. If a generic manufacturer files a Paragraph IV certification, it is claiming that either its drug does not infringe the patent or the patent is invalid.<sup>68</sup> Including a Paragraph IV certi-

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<sup>60</sup> *Id.*

<sup>61</sup> U.S. Dep’t of Health and Human Servs., FDA, CDER, *Guidance for Industry, 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, & Cosmetic Act* at 1 (June 1998) [hereinafter *180-Day Exclusivity*].

<sup>62</sup> *White Paper, supra* note 52, at 10; *180-Day Exclusivity, supra* note 61 at 2.

<sup>63</sup> 21 U.S.C. § 355(j)(2)(A)(vii) (2006).

<sup>64</sup> 35 U.S.C. § 271(e)(1) (2006); *Mylan Pharm.*, 268 F.3d at 1326.

<sup>65</sup> 35 U.S.C. § 271(e)(2).

<sup>66</sup> 21 U.S.C. § 355(j)(5)(B)(i).

<sup>67</sup> 21 U.S.C. § 355(j)(5)(B)(ii).

<sup>68</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

fication is considered an act of infringement.<sup>69</sup> Under the Act, there is a twenty-day period during which time the generic manufacturer must notify the patent owner.<sup>70</sup> Then, the patent owner has forty-five days upon notification to file an infringement claim.<sup>71</sup> If a patent owner does not file suit, then the FDA may approve the application.<sup>72</sup> Upon initiation of a patent infringement action, an automatic stay on the approval of the generic drug's ANDA is put in place until the earliest of: (1) if the court decides the patent is invalid or not infringed, the date of the court's decision; (2) if the court decides that the patent is infringed, the date on which the patent expires; (3) the date that is 30 months from patent owner's receipt of notice of filing of a Paragraph IV certification; or (4) following patent expiration, upon filing of an amended Paragraph III certification.<sup>73</sup>

The major benefit to filing an ANDA using a Paragraph IV certification is that the first generic drug manufacturer to make that certification is awarded a 180-day exclusivity period.<sup>74</sup> Originally, an FDA rule required the generic drug's manufacturer to successfully defend a patent infringement suit brought by the patent owner, but the provision was removed.<sup>75</sup> Now, the generic drug's

<sup>69</sup> 35 U.S.C. § 271(e)(2)(A).

<sup>70</sup> 21 U.S.C. § 355(j)(2)(B)(ii).

<sup>71</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>72</sup> *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001).

<sup>73</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>74</sup> The Act reads, in pertinent part:

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I).

<sup>75</sup> See discussion *infra* Part III.C. The regulations originally read:

(c) Subsequent abbreviated new drug application submission.

(1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:

manufacturer needs only file and give notice, and wait the forty-five days in case the patent owner decides to file suit for patent infringement.<sup>76</sup>

Moreover, while the Act seems to achieve Congress' goal of encouraging innovation and getting generics to market faster, as discussed below, it has several negative consequences, such as multiple suits for patent infringement and antitrust violations. In addition, because of the automatic stays put in place during the patent infringement suits, the generics do not always enter the market sooner.<sup>77</sup>

### C. *Developments Since Enactment*

Since the Act was enacted, the FDA has allowed filing of ANDAs, which, in turn, allow generic drug makers to piggyback on the innovator's research and clinical trials.<sup>78</sup> Since the generic manufacturers do not need to run clinical trials, themselves, they save money. Piggybacking on innovator's research raises an interesting antitrust question, particularly in light of the fact that once a generic manufacturer piggybacks on the research, it may challenge the innovator's patent. In antitrust, competitors are allowed to restrict the use of assets to avoid free riding.<sup>79</sup> However, this piggybacking on the innovator's research raises an antitrust issue apart from the patent settlements problem. "Compelling . . . firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities."<sup>80</sup> In *Rothery Storage & Van Co. v. Atlas Van Lines*,<sup>81</sup> the court allowed Atlas to restrict the use of its materials to Atlas affiliates operating as Atlas agents to prevent free riding by other van lines.<sup>82</sup> Even though boycotts

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(i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or

(ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

21 C.F.R. § 314.107 (1995) (current version at 21 C.F.R. 314.107 (2007)).

<sup>76</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>77</sup> *Id.*

<sup>78</sup> Weiswasser & Danzis, *supra* note 5, at 585.

<sup>79</sup> *See Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 215–16, 221 (D.C. Cir. 1986).

<sup>80</sup> *Verizon Comm. Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407–08 (2004).

<sup>81</sup> 792 F.2d 210 (D.C. Cir. 1986).

<sup>82</sup> *Id.* at 221.

were per se illegal at the time of *Rothery Storage*, the judge held the boycott was not a Sherman Act violation because it was designed to make the company more efficient, not to restrict quantity or raise prices.<sup>83</sup>

Since 1984, the 180-day exclusivity period has been further clarified. In *Mova Pharmaceutical Corp. v. Shalala*,<sup>84</sup> Mova sued the FDA for approving Mylan Pharmaceuticals, Inc.'s generic version, when Mova had filed an earlier application with a Paragraph IV certification.<sup>85</sup> Mova's application had not been approved by the FDA because it was subsequently sued by Pharmacia & Upjohn Company for patent infringement.<sup>86</sup> Because of the patent infringement suit, the FDA was unable to approve Mova's application until it had successfully defended the suit.<sup>87</sup> Mova claimed that the FDA could not approve Mylan's application until 180 days after Mova had begun to market its generic version.<sup>88</sup> At that time, the FDA required the first applicant using a Paragraph IV certification to "successfully defend against a suit for patent infringement."<sup>89</sup> The court held that the successful defense requirement was inconsistent with the Hatch-Waxman Act and enjoined the FDA from approving Mylan's application.<sup>90</sup> Later, the FDA removed the successful defense requirement from its regulations.<sup>91</sup>

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<sup>83</sup> *Id.* at 215, 221.

<sup>84</sup> 140 F.3d 1060 (D.C. Cir. 1998).

<sup>85</sup> *Id.* at 1062.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at 1062–63.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 1065 (quoting 21 C.F.R. § 314.107(c)(1)).

<sup>90</sup> *Id.* at 1074.

<sup>91</sup> The regulations now read:

(c) Subsequent abbreviated new drug application submission.

(1) If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:

- (i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or
- (ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

In 1996, the Boston Consulting Group did a study of the Act called “Sustaining Innovation in U.S. Pharmaceuticals: Intellectual Property Protection and the Role of Patents” (the 1996 Study).<sup>92</sup> The study found that: (1) pharmaceutical innovation is highly dependent upon effective patent protection; (2) despite the best intentions of Congress to balance two public policy objectives—innovation and cost control—effective intellectual property protection for U.S. pharmaceuticals has deteriorated significantly since passage of the Hatch-Waxman Act; (3) unanticipated marketplace changes have further eroded the incentives for pharmaceutical innovation; (4) the resulting imbalance of the two public policy objectives may have serious implications for the pharmaceutical research pipeline; and (5) legislative action to rebalance these objectives should be seriously considered.<sup>93</sup>

As to the first point, the 1996 Study found that before the Act, innovators’ patents had market exclusivity for fourteen to seventeen years: “nine years of effective patent life plus a five- to eight-year period between patent expiration and the marketing of a generic copy.”<sup>94</sup> With the passing of the Act, generic drug manufacturers are now able to rely on safety and effectiveness data from the innovator, which enables them to enter the market immediately upon expiration of the patent, thereby shrinking the patent’s effective life to an average of 11.7 years.<sup>95</sup> In all other areas of patent law, this sort of piggybacking on an innovator’s clinical trials would be patent infringement, but the Act exempts it in this situation.<sup>96</sup> Furthermore, the ability to rely on an innovator’s clinical trials reduced the cost of bringing a generic drug to market from “tens to hundreds of millions of dollars to under one million dollars . . . less than 1/500th the cost of developing a pioneer drug.”<sup>97</sup>

Second, the 1996 Study discovered that several marketplace changes made it even less likely for innovators to develop drugs.<sup>98</sup> First, the cost to develop a drug went from \$100 million in 1984 to \$500 million in 1996.<sup>99</sup> In addi-

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21 C.F.R. § 314.107 (2007).

<sup>92</sup> Mossinghoff, *supra* note 37, at 116.

<sup>93</sup> *Id.* at 117–18.

<sup>94</sup> *Id.* at 121.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 122.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 123.

<sup>99</sup> *Id.*

tion, the time to develop a drug increased from five to seven years, to almost fifteen years.<sup>100</sup>

Because of the erosion in market share caused by generic drugs and the increased cost to develop new drugs, the 1996 Study concluded that pharmaceutical companies will cut back on research and development.<sup>101</sup> Unfortunately, those cutbacks “will most likely be made in high-risk categories” such as “[c]ancer, AIDS, [and] Alzheimer’s.”<sup>102</sup>

Finally, the 1996 Study proposed several legislative solutions to the problem. One option would be to credit more time to the patent for the clinical research phase—the Act provides for only half of the time for this phase to be credited towards an extension.<sup>103</sup> Furthermore, all regulatory review activities that take place after the patent application is filed should be considered in determining the length of the extension.<sup>104</sup>

In theory, the Act accomplishes Congress’ goals. In reality, however, it not only does not increase the effective patent life for innovators, but also results in patent infringement suits and subsequent antitrust suits.

#### IV. ANTITRUST & SETTLING PATENT INFRINGEMENT SUITS

Once a generic drug maker files a Paragraph IV certification and the innovator files a patent infringement suit, the suit must be settled in some way. Often, the suit is settled by the innovator paying the generic manufacturer a sum of money to hold off on putting its generic drug on the market until the patent expires. Unfortunately, that violates Section 2 of the Sherman Act because it is an agreement between competitors.

This section will first describe the different types of settlements used in patent infringement suits. Then, it will describe how the settlements run into antitrust problems. Finally, it will discuss the resulting antitrust suits.

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<sup>100</sup> *Id.*

<sup>101</sup> *Id.* at 125.

<sup>102</sup> *Id.* at 124–25.

<sup>103</sup> *Id.* at 125–26.

<sup>104</sup> *Id.* at 126–27.

### A. Patent Infringement Settlements

There are three different types of settlement agreements in patent infringement suits.<sup>105</sup> The first type is a supply agreement.<sup>106</sup> In a supply agreement, the innovator allows the generic manufacturer to sell the brand name under the innovator's generic name.<sup>107</sup> Effectively, the generic manufacturer becomes a distributor of the innovator's drug.<sup>108</sup> The second type of settlement is a license.<sup>109</sup> In a license agreement, the innovator allows the generic manufacturer to use its patent.<sup>110</sup> In some agreements, the generic manufacturer can immediately market its generic version, but, in others, there is a waiting period.<sup>111</sup> The final type of settlement is brand payments, where the innovator pays the generic manufacturer to not market the drug, sometimes called reverse payment settlements.<sup>112</sup> According to an FTC study, innovators have paid generic manufacturers between \$1.75 million and \$132.5 million to wait until a patent expires, sometimes up to ten years.<sup>113</sup> This third type of settlement agreement poses anti-trust problems because the innovator is paying the generic manufacturer to keep its product off the market, thereby keeping the price of the drug higher.

Additionally, because of the structure of the 180-day exclusivity period, other generic drug makers must wait until 180 days after the first generic manufacturer begins to commercially market its generic before they can enter the market.<sup>114</sup> Thus, “[i]f the brand name manufacturer can reach a settlement agreement, convincing the first ANDA filer not to enter the market, he prevents all generic entry.”<sup>115</sup>

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<sup>105</sup> John Fazzino, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property & Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POL'Y 1, 13 (2006).

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at 13–14.

<sup>112</sup> *Id.* at 14.

<sup>113</sup> *Id.*

<sup>114</sup> See discussion *supra* Part III.B.

<sup>115</sup> Fazzino, *supra* note 105, at 12. This type of agreement would fail the Eleventh Circuit's three-part test because it goes beyond the scope of the patent.

### B. *Antitrust and Patent Infringement Settlements*

Three federal statutes deal with antitrust law: the Sherman Act, the Clayton Act, and the Federal Trade Commission Act (FTC Act). As discussed above,<sup>116</sup> the Sherman Act has two sections. Section 1 addresses agreements between competitors. Section 2 addresses monopoly by one company.

Because patent infringement settlements typically involve agreements between brand name and generic manufacturers, they are often analyzed under section 1 of the Sherman Act. The settlements are agreements between horizontal competitors to either restrict the supply or the price of the drugs. Thus, courts can contend with these settlements using either a per se or rule of reason approach. If a court uses a per se approach, all settlements will be automatically illegal regardless of positive effects the agreement may have on the market. If a court uses a rule of reason approach, it will look at the relevant market and weigh any positive effects of the agreement on competition.

In addition to the Sherman Act, the Clayton Act also deals with antitrust by allowing private suits.<sup>117</sup> “[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor . . . and shall recover *threefold the damages by him sustained*, and the cost of suit, including a reasonable attorney’s fee.”<sup>118</sup> When a private person wins a suit for an antitrust violation, he is awarded treble damages.<sup>119</sup> In a civil suit, the plaintiff must show that he has been injured, that his injury is an antitrust injury, or the result of a restraint of competition, and that he is the efficient enforcer—that he has something at stake.<sup>120</sup> In dealing with pharmaceutical companies, private citizens can sue brand name manufacturers for keeping prices high by not allowing generics on the market.<sup>121</sup> This is particularly problematic because plaintiffs can receive treble damages. If the risk of treble damages outweighs the profit, this even further discourages patent settlements.

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<sup>116</sup> See discussion *supra* Part II.

<sup>117</sup> Clayton Act, 15 U.S.C. § 15(a) (2006).

<sup>118</sup> *Id.* (emphasis added).

<sup>119</sup> *Id.*

<sup>120</sup> *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (“Plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful”); *Todorov v. DCH Healthcare Auth.*, 921 F.2d 1438, 1449 (11th Cir. 1991) (determining if the plaintiff is an “efficient enforcer of the antitrust laws . . . requires some analysis of the directness or remoteness of the plaintiff’s injury”).

<sup>121</sup> See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

Finally, the FTC Act deals with anticompetitive practices.<sup>122</sup> The FTC Act states that “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful”<sup>123</sup> and, therefore, incorporates and prevents conduct that violates the Sherman Act.<sup>124</sup> The FTC Act also empowers the FTC to “prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.”<sup>125</sup> As a result, the FTC plays a large role in patent infringement settlements between innovators and generic pharmaceutical manufacturers. The FTC has applied its statutory authority to challenge settlements between innovators and generic manufacturers. In *In re Schering-Plough, Corp.*,<sup>126</sup> the FTC rejected settlements made by Schering-Plough with two generic competitors.<sup>127</sup> After a rule of reason analysis, the FTC held that the settlements violated section 5 of the FTC Act and section 1 of the Sherman Act because of Schering-Plough’s payment to the generic manufacturer in exchange for the generic’s delay to competitive entry.<sup>128</sup> Similarly, the FTC rejected Bristol-Myers’ agreement with Apotex.<sup>129</sup>

In the Bristol-Myers case discussed above, Apotex filed an ANDA with a Paragraph IV certification with the FDA in 2002.<sup>130</sup> Bristol-Myers’ patent for Plavix would not expire until 2011, but Apotex claimed it was invalid because Plavix’s composition could be inferred from an already expired patent.<sup>131</sup> In January 2006, the FDA approved Apotex’s generic version, and Apotex threat-

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<sup>122</sup> 15 U.S.C. § 45(a) (2006).

<sup>123</sup> 15 U.S.C. § 45(a)(1).

<sup>124</sup> See, e.g., *Fashion Originators’ Guild of Am., Inc. v. FTC*, 312 U.S. 457, 463–64 (1941) (finding if actions run “counter to the public policy declared in the Sherman and Clayton Acts, the Federal Trade Commission has the power to suppress it as an unfair method of competition”).

<sup>125</sup> 15 U.S.C. § 45(a)(2).

<sup>126</sup> No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003).

<sup>127</sup> *Id.* On appeal, however, the Eleventh Circuit reversed and held the settlements valid. *Schering-Plough Corp v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

<sup>128</sup> *In re Schering-Plough, Corp.*, No. 9297, 2003 WL 22989651.

<sup>129</sup> Saul, *supra* note 1.

<sup>130</sup> John Carreryrou & Joann S. Lublin, *Emergency Room: How Bristol-Myers Fumbled Defense of \$4 Billion Drug – CEO Dolan’s Plan to Delay Generic Went Haywire; Board to Discuss His Fate – Doing a Deal with the ‘Devil’*, WALL ST. J., Sept. 2, 2006, at A1; see *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317 (S.D.N.Y. 2006).

<sup>131</sup> Carreryrou, *supra* note 130.

ened to market its generic drug before settlement of the patent infringement suit.<sup>132</sup> As a result, Bristol-Myers' CEO, Peter Dolan, tried to settle with Apotex by offering to pay \$40 million in exchange for Apotex delaying introduction of its generic version until 2011, and Apotex also agreeing not to compete with an authorized generic manufactured by Bristol-Myers.<sup>133</sup> The settlement was rejected by the FTC, however, as anticompetitive.<sup>134</sup> Bristol-Myers and Apotex continued negotiations, but the FTC also rejected the second settlement.<sup>135</sup> Unfortunately, provisions in the event of a rejection by antitrust regulators in the second settlement crippled Bristol-Myers because it prevented the drug maker from seeking an injunction against Apotex's generic version, allowing Apotex to flood the market with its generic version. Even if Bristol-Myers wins the patent infringement suit, it will be unable to recoup its lost profits because Apotex was able to sell six months worth of its generic version before Bristol-Myers obtained the injunction.<sup>136</sup> Consequently, CEO Peter Dolan was fired by Bristol-Myers.<sup>137</sup>

Currently, most courts do not share the FTC's view that patent infringement settlements (especially reverse payment settlements) violate antitrust laws.<sup>138</sup> Additionally, although both the Senate and the House of Representatives have proposed legislation that would go a long way toward codifying the FTC's view, the proposed legislation has not been enacted.<sup>139</sup> The FTC and proponents of the proposed legislation argue that any payments made by the innovator to the generic manufacturer are, by nature, anticompetitive.<sup>140</sup>

The Senators and the FTC, however, ignore the fact that the Patent Act grants patent holders the prerogative to structure settlements, unless the patent is

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<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> Saul, *supra* note 1.

<sup>136</sup> Arlene Weintraub, *The Power of the Pipeline: Bristol-Myers Squibb is Beset with Troubles, but Its New-Drug Potential Makes It a Target*, BUS. WK., Feb. 26, 2007, Vol. 4023 ("Bristol-Myers] lost more than \$700 million in Plavix sales in the last quarter alone.")

<sup>137</sup> *Id.* There were other factors in Mr. Dolan's firing, but the Apotex settlement issue was a major part of it. See John Carey, *Why Peter Dolan Got the Boot*, BUS. WK., Sept. 25, 2006.

<sup>138</sup> John E. Osborn, *Life Sciences Innovation & Antitrust Law*, THE NAT'L L.J., Sept. 18, 2006.

<sup>139</sup> See, e.g., Press Release, Sen. Grassley, Grassley, Kohl, Leahy and Schumer Introduce Bill to Stop 'Payoffs' That Delay Generic Drugs (June 27, 2006), available at [http://grassley.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease\\_id=b292869c-4975-41a9-a6ad-7230ba8c03a2&Month=6&Year=2006](http://grassley.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=b292869c-4975-41a9-a6ad-7230ba8c03a2&Month=6&Year=2006).

<sup>140</sup> *Id.*; Osborn, *supra* note 138.

a sham.<sup>141</sup> The FTC “effectively dismisses the presumption by suggesting that no such settlement would be necessary if the patent were, in fact, capable of precluding the generic product from coming into the market.”<sup>142</sup> As stated by the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,<sup>143</sup> a patent is inherently anticompetitive and grants the owner the right to keep competitors out of the market.<sup>144</sup> In addition, the FTC’s position does not take account of the complexity of patent infringement analysis. Defending a patent suit is extremely expensive and a full trial is not cost-effective if a reasonable settlement could be reached. Moreover, businesses, such as pharmaceutical companies, prefer to avoid the uncertainty of litigation. Thus, the ability to settle patent infringement suits is not only granted in the Patent Act, but also crucial to businesses for financial reasons.

From an economic view, pharmaceutical companies will not continue to innovate new drugs if they know that they will be forced to litigate patent infringement suits and, if they try to settle those suits, antitrust suits. Because of litigation, these companies will expend any profits gained from the patent. Yet, if the companies do not litigate, the profits will be lost because of generics entering the market earlier.

### C. Resulting Antitrust Suits

Consistent with the FTC’s view that certain patent infringement settlements violate antitrust laws, there have been numerous private antitrust suits based on these settlements, as well as other efforts by pharmaceutical companies to exclude or delay generic competition. In *Louisiana Wholesale Drug Company, Inc. v. Biovail Corp.*<sup>145</sup> and the related *Twin Cities Bakery Workers Health & Welfare Fund v. Biovail Corp.*,<sup>146</sup> private citizens sued Biovail because of higher prices resulting from Biovail’s successful attempt to keep Andrx’s generic version of Tiazac off the market.<sup>147</sup> Biovail had held the patent to Tiazac, a drug used to treat hypertension and angina, since September 1995.<sup>148</sup> In both

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<sup>141</sup> Osborn, *supra* note 138.

<sup>142</sup> *Id.*

<sup>143</sup> 344 F.3d 1294 (11th Cir. 2003).

<sup>144</sup> *Id.* at 1304–05.

<sup>145</sup> 437 F. Supp. 2d 79 (D.D.C. 2006).

<sup>146</sup> No. Civ. A. 01-2197(JR), 2005 WL 3675999 (D.D.C. Mar. 31, 2005).

<sup>147</sup> *La. Wholesale Drug Co.*, 437 F. Supp. 2d 79; *Bakery Workers Health & Welfare Fund*, 2005 WL 3675999.

<sup>148</sup> *Bakery Workers Health & Welfare Fund*, 2005 WL 3675999, at \*1.

cases, the court ruled in favor of Biovail because “the plaintiffs could not prove that Biovail’s unlawful acts caused them injury.”<sup>149</sup>

In *Louisiana Wholesale Drug*, the plaintiffs alleged that Biovail was developing its own generic version, but because it had successfully stopped Andrx, it did not put its generic version on the market.<sup>150</sup> Allegedly, Biovail and its distributor, Forest Laboratories, estimated the generic demand and prepared to produce enough to supply 100% of the demand.<sup>151</sup> Biovail planned to provide incentives to encourage its large buyers to purchase Biovail’s generic version, not Andrx’s.<sup>152</sup> Additionally, Biovail and Forest would regulate prices in order to benefit from bringing its own generic to the market.<sup>153</sup> However, Biovail and Forest never brought the generic to market because of the listing of another patent that delayed Andrx’s generic drug, and “ma[de] it unnecessary for Biovail to compete against itself.”<sup>154</sup> As a result, Louisiana Wholesale sued for treble damages under section 4 of the Clayton Act claiming that it was forced to pay “supra-competitive prices for Tiazac.”<sup>155</sup> The court ruled that if the plaintiff’s claims were true, Biovail would have violated antitrust laws because “[i]llegally-maintained supra-competitive pricing is the kind of injury the anti-trust laws were designed to prevent, and injuries caused by such activity flowed from an illegal scheme.”<sup>156</sup> The court never determined if the plaintiff’s claims were true, however, because the claim was barred by the statute of limitations.<sup>157</sup>

In *Andrx Pharmaceuticals, Inc. v. Elan Corp.*,<sup>158</sup> the court held that, if the allegations were true, Elan’s settlement with SkyePharma, Inc. violated anti-trust laws.<sup>159</sup> Elan owned a patent for a naproxen medication for which SkyePharma filed an ANDA for a generic version using a Paragraph IV certification.<sup>160</sup> In response, Elan filed a patent infringement suit.<sup>161</sup> Elan and SkyePharma entered into a settlement agreement “in which SkyePharma admit-

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<sup>149</sup> *La. Wholesale Drug Co.*, 437 F. Supp. 2d at 81.

<sup>150</sup> *Id.* at 81–82.

<sup>151</sup> *Id.* at 82.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 84.

<sup>156</sup> *Id.* at 85.

<sup>157</sup> *Id.*

<sup>158</sup> *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 1231.

<sup>161</sup> *Id.*

ted to infringing the . . . patent in exchange for a license from Elan to manufacture a generic . . . naproxen medication.”<sup>162</sup> Andrx sued Elan and SkyePharma claiming that the agreement was a restraint of trade because SkyePharma had no intention of selling the generic version, thereby never triggering the 180-day exclusivity period as the first filer.<sup>163</sup> While the court held that the *Noerr-Pennington* doctrine<sup>164</sup> shielded Elan from antitrust liability, it also found that, if the allegations Andrx made were true, the agreement was an antitrust violation.<sup>165</sup> Because the agreement between Elan and SkyePharma barred any generic from entering the market (since SkyePharma never triggering the 180-day exclusivity period), it exceeded the scope of the patent.<sup>166</sup>

Antitrust suits pose a problem for the pharmaceutical industry. Because of the possibility of treble damages in private suits, pharmaceutical companies may try to compensate in advance by raising prices. This defeats the purpose of the Hatch-Waxman Act—lower prices for consumers. If companies know they could be forced to defend an antitrust suit when they are only trying to protect their patent rights, they will factor the expected cost of litigation and damages into the initial prices of the drugs. However, if the FTC and the FDA give pharmaceutical companies certainty in litigation costs and the processes involved, then pharmaceutical companies will be less likely to over-estimate these costs.

As described above, Biovail developed its own generic version years earlier than it would have, had it not been for the unsuccessful challenge by Andrx. In addition to those costs, Biovail defended itself in numerous litigations. At some point, Biovail must recoup these losses, and the most likely means is increased drug pricing. Further, Elan and SkyePharma were able to bar all generics from entering the market because they never triggered the 180-day exclusivity period. If there was more certainty in settling patent infringement suits, these added costs and delays to generics might not have occurred

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<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> The *Noerr-Pennington* doctrine states that a defendant is immune from antitrust liability when he is petitioning the government to change the law in favor of the defendant. *Id.* at 1233 (citing *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965)). Thus, if a defendant resorts to litigation in order to obtain an anticompetitive outcome, he is not liable under the Sherman Act. *Id.*

<sup>165</sup> *Id.* at 1233 (the *Noerr-Pennington* doctrine grants immunity to defendants “who exercise their right to petition government by resorting to administrative and/or judicial proceedings”).

<sup>166</sup> *Id.* at 1235.

because Elan and Biovail would have had better knowledge of how to appropriately structure a settlement agreement.

## V. POSSIBLE SOLUTIONS AND THEIR PROBLEMS

Presently, under the FTC's approach it is extremely difficult to settle a patent infringement suit without running into antitrust issues. Nevertheless, there are actions that would increase certainty in dealing with patent infringement issues. First, Congress could revise the Hatch-Waxman Act. Second, patent infringement suits could be settled differently, using a consistent standard such as the one developed by the Eleventh Circuit.

### A. *Change the Hatch-Waxman Act*

Congress could revise the Hatch-Waxman Act to explicitly state that antitrust laws do or do not apply to Hatch-Waxman Act settlements. The Supreme Court has held that, unless the statute says otherwise, antitrust laws apply.<sup>167</sup> If Congress "intend[s] to repeal the antitrust laws, that intent governs."<sup>168</sup> Congress must make that intent clear, however, unless there is implied immunity.<sup>169</sup> Nevertheless, implied immunity is applied only in rare situations that typically already have pervasive regulation or specific conflicts with antitrust laws.<sup>170</sup>

Antitrust saving clauses have been used in other statutes. Most recently, the Supreme Court held that antitrust laws did not apply in a securities laws case.<sup>171</sup> The issue was "whether the Securities and Exchange Commission's

<sup>167</sup> See *United States v. Trans-Mo. Freight Ass'n*, 166 U.S. 290, 325 (1897).

<sup>168</sup> *Billings v. Credit Suisse First Boston Ltd.*, 426 F.3d 130, 147 (2d Cir. 2005), *rev'd on other grounds sub nom. Credit Suisse Sec. (USA) LLC v. Billings*, 127 S. Ct. 2383 (2007) (quoting *Nat'l Gerimedical Hosp. & Gerontology Ctr. v. Blue Cross of Kansas City*, 452 U.S. 378, 389 (1981)).

<sup>169</sup> *Id.* ("Implied immunity will be found only in the face of a 'plain repugnancy between the antitrust and regulatory provisions,' only if repeal is necessary to make the regulatory provisions work, 'and even then only to the minimum extent necessary.'" (citations omitted)).

<sup>170</sup> *Id.* at 146–60; see *Gordon v. NYSE*, 422 U.S. 659, 691 (1975) (immunity granted because Congress gave the SEC to power to regulate and fix rates); *Silver v. NYSE*, 373 U.S. 341, 353 (1963) (implied immunity was not granted here; however, the Court implied that if there was the power of the SEC to review conduct, then the conduct may be immune from antitrust laws particularly when the reviewing agency is concerned with competition). *But see United States v. Phila. Nat'l Bank*, 374 U.S. 321, 350 (1963) (finding no implied antitrust immunity because the Bank Merger Act did not give rise to a strong implication of a repeal of antitrust laws. "No express immunity is conferred by the Act . . . Contrast this with the express exemption provisions of . . . the Federal Aviation Act . . . , Federal Communications Act . . .").

<sup>171</sup> *Credit Suisse Sec.*, 127 S. Ct. at 2383.

regulation of investment banks gives those banks immunity from antitrust lawsuits.”<sup>172</sup> The district court held that the “securities laws impliedly repealed federal antitrust laws and preempted state antitrust laws.”<sup>173</sup> On appeal, the Second Circuit reversed and held that the regulation by the SEC did not result in antitrust immunity.<sup>174</sup> The Second Circuit noted that there is neither legislative history indicating that Congress intended to have antitrust immunity apply, nor are the securities laws irreconcilable with antitrust laws.<sup>175</sup> The Supreme Court reversed the Second Circuit, however, and held that the securities laws implicitly precluded the application of antitrust laws in this case.<sup>176</sup>

In contrast, in *Verizon Communications Inc. v. Law Office of Curtis V. Trinko, LLP*,<sup>177</sup> the Supreme Court held that the Telecommunications Act of 1996 did not affect the application of antitrust laws.<sup>178</sup> Under the Telecommunications Act, Verizon had to share its network with competitors, and signed interconnection agreements with rivals allowing them to use its network.<sup>179</sup> Curtis V. Trinko, LLP claimed, however, that Verizon was not filling the orders of its competitors on time in an effort to “deter potential customers [of rivals] from switching.”<sup>180</sup> The complaint sought damages for violation of Section 2 of the Sherman Act.<sup>181</sup> The district court dismissed the antitrust claim, but the Second Circuit reinstated it.<sup>182</sup> The Supreme Court stated that “a detailed regulatory scheme such as that created by the 1996 Act ordinarily raises the question whether the regulated entities are not shielded from antitrust scrutiny altogether by the doctrine of implied immunity.”<sup>183</sup> The Court also noted that Congress added an “antitrust-specific saving clause providing that ‘nothing in this Act or the amendments made by this Act shall be construed to modify, impair, or supersede the applicability of the antitrust laws.’”<sup>184</sup> Nevertheless, the Court held

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<sup>172</sup> Alan Murray, *Business: Wal-Mart’s Lesson for Wall Street*, WALL ST. J., Dec. 13, 2006, at A2.

<sup>173</sup> *Billing*, 426 F.3d at 137 (citing *In re Initial Pub. Offering Antitrust Litig.*, 287 F. Supp. 2d 497, 499, 523–25 (S.D.N.Y. 2003)).

<sup>174</sup> *Id.* at 137.

<sup>175</sup> *Id.* at 169.

<sup>176</sup> *Credit Suisse Sec.*, 127 S. Ct. at 2389.

<sup>177</sup> 540 U.S. 398 (2004).

<sup>178</sup> *Id.* at 401–16.

<sup>179</sup> *Id.* at 402.

<sup>180</sup> *Id.* at 405.

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.* at 406.

<sup>184</sup> *Id.* (quoting 47 U.S.C. § 152).

the complaint failed to state a claim under antitrust and reversed the Second Circuit.<sup>185</sup>

If Congress revises the Hatch-Waxman Act to include an antitrust saving provision, it would clarify whether antitrust laws do or do not apply to patent infringement settlements. To determine whether or not to add an antitrust saving clause, Congress would have to decide if the regulation by the FDA is similar to the regulation by the SEC in *Billing* or the Telecommunications Act in *Verizon Communications, Inc.*

### **B. The Eleventh Circuit Approach to Patent Infringement Settlements**

There may be a way to settle patent infringement suits without running into antitrust issues. To date, the FTC has not recognized a good way to settle patent infringement suits that avoids any antitrust problems.<sup>186</sup> To change this, there would have to be a change in the way the FTC deals with patent infringement settlements. The Eleventh Circuit has developed a three-part test to determine if a patent infringement settlement violates the Sherman Act.<sup>187</sup> The Supreme Court has denied certiorari in each of the cases in which the Eleventh Circuit applied its three-part test.<sup>188</sup>

According to the Eleventh Circuit, because a “patent grants its owner the lawful right to exclude others,” the owner of a patent may “exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions.”<sup>189</sup> Thus, in analyzing a patent infringement settlement agreement, a court must first identify the protection afforded by the patent, then look to see if the agreement resonates beyond the exclusionary effects of the patent. Finally, any part of the agreement

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<sup>185</sup> *Id.* at 416.

<sup>186</sup> *See, e.g.,* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) (the FTC challenged the settlement and the Supreme Court denied certiorari, and, therefore, did not provide any guidance); FTC v. Cephalon, Inc., No. 1:08-cv-00244 (D.D.C. filed Feb. 13, 2008) (FTC suing Cephalon for allegedly unlawfully blocking the sale of generic versions).

<sup>187</sup> Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1309–12 (11th Cir. 2003).

<sup>188</sup> *See* FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006) (denying certiorari); Valley Drug Co. v. Geneva Pharm., Inc., 543 U.S. 939 (2004) (denying certiorari); Walgreen Co. v. Abbott Labs., 543 U.S. 939 (2004) (denying certiorari).

<sup>189</sup> *Valley Drug*, 344 F.3d at 1304.

that goes beyond the protection granted by the patent is subject to antitrust analysis to determine if it violates the Sherman Act.<sup>190</sup>

The Eleventh Circuit applied its three-part test in *Schering-Plough Corp. v. FTC*, where it rejected the FTC's argument that the settlement was in excess of fair market value.<sup>191</sup> The FTC had ordered Schering-Plough and Upsher-Smith Laboratories to cease and desist from participating in a settlement of a patent infringement lawsuit where either one: "(1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time."<sup>192</sup> Schering-Plough held a patent on the extended-release coating on a tablet for treating high blood pressure and congestive heart disease.<sup>193</sup> In 1995, Upsher-Smith filed with the FDA for approval of a generic version of the extended release coating.<sup>194</sup> Schering-Plough responded with a patent infringement suit.<sup>195</sup> In 1997, before the trial began, Schering-Plough and Upsher-Smith started settlement discussions.<sup>196</sup> During these discussions, Schering-Plough proposed a compromise on the entry date of Upsher-Smith's generic version.<sup>197</sup> "Both companies agreed to September 1, 2001 as the generic's earliest entry date, but Upsher[-Smith] insisted upon its need for cash prior to the agreed entry date."<sup>198</sup> After negotiations, the parties agreed to a three-part licensing deal in which "Schering [paid] (1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales" in exchange for Upsher-Smith not putting its generic on the market until September 1, 2001.<sup>199</sup> In 1995, another pharmaceutical manufacturer, ESI Lederle, Inc., also filed with the FDA for approval of a generic version of the extended-release caplet.<sup>200</sup> Schering-Plough sued for patent infringement and entered settlement discussions with ESI.<sup>201</sup> In December 1997,

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<sup>190</sup> *Id.* at 1312.

<sup>191</sup> *Schering-Plough*, 402 F.3d at 1058.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 1059.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 1060.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

Schering-Plough made an offer for ESI to enter the market with its generic on January 1, 2004 and, at the suggestion of the judge, pay ESI \$5 million.<sup>202</sup>

On March 30, 2001, the FTC filed an administrative complaint against Schering-Plough, Upsher-Smith and American Home Products Corp. (ESI's parent corporation), alleging that the two settlements were illegal restraints of trade and violated section 5 of the FTC Act.<sup>203</sup> Initially, the Administrative Law Judge found the agreements lawful, despite the payments made by Schering-Plough.<sup>204</sup> The FTC appealed to the full Commission, however, and the Commission reversed the ALJ's decision.<sup>205</sup> "[T]he Commission concluded that the *quid pro quo* for the payment was an agreement to defer the entry dates, and that such delay would injure competition and consumers."<sup>206</sup>

On appeal from the FTC's ruling, the Eleventh Circuit rejected both the rule of reason and the *per se* approaches for antitrust suits, finding them "ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market."<sup>207</sup> The court stated that patents inherently have an anticompetitive effect, thus the court examined: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."<sup>208</sup> The court held that simply having a patent gave Schering-Plough the right to exclude Upsher-Smith and ESI from the market without violating antitrust laws.<sup>209</sup>

Despite what Congress does regarding adding an antitrust saving clause to the FTC Act, courts should adopt the three-part test developed by the Eleventh Circuit. The test would clarify how settlements would be evaluated. Companies would have a clear standard for dealing with settlements, allow them to structure settlements with certainty. Further, the three-part test makes sense as it allows patent owners to fully exploit their patents, but not to go beyond it.

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<sup>202</sup> *Id.* (If ESI received FDA approval by a certain date, Schering-Plough agreed to pay \$10 million).

<sup>203</sup> *Id.* at 1061.

<sup>204</sup> *Id.* (The "payments did not make the settlement anticompetitive, *per se*").

<sup>205</sup> *Id.* at 1062.

<sup>206</sup> *Id.*

<sup>207</sup> *Id.* at 1065.

<sup>208</sup> *Id.* at 1066 (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003)).

<sup>209</sup> *Id.* at 1067.

**VI. CONCLUSION**

The tension between patent law and antitrust law has created significant difficulties for pharmaceutical companies that seek to resolve the uncertainty of patent litigation by entering into settlements with generic manufacturers. This problem is compounded by the view of the FTC that the type of patent infringement settlement that arguably makes the most sense—agreeing to delay marketing the generic version in exchange for a sum of money—violates antitrust laws.

This article has proposed that the best way to evaluate whether or not a patent infringement settlement violates antitrust laws is the three-part test developed by the Eleventh Circuit. First, the test establishes the scope of the patent. Second, it looks to see if the agreement exceeds the patent's scope. Finally, if the agreement does exceed the scope of the patent, the court analyzes whether or not there is an anticompetitive effect. This method of evaluating settlements allows innovators and generic manufacturers to reach settlements with some certainty as to whether or not they are opening themselves up to an antitrust suit, while attempting to balance the conflicting interests of patent law and antitrust law.