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## Don't Bite the Hand That Provides Life-Saving Drugs: Application of the Hatch-Waxman and Sherman Acts to the Pharmaceutical Industry and the Detrimental Effects to Future Innovation in Order to Achieve Current Savings for Consumers

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DON'T BITE THE HAND THAT PROVIDES LIFE-SAVING DRUGS:  
APPLICATION OF THE HATCH-WAXMAN AND SHERMAN  
ACTS TO THE PHARMACEUTICAL INDUSTRY  
AND THE DETRIMENTAL EFFECTS  
TO FUTURE INNOVATION IN ORDER TO ACHIEVE CURRENT  
SAVINGS FOR CONSUMERS

I. INTRODUCTION

Political pressure to cure an ailing medical system in this country has driven Congress to focus on the pharmaceutical industry as the main culprit and the target of its reform.<sup>1</sup> In order to protect its constituency from the rising cost of prescription drugs,<sup>2</sup> Congress passed the Hatch-Waxman

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1. See *Promoting Availability of Lower Cost Generic Drugs: Hearings on H.R. 1 and S. 1 Before the S. Comm. on the Judiciary*, 108th Cong. (2003) [hereinafter *Hearings on Affordable Pharmaceuticals*] (statement of Sen. Patrick J. Leahy) ("The Senate has been struggling with the myriad of issues surrounding Medicare reform, and indeed the provision of quality, affordable health care generally, for years."); *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearings Before the S. Comm. on the Judiciary*, 108th Cong. 1 (2003) [hereinafter *Hearings on FTC Study*] (statement of Sen. Orrin G. Hatch) ("President Bush deserves credit for encouraging the Congress to act in the best interest of the public on these matters . . . I'm excited at the prospect of finally getting the job done for our seniors and those who are disabled in our society."); *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearings Before the S. Comm. on the Judiciary*, 107th Cong. 17 (2001) [hereinafter *Hearings on Patent Settlements*] (testimony of Dir. Molly Boast, Bureau of Competition, FTC) ("The surging cost of prescription drugs is a pressing national issue. Recent reports suggest expenditures for retail outpatient prescription drugs rose in the year 2000 to \$131.9 billion . . . The Commission is encouraged that Congress . . . ha[s] shown a strong interest in this issue."); James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413, 418 (2002) ("The electoral campaign polls in 2000, as well as public opinion polls in 2001, show that many consumers, especially elders, care deeply about prescription drug pricing and the availability of generics.").

2. See *Hearings on FTC Study*, *supra* note 1, at 27 (statement of Timothy J. Muris, Chairman, FTC) (stating that for sixth consecutive year increase in prescription drug spending has exceeded all other health services by wide margin); *Hearings on Patent Settlements*, *supra* note 1, at 17 (statement of Dir. Molly Boast) (stating surging cost of prescription drugs is national crisis with drug costs rising in 2000 to \$131.9 billion, an 18.8% increase from previous year); Yuk Fung Hui, *FDA's Proposed Rules on Patent Listing Requirements for New Drug and 30-Month Stays on ANDA Approval (Proposed Oct. 24, 2002)*, 12 ANNALS HEALTH L. 325, 325 n.1 (2003) (citing report in San Jose Mercury News that Medicare spending on drugs will exceed \$400 billion in 2002); Marcy L. Lobanoff, *Anti-competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch-Waxman Act*, 50 EMORY L.J. 1331, 1331 n.1 (2001) (citing study that states drug claim expenses to reach fifteen percent of health plan costs in 2001, up from ten percent in 1995); M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industry: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 363 (2002) (referring to FTC reports of increasing drug costs). A study by Health Care Financing Administration, cited by

Act (the "Act")<sup>3</sup> in 1984 to promote faster entry of generic drugs into the marketplace. While the Act has been successful in achieving the desired result,<sup>4</sup> the language of the Act has enabled brand-name and generic manufacturers to enter into agreements that potentially delay the entry of generic drug substitutes and thus violate federal antitrust laws set forth in the Sherman Act.<sup>5</sup> In response, Congress introduced legislation designed to eliminate these agreements,<sup>6</sup> the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) have increased their surveillance of antitrust violations within the pharmaceutical industry<sup>7</sup> and courts are be-

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the FTC, has shown that prescription drug spending has been increasing by the rate of 12-19% annually. *See id.*

3. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. § 355 (2000)); *see also* Ann K. Wooster, Annotation, *Construction and Application of the Hatch-Waxman Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Codified as Amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. FED. 487, 507-15 (2002) (describing construction and application of Act). For a complete discussion of the Act, *see infra* notes 46-65 and accompanying text.

4. *See* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY x (July 1998) (studying "the increase in competition in the pharmaceutical market and its effects on the profits of drug manufacturers and the prices paid for prescription drugs"). This study found that in 1984, prior to the passage of the Act, generic substitutes accounted for only nineteen percent of the market, yet by 1996, generic drugs accounted for forty-three percent of the market, resulting in savings to consumers of \$8-10 billion in 1994 alone. *See id.* at ix (reciting findings of study).

5. For a discussion of the problems caused by the language of the Act, *see infra* notes 66-85 and accompanying text.

6. *See generally* Drug Competition Act of 2003, S. 946, 108th Cong. (2003) ("A bill to enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding brand name drugs and generic drugs."); Prescription Drug Fair Competition Act of 2002, H.R. 5272, 107th Cong. (2002) ("A bill to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals."); Drug Competition Act of 2001, H.R. 1063, 107th Cong. (2001) ("A bill to enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding brand name drugs and generic drugs."); Drug Competition Act of 2001, S. 754, 107th Cong. (2001) (providing for legislation similar to that of H.R. 1063).

7. *See Hearings on FTC Study, supra* note 1, at 77 (statement of Sen. Leahy) ("[I]t was the Federal Trade Commission that played such an important role in exposing the issues of drug companies paying their generic competitors . . . not to enter the marketplace."); FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), available at <http://www.ftc.gov/os/2002/07/generic-drugstudy.pdf> [hereinafter *FTC STUDY*] (studying abuses under Hatch-Waxman Act); Morse, *supra* note 2, at 359 (stating "FTC has devoted substantial antitrust enforcement resources" to targeting pharmaceutical industry); Scott P. Perlman & Jay S. Brown, *FTC Targets Patent Settlement Agreements: Recent Actions Illustrate Permissible and Unlawful Deals*, NAT'L L.J., Nov. 11, 2002, at C1 (discussing interplay between intellectual property and antitrust concerns within pharmaceutical industry). The authors state:

ing called upon more frequently to rule on the difficult task of analyzing antitrust violations in the pharmaceutical patent arena.<sup>8</sup>

While the involvement of the federal legislature and judiciary is laudable and the need to protect consumers is obvious,<sup>9</sup> this involvement will decrease the pharmaceutical industry's investment in new research.<sup>10</sup> These actions are eroding the constitutionally protected rights of patent holders in the drug market, placing this country's future pipeline to life-saving drugs in a precarious position.<sup>11</sup> Without the security of patent protection to recoup substantial research and development costs, brand-

Since the late 1990s, U.S. antitrust enforcement authorities have greatly increased their scrutiny of the potential anti-competitive effects of patent settlements. In 1997, then-Department of Justice Antitrust Division chief Joel Klein warned of increased DOJ scrutiny and called for legislation subjecting patent settlement agreements to a reporting regime akin to Hart-Scott-Rodino premerger notification.

*Id.* The FTC's study examined conduct of brand-name and generic drug companies that the FTC had previously investigated under the Act to determine if that conduct was an isolated occurrence or part a regular pattern of anti-consumer activity. See FTC STUDY, *supra*, at i (noting subject of study). The study states: "Through vigorous enforcement of the antitrust laws, the FTC has taken an active role in ensuring that consumers benefit from competition in the pharmaceutical industry." *Id.*

8. See, e.g., *Andrx Pharm., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (holding generic manufacturers have standing to sue under Clayton and Sherman Acts for alleged collusive agreements between pioneer and other generic manufacturers); *In re Terazosin Hydrochloride Antitrust Litig.*, 203 F.R.D. 551 (S.D. Fla. 2000) (finding *per se* antitrust violations), *rev'd and remanded sub nom. Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003); HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE § 5.6, at 249-56 (2d ed. 1999) (discussing difficulties courts face in applying antitrust law to certain business arrangements); Morse, *supra* note 2, at 399-401 (recounting series of judicial attempts to evaluate antitrust violations in pharmaceutical industry); O'Reilly, *supra* note 1, at 429-30 (noting *Biovail* decision has "opened the door for a substantial amount of litigation . . . based upon antitrust grounds").

9. See *Hearings on Patent Settlements*, *supra* note 1, at 18 (statement of Dir. Molly Boast) ("Within the next 5 years, patents on brand-name drugs with combined U.S. sales approaching \$20 billion will expire . . . . The successful entry of generic version of these drugs should affect dramatically the amount consumers pay for the drugs they need."); see also *Generic Drugs: The Stalling Game*, CONSUMER REPS., July 2001, at 36 [hereinafter *Generic Drugs*] (stating that over next five years patents will expire on twenty-one best-selling drugs in United States with annual sales of \$20 billion).

10. See *Hearings on FTC Study*, *supra* note 1, at 66 (statement of Bruce N. Kuhlik, Senior Vice President & General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA)) ("Better treatments—and even cures—can come only from the pharmaceutical research industry, and can come only if patent incentives are maintained.").

11. See 35 U.S.C. § 154(a)(2) (2000) (granting patent for twenty years). Despite the statutorily imposed duration of the patent, provisions in the Act allow generic manufacturers to infringe on the patent holder by testing the drug with the specific intention of inventing around the patent to get approval from the FDA. See 35 U.S.C. § 271(e)(1) (2000) (stating there is no "infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably

name pharmaceuticals will find the prospects of investing in research for a multitude of potentially life-saving drugs too costly.<sup>12</sup> Care must be taken by all parties involved not to be overly short-sighted by substituting guaranteed future access to life-saving drugs for temporary cost savings to the current consumer.

This Note analyzes the current tension between patent and antitrust law, specifically within the pharmaceutical industry in light of *In re Cardizem CD Antitrust Litigation*,<sup>13</sup> the Sixth Circuit's recent decision adopting a *per se* illegality analysis.<sup>14</sup> Part II examines the current and traditional interplay between antitrust and patent law,<sup>15</sup> the Hatch-Waxman Act<sup>16</sup> and the loopholes contained therein.<sup>17</sup> Part III examines the facts and holdings of the *Cardizem CD Litigation* and the application of the *per se* illegality rule.<sup>18</sup> Part IV discusses the competing policies of pro-consumerism and pro-innovation.<sup>19</sup>

## II. OVERVIEW OF THE SHERMAN AND HATCH-WAXMAN ACTS

### A. *Historical Interplay of Antitrust and Patent Law*

Since the start of the twenty-first century, patent holders have become subject to an increasing amount of antitrust scrutiny, yet for a large portion of the country's history patent holders were exempted from the application of antitrust laws. The Framers of the Constitution realized the value of innovation in their new country and placed enough importance on it to protect it with the language of the Constitution.<sup>20</sup> It was not until 1890 that Congress enacted the Sherman Act, a comprehensive piece of

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related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs").

12. See PhRMA, *Fact Sheet: Pharmaceutical Patent Incentives*, at <http://www.phrma.org/publications/publications/17.06.2003.746.cfm> (last visited Jan. 14, 2004) (stating that since passage of Act, which weakened pharmaceutical patents, innovation has become more difficult for discovering new cures, and risk associated with developing new drugs demonstrates importance of proper patent protection).

13. 332 F.3d 896 (6th Cir. 2003).

14. See *id.* at 906-07 (discussing restraints subjected to *per se* rule).

15. For a historical explanation of antitrust and patent law, see *infra* notes 20-45 and accompanying text.

16. For an overview of the Hatch-Waxman Act, see *infra* notes 46-65 and accompanying text.

17. For an explanation of interpretational problems with the Act, see *infra* notes 66-77.

18. For a discussion of the facts and analysis in *Cardizem*, see *infra* notes 86-184 and accompanying text.

19. For a discussion of the need for a strong pro-innovation policy, see *infra* notes 185-99 and accompanying text.

20. See U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."). See generally 35 U.S.C §§ 1-376 (2000) (providing federal patent law).

legislation that delineates U.S. antitrust law.<sup>21</sup> Section 1 of the Sherman Act made it illegal to engage in the restraint of trade or commerce through contract, combination or conspiracy.<sup>22</sup> Section 2 of the Sherman Act made it illegal to monopolize or attempt to monopolize trade or commerce, either singly or with others.<sup>23</sup> For much of the time period following the passage of the Sherman Act—primarily the early twentieth century—the federal government, including the judiciary, viewed a patent as a constitutionally mandated monopoly granted to the holder of that patent; the result being that patent holders were typically exempt from antitrust scrutiny.<sup>24</sup>

The Sherman Act has sparked both considerable debate and general confusion in its greater than one hundred years of existence.<sup>25</sup> The “vague and malleable”<sup>26</sup> language of the Sherman Act has caused problems and debates resulting in difficulty for the courts that are ultimately called upon to decide the meaning of the law.<sup>27</sup> Additionally, problems of interpretation arose from a failure of legal scholars to discern the intent of the drafters of the Sherman Act,<sup>28</sup> and more specifically,

21. See generally 15 U.S.C. §§ 1-4809 (2000) (providing codification of Sherman Act).

22. See *id.* § 1. Section 1 states:

Every contract, combination in the form of trust, or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal. 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, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

*Id.*

23. See *id.* § 2. Section two states:

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$10,000,000 if a corporation, or, if any other person, \$350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

*Id.*

24. See Sheila F. Anthony, *Antitrust and Intellectual Property Law: From Adversaries to Partners*, 28 AIPLA Q.J. 1, 5 (2000) (“[F]or a long time, the courts held that the patent exception was so broad as to immunize from antitrust scrutiny the conduct of firms holding patents.”). The author, Sheila F. Anthony, was a commissioner of the FTC. See *id.* (providing biographical information about Commissioner Anthony).

25. See HOVENKAMP, *supra* note 8, § 2.1a, at 48 (noting general debate and argument over concern and intent of Sherman Act framers).

26. *Id.* at 47.

27. See *id.* (stating that plain language of statute gives no indication to meaning of phrase).

28. See *id.* at 48 (“[The Sherman Act’s] ambiguous language has produced considerable scholarly dispute over Congressional intent.”).

whom Congress was trying to protect with its passage.<sup>29</sup> A final source of confusion has arisen since the mid-twentieth century due to the heightened development of various schools of economic theory;<sup>30</sup> essentially, what is known today about the economics of competition and monopoly<sup>31</sup> was not available to those who drafted the Sherman Act, making it difficult to interpret in the context of a modern society.<sup>32</sup>

As previously stated, patent holders in the early post-Sherman Act era were traditionally exempt from antitrust scrutiny; however, by the 1950s, the Supreme Court began to narrow patent holders' immunity.<sup>33</sup> This shift began the current trend of recognizing the coexistence of antitrust and patent law. However, two factors commonly complicate this coexistence: (1) free riding and economies of scale<sup>34</sup> and (2) difficult reconciliation of the substantial bodies of patent and antitrust law.<sup>35</sup>

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29. See *id.* at 48, 50-51 (reconciling factual record of United States in 1890 with intent of Sherman Act). There were a variety of legal and economic theories about the purposes served by the Sherman Act, the segment of the American population protected and the intent of Congress. See *id.* at 50 (noting existence of various legal and economic theories). Hovenkamp states that the majority of these theories, aside from the theory of small firm and farmer lobbying efforts, are inconsistent with the historical facts of the late nineteenth century. See *id.* According to Hovenkamp, the most likely reason for the Sherman Act was that Congress was concerned with the sugar trusts, Standard Oil and Carnegie Steel and passed the Act to empower small firms and farmers because of a fear of "private bigness." *Id.* at 50-51.

30. See *id.* at 48 (discussing Chicago School antitrust analysis, Public Choice theory and Pareto-efficiency, as they pertain to Sherman Act).

31. See *id.* ("Most of the modern welfare economics of competition and monopoly was developed during the 1930s and after.")

32. See generally *id.* at 47-58 (explaining development of American antitrust policy as well as courts', scholars' and enforcement agencies' difficulties with Sherman Act and its scope and intent).

33. See Anthony, *supra* note 24, at 5 (citing *United States v. Line Material Co.*, 333 U.S. 287 (1948), which struck down patent pooling arrangement for price fixing). "[T]he 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." *Line Material Co.*, 333 U.S. at 308.

34. See HOVENKAMP, *supra* note 8, § 5.5a, at 239 (noting first complicating factor). Hovenkamp states:

The free rider problem derives from the fact that intellectual property rights can easily be appropriated if they are not given greater legal protection than is given to more tangible property rights. If the innovator cannot effectively exclude others from copying the innovation, then many of the returns to innovation will be lost and we can expect less innovation to occur. Economies of scale exist because the costs of *duplicating* products or processes protected by intellectual property are so much lower than the cost of developing them in the first place.

*Id.*

35. See *id.* (noting second complicating factor). Hovenkamp states: The second complicating factor is that patents, as well as copyrights and trademarks, are governed by detailed federal statutes that create numerous potential conflicts with antitrust policy. As a result, the antitrust laws and the federal intellectual property laws must be interpreted so as to accommodate one another.

During the 1970s, in an attempt to continue this trend of coexistence of patent and antitrust law, the DOJ issued the “Nine No-Nos,” a statement of government policy towards patent rights and antitrust enforcement.<sup>36</sup> This policy was not held in high regard<sup>37</sup> because it presumed that a patent ensured monopoly power in its specific market, resulting in antitrust and patent law becoming more adversarial, rather than complementary.<sup>38</sup> Additionally, since its creation in 1982, there is a concern that the Federal Circuit could act as an alternative forum to have traditional antitrust disputes resolved. By tying a legitimate antitrust issue with a speculative or minimal patent claim, a party may appeal to the Federal Circuit, thereby circumventing its regional circuit court’s unfavorable or adverse precedent.<sup>39</sup>

*Id.* (citations omitted).

36. *See id.* § 5.5c, at 243 n.27 (“The forbidden practices were popularly referred to as the ‘Nine No Nos.’”); Anthony, *supra* note 24, at 5-6 (elaborating on conduct that was considered suspect under “Nine No-Nos”). The “Nine No-Nos” were:

1. Tying the purchase of unpatented materials as a condition of the license[;]
2. Grantbacks[;]
3. Restricting the right of the purchaser of the product in the resale of the product[;]
4. Restricting the licensee’s ability to deal in products outside the scope of the patent[;]
5. A licensor’s agreement not to grant further licenses[;]
6. Mandatory package licenses[;]
7. Royalty provisions not reasonably related to the licensee’s sales[;]
8. Restrictions on a licensee’s use of a product made by a patented process[; and]
9. Minimum resale price provisions for the licensed products.

Hovenkamp, *supra* note 8, § 5.5c, at 243 n.27.

37. *See* Anthony, *supra* note 24, at 5 (referring to “Nine No-Nos” as “a now-infamous government policy”).

38. *See id.* at 6 (summarizing historic view that antitrust and patent law were opposing policies and DOJ’s position that patents automatically conferred market power exacerbated that view).

39. Although important, the impact of the Federal Circuit’s decisions in the field of antitrust law is outside the scope of this Note. For a complete discussion of this topic, see Scott A. Stempel & John F. Terzaken III,  *Casting a Long IP Shadow over Antitrust Jurisprudence: The Federal Circuit’s Expanding Jurisdictional Reach*, 69 ANTITRUST L.J. 711, 711-12 (2002) (describing trend of Federal Circuit to decide appeals of antitrust claims that implicate issues of patent law). According to the authors:

[T]he Federal Circuit has recently taken a much more expansive view of the circumstances under which a plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal patent law, thereby defining the appellate path as leading to the Federal Circuit. This trend, taken together with recent decisions expanding the circumstances under which the Federal Circuit will apply its own, rather than regional circuit, precedent in resolving non-patent issues has potentially far-reaching consequences for how the apparent tensions between antitrust law and the protection of IP rights will be resolved in the courts. Indeed, these developments have led critics to argue that we are now wit-



In 1995, the DOJ, in conjunction with the FTC, issued the “Antitrust Guidelines for the Licensing of Intellectual Property” (the “Guidelines”).<sup>40</sup> The Guidelines are an attempt to create a more “complementary approach” between antitrust and patent law.<sup>41</sup> The government’s active communication with the intellectual property community in shaping the policy renders the Guidelines a more accepted approach to enforcement.<sup>42</sup> The Guidelines take a three-principle approach to patent rights as they pertain to antitrust enforcement: (1) while the underlying antitrust principles for patent issues remain the same as those for non-intellectual property issues, the DOJ and FTC recognize the distinct characteristics of patents and will take their unique circumstances into account;<sup>43</sup> (2) the DOJ and FTC will no longer presume that a patent confers market power upon the holder;<sup>44</sup> and (3) the DOJ and FTC will consider licensing of patent rights to be procompetitive.<sup>45</sup>

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nessing the realization of the fears expressed by Congress before the Federal Circuit even heard its first case—a Federal Circuit that would serve as an alternative forum to influence the interpretation of traditional antitrust jurisprudence. Intellectual property owners, on the other hand, likely applaud the Federal Circuit’s double-barreled expansion of its dominion over the application of the antitrust laws in this arena as a logical fulfillment of that court’s statutory mandate to bring uniformity to the interpretation and application of the patent laws.

*Id.*

40. U.S. DOJ & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (Apr. 6, 1995), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> [hereinafter GUIDELINES] (“These Guidelines state the antitrust enforcement policy of the U.S. Department of Justice and the Federal Trade Commission . . . with respect to the licensing of intellectual property protected by patent, copyright, and trade secret law, and of know-how.”).

41. See Anthony, *supra* note 24, at 7 (“The *Antitrust Guidelines for the Licensing of Intellectual Property* . . . , issued jointly by the FTC and DOJ in 1995, describe the agencies’ current complementary approach to applying antitrust principles in cases involving intellectual property rights.”); see also GUIDELINES, *supra* note 40, §§ 1.0-2.0, at 1-2 (stating agencies’ recognition of rights, benefits and protections unique to intellectual property).

42. See Anthony, *supra* note 24, at 7 (stating Commissioner Anthony’s gratitude to intellectual property bar for assistance rendered to FTC in shaping policy).

43. See GUIDELINES, *supra* note 40, § 2.1, at 3-4 (“Intellectual property has important characteristics . . . that distinguish it from many other forms of property. These characteristics can be taken into account by standard antitrust analysis . . . .”); see also Anthony, *supra* note 24, at 8 (summarizing Guidelines approach in section 2.1).

44. See GUIDELINES, *supra* note 40, § 2.2, at 4 (“The Agencies will not presume that a patent . . . necessarily confers market power upon its owner.”); see also Anthony, *supra* note 24, at 8 (regarding approach of Guidelines as refinement from earlier antitrust policy towards intellectual property).

45. See GUIDELINES, *supra* note 40, § 2.3, at 5 (stating general approval of licensing arrangements as beneficial to consumers and resulting in increase and promotion of innovation); see also Anthony, *supra* note 24, at 8 (noting that licensing can allow for beneficial combination of intellectual property, increasing speed to market while reducing cost).

### B. *The Hatch-Waxman Amendments*

The Federal Food, Drug, and Cosmetic Act (FDCA)<sup>46</sup> regulates the manufacture and distribution of pharmaceutical products in the United States.<sup>47</sup> In 1984, Congress passed the Hatch-Waxman Act (the "Act"),<sup>48</sup> which contained a series of amendments to the FDCA designed to reduce the burdensome regulatory process for generic drug manufacturers.<sup>49</sup> Congress intended these amendments to hasten the entry of low-cost substitute drugs into the market,<sup>50</sup> while granting patent-based incentives to brand-name firms to continue the necessary research and development.<sup>51</sup>

Prior to the passage of the Act, a generic manufacturer of a brand-name drug would have to undergo the exact same regulatory process as the manufacturer of the pioneer drug.<sup>52</sup> The Act short-circuited this process by allowing the generic manufacturer to file an Abbreviated New Drug Application (ANDA),<sup>53</sup> which allowed development of the generic drug to "essentially piggy-back on the pioneer drug's human clinical trials

46. 21 U.S.C. §§ 301-99 (2000).

47. *See id.* § 331 (stating generally that FDCA regulates food, drugs, devices and cosmetics delivered or introduced into interstate commerce).

48. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. § 355 (2000)).

49. *See* H.R. REP. NO. 98-857, pt. 1, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649 (stating that legislation is "necessary to establish" abbreviated generic drug approval procedure due to FDA failure to do same).

50. *See id.* at 16-17 (stating congressional finding that additional human clinical trials by generic manufacturers as required by current FDCA is considered wasteful and unnecessary by FDA and that Congress found consumer savings to be approximately \$920 billion over next twelve years); *see also* Wooster, *supra* note 3, at 508 (stating congressional approval of Act after deciding that FDCA delayed entry of generic drugs into market because of "cumbersome drug approval process").

51. *See* H.R. REP. NO. 98-857, pt. 1, at 15 (stating purpose of bill); *see also* Wooster, *supra* note 3, § 2[a], at 508 (stating one of Act's policy goals was inducement to brand-name manufacturers to invest in research and development). Specifically, the House Report states:

The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval. The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval. Under current law, a patent continues to run while the maker of the product is testing and awaiting approval to market it.

H.R. REP. NO. 98-857, pt. 1, at 15.

52. *See* H.R. REP. NO. 98-857, pt. 1, at 16 (noting result of 1962 amendments was that generic drug must meet same requirements as pioneer drug for FDA approval with exception of abbreviated process for generic copies of pre-1962 approved drugs).

53. 21 U.S.C. § 355(j) (2000). This subsection is entitled "Abbreviated new drug applications." *Id.* Section 355(j)(1) states: "Any person may file with the Secretary an abbreviated application for the approval of a new drug." *Id.*

and labeling.”<sup>54</sup> Part of the ANDA requires the generic manufacturer to file a certification regarding its knowledge of any patents claiming the listed drug with the Food and Drug Administration (FDA), the agency that oversees the drug approval process.<sup>55</sup> A generic manufacturer may make four types of certification: (1) “that such patent information has not been filed;”<sup>56</sup> (2) “that such patent has expired;”<sup>57</sup> (3) “the date on which such patent will expire;”<sup>58</sup> or (4) “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”<sup>59</sup>

Due to the obvious potential for dispute over whether, in fact, the existing patent is invalid or will not be infringed, the fourth type of certification (“Paragraph IV certification”) places additional requirements on and provides potential incentives to the generic manufacturer.<sup>60</sup> After making a Paragraph IV certification, the generic manufacturer must give notice to the owner of the disputed patent.<sup>61</sup> The patent holder has forty-

54. Wooster, *supra* note 3, § 2[a], at 508-09 (indicating Act’s amendment allowing manufacturers to complete abbreviated new drug application rather than complete new application).

55. See 21 U.S.C. §355(j)(2)(A)(vii) (requiring applicant to certify to FDA, to best of applicant’s knowledge, new drug’s relationship to patents existing for listed drug upon which applicant is relying).

56. *Id.* § 355(j)(2)(A)(vii)(I).

57. *Id.* § 355(j)(2)(A)(vii)(II).

58. *Id.* § 355(j)(2)(A)(vii)(III).

59. *Id.* § 355(j)(2)(A)(vii)(IV).

60. See *id.* § 355(j)(5)(B)(iii) (describing incentives and restrictions of Paragraph IV). Specifically, section 355(j)(5)(B)(iii) states:

If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . . .

*Id.*

61. See *id.* § 355(j)(2)(B) (providing notice requirement). Section 355(j)(2)(B) states:

(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

five days from receipt of the notice to institute an action for infringement.<sup>62</sup>

If the patent holder fails to file an infringement action, the generic manufacturer can obtain a declaratory judgment in the matter that results in immediate FDA approval of the ANDA.<sup>63</sup> If, however, the patent holder files an action for infringement, the FDA immediately places a thirty-month stay on the approval pending the outcome of the litigation.<sup>64</sup> Regardless of which event occurs first, resolution of the patent dispute in favor of the generic drug's manufacturer or expiration of the thirty-month stay, the FDA will then approve the ANDA.<sup>65</sup>

### C. *The "Loopholes": The Thirty-Month Stay and 180-Day Exclusivity*

The imprecise language of the thirty-month stay mandated by the FDA<sup>66</sup> and the 180-day exclusivity grant<sup>67</sup> in the Act created "loopholes"

- (ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

*Id.*

62. *See id.* § 355(j)(5)(B)(iii) (stating chronology of Paragraph IV certification and notice to patent holders to initiate action for infringement).

63. *See id.* § 355(j)(5)(B)(iii)(III). This section states:

Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

*Id.*

64. *See id.* § 355(j)(5)(B)(iii) (stating that if action for infringement is brought within forty-five days of notice, approval of ANDA is placed on hold for thirty-month period beginning from date notice was received by FDA).

65. *See id.* (stating that if action for infringement is brought, approval of ANDA would occur either at end of mandatory thirty-month stay or whenever court in infringement action orders).

66. *See id.* (providing for thirty-month stay). Section 355(j)(5)(B)(iii) states:

If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order . . . .

*Id.*

67. *See id.* § 355(j)(5)(B)(iv) (providing for 180-day exclusivity grant). Section 355(j)(5)(B)(iv) states:

that various parties have exploited, often delaying the arrival of generic drugs to the market.<sup>68</sup> The exclusivity provision gives the first generic company that files an ANDA challenging a pioneer drug's patent a six-month period to market its generic drug before competitors' subsequent ANDA applications are approved for that pioneer drug.<sup>69</sup> The exclusivity period begins to run when the generic manufacturer first markets its drug after receiving FDA approval of its ANDA.<sup>70</sup> Congress included this exclusivity grant in the Act as an incentive to litigate against pioneer drug companies.<sup>71</sup> Without that incentive, a single generic company, the "first-to-file," would bear all of the risk in challenging the patent holder.<sup>72</sup> If the patent holder brought an unsuccessful cause of action against that generic company—i.e., the patent was declared invalid—then all subsequent generic companies could immediately begin marketing without having borne any risks or costs of litigation.<sup>73</sup> As a consequence of both skillful

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If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

- (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
- (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

*Id.*

68. See *Hearings on FTC Study*, *supra* note 1 (statement of Timothy J. Muris, Chairman, FTC) (reporting findings from FTC Study). Chairman Muris informed the Senate Judiciary Committee that the FTC's study examined 104 brand-name drugs from 1992 to 2000. See *id.* Chairman Muris reported the study found eight brand-name drugs whose manufacturer/patent holder obtained more than one thirty-month stay, resulting in delays of generic entry anywhere from four to forty months. See *id.* With respect to the 180-day period of exclusivity, Chairman Muris reported the study found fourteen instances where litigation was settled with the potential to "park" the first generic's exclusivity, thus preventing subsequent generic entry. See *id.*

69. See 21 U.S.C. § 355(j)(5)(B)(iv) (stating no subsequent ANDA applicant may receive approval until 180 days after initial applicant's commercial marketing of drug or favorable court decision).

70. See *id.* (defining two triggering devices in Act concerning initiation of 180-day exclusivity period, commercial triggering and court decision triggering).

71. See O'Reilly, *supra* note 1, at 415-16 ("The six-month reward means the first-to-file has an incentive to litigate. Only after that 180 days would other generic copies be permitted to enter the market.").

72. See *id.* at 420-21 (discussing confusion over which generic manufacturer would receive exclusivity rights). The "first-to-file" refers to the first generic company to assert a Paragraph IV certification against a pioneer drug's patent in an ANDA application. See *id.* at 415.

73. See *id.* at 414 (noting that dozens of competing generic manufacturers would be free riders on first successful challenger to pioneer's patented drug).

lawyering<sup>74</sup> and silence in the legislative history of the Act,<sup>75</sup> the grantee and patent holder have used the grant to “blockade” subsequent generic manufacturers who have filed ANDA applications for the same pioneer drug.<sup>76</sup> By not marketing the drug after receiving final approval from the FDA on its ANDA application, the grantee never triggers the 180-day exclusivity period, thus preventing subsequent generic manufacturers from receiving final FDA approval to initiate marketing.<sup>77</sup>

The thirty-month stay is an action by the FDA, mandated by statute, that is triggered by the filing of an infringement suit by the patent holder against the generic manufacturer that filed a Paragraph IV certification in its ANDA.<sup>78</sup> The problem with the stay stems from its application to patents on the drugs, not the drugs themselves.<sup>79</sup> Pioneer drugs may have several patents covering them, including protection of their active ingredient(s), their manufacturing process and their packaging, as well as long-term improvements made to such drugs.<sup>80</sup> Therefore, patent holders of pioneer drugs can institute infringement actions for multiple patents on a single drug, each qualifying for a thirty-month stay.<sup>81</sup> Additionally, patent

74. See *id.* (stating that “skilled Washington D.C. lawyers dreamed” up ways to have pioneer drug companies pay generic manufacturers to keep its drug off market).

75. See *id.* at 416 (referring to lack of explanation or commentary in Act’s legislative history concerning 180-day exclusivity period).

76. See Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Manufacturers*, 17 BERKELEY TECH. L.J. 317, 328 (2002) (noting that settlement of infringement litigation between pioneer manufacturer and first generic challenger does not necessarily open generic market).

77. See Morse, *supra* note 2, at 387 (detailing incentives for pioneer manufacturing firms to file patent infringement suits); Rosenthal, *supra* note 76, at 327-28 (describing loopholes and resulting collusive agreements between first generic challenger and pioneer manufacturer); see also Hui, *supra* note 2, at 327 (explaining exposure of loopholes during recent high profile litigation). Where a litigation settlement contains an agreement that the generic manufacturer will not market the drug for the duration of its 180-day exclusivity in exchange for compensation from the brand-name drug manufacturer, neither triggering event—i.e., the commercial marketing or the court decision finding the patent invalid—occurs. See Lobanoff, *supra* note 2, at 1343-44 (describing how this type of patent settlement appears anticompetitive).

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

79. See *id.* (“[A]pproval shall be made effective immediately unless an action is brought for *infringement of a patent* which is the subject of the certification . . . .”) (emphasis added).

80. See 35 U.S.C. § 154(a)(1) (2000) (stating protection of patent). Section 154(a)(1) states:

Every patent shall contain a short title of the invention and a grant . . . of the right to exclude others from making, using, offering for sale, or selling the invention . . . , and, if the invention is a process, of the right to exclude others from using, offering for sale or selling . . . products made by that process . . . .

*Id.*

81. See FTC STUDY, *supra* note 7, at 39-56 (explaining FDA patent-listing practices and use of multiple thirty-month stays); Hui, *supra* note 2, at 327-28 (explain-

holders can file subsequent patents on the pioneer drug, even after the generic manufacturer has filed its initial Paragraph IV certification.<sup>82</sup> As a result of this action, generic manufacturers must re-certify that the proposed generic drug does not infringe on the newly filed patent, causing another thirty-month stay to be placed on the generic drug if the patent holder initiates an action for infringement of the new patent.<sup>83</sup> As long as litigation continues and a stay is imposed upon the ANDA, the generic manufacturer remains barred from the market.<sup>84</sup> The FDA recently enacted a rule that will limit each pioneer drug to only one thirty-month stay under the Act, regardless of the amount of patents covering the drug.<sup>85</sup> The rule, however, is too new to have generated any substantial commentary and will, therefore, be excluded from analysis in this Note.

### III. *IN RE CARDIZEM CD ANTITRUST LITIGATION*

#### A. *Facts Surrounding the Antitrust Claims*

*Cardizem CD Litigation* (used to refer collectively to the series of cases in *In re Cardizem CD Antitrust Litigation*)<sup>86</sup> involved an agreement (the "Agreement") between defendant Hoechst Marion Roussel, Inc.

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ing how manipulation of FDA's patent-listing procedure can be used to implement multiple thirty-month stays on single drug.)

82. See FTC STUDY, *supra* note 7, at iii (noting ability of pioneer manufacturer to file new patents after generic manufacturer submits ANDA and consequence that generic manufacturer must re-certify its ANDA for every new patent filed after ANDA submission).

83. See Hui, *supra* note 2, at 327 (noting ability of pioneer companies to take advantage of multiple stays in litigation).

84. See Rosenthal, *supra* note 76, at 328 (explaining delay tactic employed by drug companies). Rosenthal explains that "[a]s long as the patent infringement litigation between the pioneer manufacturer and the first generic challenger is ongoing . . . the generic market is essentially held closed." *Id.*

85. See Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). The requirements state that:

The final rule limits to one per ANDA . . . the maximum number of statutory 30-month stays of approval to which an innovator will be entitled when it submits multiple patents for the same [pioneer drug]. Eliminating multiple 30-month stays will speed up the approval and market entry of generic drugs. The final rule also clarifies patent submission and listing requirements, which will reduce confusion and help curb attempts to take advantage of this process. Specifically, patents claiming packaging, intermediates, or metabolites must not be submitted for listing.

*Id.*

86. *In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896 (6th Cir. 2003); *In re Cardizem CD Antitrust Litig.* (Cardizem CD II), 105 F. Supp. 2d 682 (E.D. Mich. 2000); *In re Cardizem CD Antitrust Litig.* (Cardizem CD I), 105 F. Supp. 2d 618 (E.D. Mich. 2000). These cases are collectively referred to as "*Cardizem CD Litigation*."

("Hoechst"), a brand-name manufacturer of the drug Cardizem CD,<sup>87</sup> and defendant Andrx Pharmaceuticals, Inc. ("Andrx"), a potential generic manufacturer of the drug.<sup>88</sup> The Agreement delayed Andrx's entry of its drug into the market.<sup>89</sup> Also as part of the Agreement, Hoechst was to make quarterly payments of \$10 million to Andrx; in exchange, Andrx was to keep its generic version of Cardizem CD from entering the marketplace even though Andrx had received tentative FDA approval.<sup>90</sup> Andrx had received this tentative approval through a Paragraph IV certification.<sup>91</sup> Plaintiffs comprised four separate groups, each asserting similar allegations, but seeking damages under different state and federal antitrust claims.<sup>92</sup>

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87. See *Cardizem CD I*, 105 F. Supp. 2d at 622 (defining Cardizem CD as prescription heart medication consisting of once-daily dose of compound diltiazem hydrochloride prescribed primarily for treatment of angina, hypertension and heart-attack and stroke prevention).

88. See *Cardizem CD II*, 105 F. Supp. 2d at 686-89 (detailing chronology of events between Andrx and Hoechst with respect to Cardizem CD and Andrx's generic version, Cartia XT). Essentially, the patent dispute centered on what is known as a dissolution profile; that is, the percent of the active ingredient dissolving, or releasing, in the body over a given timeframe, usually eighteen hours. See *id.* (describing relevant dissolution profiles for Cardizem CD and Cartia XT).

89. See *Cardizem CD III*, 332 F.3d at 899-900 (stating fundamental terms of Agreement as \$10 million quarterly payments to Andrx, in exchange for which Andrx would refrain from marketing Cartia XT, subsequent to FDA approval). For a complete discussion of the full terms of the Agreement, see *Cardizem CD II*, 105 F. Supp. 2d at 695-99.

90. See *Cardizem CD III*, 332 F.3d at 899-900 (detailing specific terms of Agreement).

91. See *id.* at 902 (recounting approval process undergone by Andrx). Andrx filed an ANDA on September 22, 1995, seeking approval to market a generic version of Cardizem CD. See *id.* In November 1995, Carderm Capital, L.P., the licensor of Hoechst's Cardizem CD patents, was issued a new patent concerning Cardizem CD's dissolution profile, which it licensed to Hoechst. See *id.* On December 30, 1995, Andrx filed a Paragraph IV certification, claiming Cartia XT did not infringe on any patents related to Cardizem CD. See *id.* In January 1996, Hoechst and Carderm Capital filed a patent infringement suit against Andrx in the U.S. District Court for the Southern District of Florida, claiming that Cartia XT infringed on the newly issued patent for Cardizem CD. See *id.*

92. See *Cardizem CD I*, 105 F. Supp. 2d at 625-27 (defining four groups of plaintiffs and their allegations consolidated into single action). The first group of plaintiffs were "state law plaintiffs," indirect purchasers (consumers and retail pharmacies) in several states claiming violations of state consumer-protection and antitrust statutes and seeking recovery on a common law theory of unjust enrichment. See *id.* at 625. The second group of plaintiffs was a class-action group comprising any persons who directly purchased Cardizem CD from Hoechst any time after July 9, 1998. See *id.* at 625-26. They alleged that the Agreement was a horizontal market allocation between competitors to fix and maintain the price of Cardizem CD in the United States, and as such, was *per se* illegal under the Sherman Act, or alternatively, illegal under the rule of reason analysis. See *id.* at 626 n.4. The third group of plaintiffs, composed primarily of large retail and supermarket chains, also alleged Sherman Act violations, but remained individual plaintiffs not part of the class. See *id.* at 626-27. This third group's allegations were similar to the class's except they alleged only a *per se* illegal arrangement. See *id.* at 627 n.5. The fourth group consisted of two individual corporations, CVS Merid-



The defendants sought certification of two questions for interlocutory appeal to the Sixth Circuit<sup>93</sup> based on the district court's denial of defendants' motion to dismiss all counts in *Cardizem CD I*<sup>94</sup> and its grant of plaintiffs' motion for partial summary judgment in *Cardizem CD II*.<sup>95</sup> In affirming both the lower court's rulings,<sup>96</sup> the Sixth Circuit made the significant determination that the Agreement constituted a horizontal market allocation and a *per se* illegal restraint of trade under the Sherman Act.<sup>97</sup>

### B. Narrative Analysis—Agreement Deemed Presumptively Illegal

By affirming the district court's holding that the Agreement constituted a *per se* illegal restraint of trade, the Sixth Circuit effectively barred the defendants from arguing the procompetitive aspects of the Agreement.<sup>98</sup> Initially, the court explored prior Supreme Court holdings under the Sherman Act to determine whether to analyze the Agreement under the more common "rule of reason" approach<sup>99</sup> or under the more pre-

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ian, Inc. and Rite Aid Corp. These plaintiffs alleged Sherman Act violations, but were not part of the other two groups of plaintiffs. *See id.* at 627. Their allegations were substantively similar to the allegations of the other groups of plaintiffs. *See id.* at 627 n.6.

93. *See Cardizem CD III*, 332 F.3d at 900 (noting certification of appeal). The Sixth Circuit noted:

[T]he district court certified two questions for interlocutory appeal: (1) . . . In determining whether Plaintiffs properly pled antitrust injury, does the language of the Sixth Circuit's decisions in *Valley Products Co. v. Landmark* and *Hodges v. WSM, Inc.* require dismissal of Plaintiffs' antitrust claims at the pleading stage if Plaintiffs cannot allege facts showing that Defendants' alleged anticompetitive conduct was a "necessary predicate" to their antitrust injury; *i.e.*, that dismissal is required unless Plaintiffs plead facts showing that the alleged antitrust injury could not possibly have occurred absent Defendants' alleged anticompetitive conduct? (2) . . . In determining whether Plaintiffs' motions for partial summary judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act and under the corresponding state antitrust laws at issue in this litigation.

*Id.* (citations omitted).

94. *See Cardizem CD I*, 105 F. Supp. 2d at 681 (denying all counts of defendants' motions to dismiss).

95. *See In re Cardizem CD Antitrust Litig.* (Cardizem CD II), 105 F. Supp. 2d 682, 706-07 (E.D. Mich. 2000) (granting plaintiffs' motion for partial summary judgment that Agreement constituted *per se* violation of Sherman Act).

96. *See Cardizem CD III*, 332 F.3d at 915 (affirming both district court's denial of motion to dismiss by defendants and grant of partial summary judgment to plaintiffs that Agreement constituted *per se* violation of Sherman Act).

97. *See id.* at 908 (concluding Agreement between competitors was to eliminate competition in United States for Cardizem CD).

98. *See id.* at 909 ("[T]he law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed . . . presence of procompetitive effects is irrelevant.").

99. *See id.* at 906 (citing *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997)). The court noted that "[m]ost restraints are evaluated using a 'rule of reason.'" *Id.*

sumptive *per se* analysis.<sup>100</sup> Upon subsequent examination of the terms of the Agreement, the court determined the agreement embodied a “classic example of a *per se* illegal restraint of trade.”<sup>101</sup>

The circuit court faced two questions<sup>102</sup> on interlocutory appeal certified by the district court pursuant to 28 U.S.C. § 1292(b).<sup>103</sup> By first deciding which mode of analysis—i.e., the rule of reason or the *per se* approach—should be applied to the Agreement, the court believed the resolution of that issue would aid its consideration of the second question—whether the plaintiffs sufficiently alleged an “antitrust injury.”<sup>104</sup>

The court first looked to Supreme Court precedent regarding the relevant antitrust law to determine the scope of the rule of reason and the requirements for properly applying the *per se* illegality approach.<sup>105</sup> The court recognized that a literal reading of the Sherman Act would lead to the conclusion that all agreements that restrain trade are illegal, but that the Supreme Court has interpreted the language of that act to prohibit only unreasonable restraints.<sup>106</sup> The rule of reason approach, as developed by the Supreme Court, requires the finder of fact to evaluate various conditions, both pre- and post-restraint, to determine whether the potential procompetitive effects of the restraint outweigh its harmful effects.<sup>107</sup> The court found that the *per se* approach was to be applied when a court could predict, from experience, that a particular type of restraint would almost always be condemned under the rule of reason.<sup>108</sup> The two signifi-

100. *See id.* (“Some types of restraints, however, . . . are deemed unlawful *per se.*”).

101. *Id.* at 907-08 (deciding first to address whether Agreement was *per se* illegal restraint of trade and listing pertinent facts of Agreement that demonstrated *per se* illegality).

102. *See id.* at 900 (reciting certified questions).

103. *See* 28 U.S.C. § 1292(b) (2000) (granting district court permission to certify to circuit court controlling questions of law to which there is substantial ground for difference of opinion).

104. *See Cardizem CD III*, 332 F.3d at 906 (expressing belief that whether Agreement was *per se* illegal would “shed light” on adequacy of alleged antitrust violation). The allegations of antitrust injury are outside the scope of this Note and will not be addressed.

105. *See id.* at 906-07 (analyzing Sherman Act line of cases to determine relevant applications of antitrust law, focusing on rule of reason analysis versus *per se* illegality analysis).

106. *See id.* at 906.

107. *See id.* (citing *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 342 (1982), which described rule of reason approach). In *Maricopa County*, Justice Stevens wrote:

Under [a rule of reason] approach, the “finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account 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.” 457 U.S. 332 at 342.

108. *See Cardizem CD III*, 332 F.3d at 906 (examining Supreme Court decisions applying *per se* analysis and finding language indicating its appropriateness only

cant consequences of applying a *per se* approach are a conclusive presumption of illegality to the restraint, barring the defendant from raising any procompetitive justifications,<sup>109</sup> and the ability of the court to conclude that a restraint, which may otherwise be permitted under a rule of reason analysis, is illegal.<sup>110</sup> The court then identified certain types of restraints the Supreme Court has held to be subject to a *per se* rule, including “horizontal restraints pertaining to prices.”<sup>111</sup> The court, further using Supreme Court language, stated that the classic example<sup>112</sup> of a *per se* restraint is between competitors at the same level of the market that agree to allocate the market in order to reduce competition.<sup>113</sup>

The court applied its analysis of the relevant antitrust law to the terms of the Agreement and concluded that it was a horizontal agreement to remove competition in the Cardizem CD market.<sup>114</sup> The court made the following findings: (1) Andrx was Hoechst’s only competitor at the time of the Agreement;<sup>115</sup> (2) Hoechst and Andrx agreed on \$10 million payments per quarter from Hoechst to Andrx, and, in return, Andrx would refrain from marketing its generic version of Cardizem CD, even after receiving FDA approval;<sup>116</sup> (3) from July 1998 until June 1999, Andrx did not market its generic version of the drug, and Hoechst paid Andrx \$89.83 million during that same period;<sup>117</sup> (4) by delaying entry into the market, Andrx prevented the start of its 180-day exclusivity period, which kept all other potential generic competitors out of the market;<sup>118</sup> and (5) the

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where court has experience predicting activity’s anticompetitive effects); *In re Cardizem CD Antitrust Litig.* (Cardizem CD II), 105 F. Supp. 2d 682, 694 (E.D. Mich. 2000) (finding Sixth Circuit’s application of *per se* analysis only where prior cases have established anticompetitive effects of sufficiently similar business practice).

109. See *Cardizem CD III*, 332 F.3d at 906 (reciting Supreme Court holding that where *per se* analysis applies, there will be no analysis of procompetitive justifications); *Cardizem CD II*, 105 F. Supp. 2d at 693 (concluding that once restraint is deemed *per se* illegal, no further inquiries into merits of restraint are warranted).

110. See *Cardizem CD III*, 332 F.3d at 906 n.11 (citing *Maricopa County*, 457 U.S. at 344; *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 609 (1972)). The *Cardizem CD III* court noted: “The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach.”

111. *Id.* at 907.

112. See *id.*

113. See *id.* (citing *Topco*, 405 U.S. at 608, which explained horizontal restraint as agreement between competitors at same level who allocate territories to minimize competition); *Cardizem CD II*, 105 F. Supp. 2d at 694 (noting similar language in Sixth Circuit opinion *Betherur v. Aultman Hospital Ass’n*, 78 F.3d 1079, 1088 (6th Cir. 1996)).

114. See *Cardizem CD III*, 332 F.3d at 908 (noting core of Agreement between Andrx and Hoechst entailed classic horizontal agreement to eliminate competition).

115. See *id.* at 907.

116. See *id.*

117. See *id.*

118. See *id.*

Agreement resulted in the protection of Hoechst's exclusive access to the U.S. market until the end date contemplated by both parties.<sup>119</sup> The court concluded: "There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition . . . , a classic example of a *per se* illegal restraint of trade."<sup>120</sup>

Following its determination that the Agreement constituted a horizontal market allocation between competitors, the court analyzed the defendants' arguments against the *per se* determination and found none of them persuasive.<sup>121</sup> The defendants submitted a multitude of arguments to the district court in an attempt to avoid the determination that the Agreement was a *per se* illegal restraint of trade;<sup>122</sup> however, the circuit court addressed only three of those arguments, referring instead to the district court's analysis regarding the others.<sup>123</sup> First, the defendants characterized the Agreement as an attempt to enforce patent rights or, alternatively, as an interim settlement.<sup>124</sup> While the court agreed that federal law permits one to take advantage of a monopoly that occurs as a result of rights accruing under a patent, it regarded this characterization as meritless.<sup>125</sup> The court argued that the Agreement went beyond the specific patent at issue in the litigation and encompassed all of Andrx's products that were potential bioequivalents to Cardizem CD.<sup>126</sup> Second, the de-

119. *See id.*

120. *Id.* at 908.

121. *See id.*

122. *See In re Cardizem CD Antitrust Litig. (Cardizem CD II)*, 105 F. Supp. 2d 682, 694-95 (E.D. Mich. 2000) (reciting arguments defendants intended to make avoiding *per se* treatment). At trial, the defendants asserted the following arguments: (1) Hoechst and Andrx were neither horizontal nor potential horizontal competitors as the terms are defined; (2) the Agreement was not an attempt to allocate markets or fix prices; (3) the Agreement was reasonably ancillary to procompetitive activity, not a "naked" restraint of trade; (4) the Agreement should be viewed as analogous to a patent settlement and, thus, analyzed under the rule of reason; and (5) the Agreement is immune from antitrust scrutiny under the *Noerr-Pennington* doctrine. *See id.*

123. *See Cardizem CD III*, 332 F.3d at 908 (citing district court opinion for greater analysis with respect to finding defendants' arguments for avoiding *per se* analysis unpersuasive). Interestingly, the circuit court allocated only one page of its opinion to addressing the defendants' arguments for avoiding *per se* treatment, whereas the district court spent seven pages addressing the same topic. *Compare Cardizem CD III*, 332 F.3d at 908-09, with *Cardizem CD II*, 105 F. Supp. 2d at 700-06.

124. *See Cardizem CD III*, 332 F.3d at 908.

125. *See id.* (describing defendants' arguments as unpersuasive and noting that Agreement bolstered patent's effectiveness).

126. *See id.* at 908 n.13 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro)*, 261 F. Supp. 2d 188, 242 (E.D.N.Y. 2003)). In *Cipro*, the court stated:

[W]hen the *Cardizem* court condemned the HMR [Hoechst]/Andrx agreement, it emphasized that the agreement restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending [patent] litigation . . . . Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.

defendants claimed that the novelty of this area of law precluded a designation of *per se* illegality.<sup>127</sup> The court also regarded this argument as without merit, relying on the Supreme Court's previous holding that the Sherman Act "establishes one uniform rule applicable to all industries alike."<sup>128</sup> Finally, the defendants asserted that the *per se* designation was inapplicable because the Agreement was, in fact, not anticompetitive and actually contained procompetitive benefits.<sup>129</sup> The court referred to the defendants' argument as "simply irrelevant"<sup>130</sup> because the *per se* designation forecloses the defendants' opportunity to raise any procompetitive justifications.<sup>131</sup>

### C. Critical Analysis—Rule of Reason Approach?

While the Sixth Circuit may have correctly characterized the Agreement as an illegal restraint of trade under the Sherman Act, the court improperly designated the Agreement *per se* illegal instead of applying the more commonly used rule of reason analysis.<sup>132</sup> In fact, in reference to the *Cardizem CD II* decision and others like it, the chairman of the ABA Antitrust Section, Intellectual Property Division stated that cases applying the *per se* designation should not be "overread."<sup>133</sup> A more considered

261 F. Supp. at 242.

127. See *Cardizem CD III*, 332 F.3d at 908.

128. *Id.* (citing *United States v. Socony-Vacuum Oil*, 310 U.S. 150, 222 (1940)).

129. See *id.* at 908-09.

130. See *id.* at 909.

131. See *id.* (citing *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 351 (1982)). The *Cardizem CD III* court stated:

The respondents' principal argument is that the *per se* rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the *per se* concept. The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application.

*Id.*

132. See *State Oil Co. v. Khan*, 522 U.S. 3, 21 (1997) (noting that *per se* application cannot remain static but must change to accommodate agreements made in varying circumstances and times); *Cipro*, 261 F. Supp. 2d at 232-33 (noting that while there is facial appeal in applying *per se* treatment, circumstances surrounding these types of agreements pose obstacle to its use); HOVENKAMP, *supra* note 8, § 5.6b, at 253 ("Because *per se* rules are empirical judgments, their fate is to go through a continual evolutionary process."); Morse, *supra* note 2, at 361, 367, 373 (stating necessity of applying rule of reason analysis in all patent settlement cases because difficulty of analyzing patent issues should caution courts away from facial appeal of *per se* analysis and noting further that it is appropriate for all courts dealing with patent settlements to adopt bright line policy of rule of reason analysis to all patent settlement cases).

133. See Morse, *supra* note 2, at 399 (discussing effect of *per se* label on analysis of these cases).

approach, using the rule of reason, would not have eliminated a future determination concerning the alleged illegality of the Agreement.<sup>134</sup> Moreover, such an approach would have allowed the court to conclude that the defendants engaged in an illegal restraint of trade without foreclosing consideration of key factors necessary to evaluate the Agreement fully.<sup>135</sup>

Policy considerations—primarily the ongoing debate about prescription drugs and how much protection should be afforded the consumer versus the innovator—also dictate a more cautious approach to patent settlement arrangements between pioneer and generic drug companies.<sup>136</sup> Additionally, the court's analysis of the relevant Supreme Court antitrust holdings regarding the proper application of a *per se* designation failed to elaborate on other key aspects of those rulings, casting doubt upon the soundness of the court's approach.<sup>137</sup> Finally, in *In re Ciproflaxcin Hydrochloride Antitrust Litigation* (“*Cipro*”),<sup>138</sup> a similar case decided in the period between *Cardizem CD II* and *Cardizem CD III*, the court sought to distance itself from the analysis employed in *Cardizem CD II*, which the *Cardizem CD III* court supported and upheld.<sup>139</sup> Ironically, the *Cardizem CD III* court actually cited *Cipro* as support for its *per se* application.<sup>140</sup>

### 1. Rule of Reason Does Not Confer Legality

A finding by the court that the Agreement would be analyzed under the rule of reason would not have foreclosed the possibility of concluding that the Agreement was an illegal restraint of trade under the Sherman Act. Indeed, those courts and commentators who have evaluated the Agreement have stated that the Agreement was likely an illegal restraint of trade.<sup>141</sup> The Supreme Court and other courts, however, have made it

134. For a discussion of the rule of reason approach, see *infra* notes 141-43 and accompanying text (stating generally that rule of reason determinations do not lend presumption of legality to arrangement, nor do they foreclose opportunity to condemn arrangement at later date).

135. For a complete discussion surrounding the consequences of a rule of reason designation, see *infra* notes 141-43 and accompanying text.

136. For a complete discussion of the policy implications contradicting the court's analysis, see *infra* notes 185-99 and accompanying text.

137. For a complete discussion on the court's misinterpretation of Supreme Court precedent, see *infra* notes 167-84 and accompanying text.

138. 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

139. See *In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896, 900 (6th Cir. 2003) (affirming *Cardizem CD II* grant of summary judgment because Agreement was *per se* illegal).

140. See *id.* at 908 n.12, 909 n.13 (citing *Cipro* in support of *per se* illegal finding on basis that Agreement went beyond bounds of patent protection and encouraged continuing litigation).

141. See *Cipro*, 261 F. Supp. 2d at 242 (discussing negative impact on generic drug trade resulting from settlement agreements); see also Morse, *supra* note 2, at 399-401 (stating generally that *Cardizem CD II* holding should be read to condemn interim settlement agreements that do not fully resolve pending patent litigation). In *Cipro*, the district court noted that:

clear that a *per se* determination is not necessary solely for the purpose of condemning an arrangement; moreover, an arrangement analyzed under the rule of reason is not given a presumption of legality.<sup>142</sup> Therefore, while the court may have been predisposed to the “illegality” of the Agreement, it did not need to make a finding of *per se* illegality at the summary judgment stage in order to condemn the Agreement.<sup>143</sup>

## 2. In re Ciprofloxacin Hydrochloride Antitrust Litigation (“Cipro”)

The court in *Cipro* dealt with a factual situation similar to that presented in *Cardizem CD Litigation*.<sup>144</sup> As in *Cardizem CD Litigation*, the

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[In the *Cardizem* and *Terazosin* cases,] the brand-name drug manufacturers entered into agreements with prospective generic competitors on the verge of commencing marketing in exchange for the generic manufacturer’s agreement to stay off the market pending the outcome of the patent litigation. This fact, in connection with the agreements’ other restraints, *underscores the anticompetitive nature of the agreements* . . . .

261 F. Supp. 2d at 242 (emphasis added).

142. See *State Oil Co. v. Khan*, 522 U.S. 3, 22 (1997) (overruling prior case that found vertical maximum price fixing to be *per se* illegal); *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 104-05 (1984) (holding that NCAA control over televising college football contests was restraint on price and output likely to have anticompetitive effect, but finding it *per se* illegal was not necessary); *Cipro*, 261 F. Supp. 2d at 257-58 (stating that decision does not conclusively determine legality of agreements rendering them “not subject to further scrutiny” because “plaintiffs [could] show that the challenged agreements are unreasonable restraints of trade under the rule of reason”); see also HOVENKAMP, *supra* note 8, § 5.6b, at 253 (“As the development of [Supreme Court] cases suggests, the most difficult aspect of the jurisprudence of the *per se* rule is determining when it should be followed.”). In *State Oil*, the Court noted that in overruling the *per se* unlawfulness of the action, it was not finding it “*per se* lawful.” 522 U.S. at 22. Rather, the Court stated the action belonged with the majority of commercial activities, properly relegated to a rule of reason analysis, which will “effectively identify” situations that amount to anticompetitive conduct. See *id.* Prior to *State Oil*, the Court stated in *NCAA*: “The fact that a practice is not categorically unlawful in all or most of its manifestations certainly does not mean that it is universally lawful . . . . The essential point is that the rule of reason can sometimes be applied in the twinkling of an eye.” 468 U.S. at 109 n.39 (citation omitted).

143. See *Cipro*, 261 F. Supp. 2d at 257 (“At this early juncture, this case should not be relegated to the *per se* category reserved for the most blatant antitrust violations.”).

144. See *id.* at 194-97 (stating factual background involving agreement between Bayer and generics). Barr Laboratories, Inc. (“Barr”), a generic drug manufacturer, filed a Paragraph IV certification in an ANDA for Cipro on October 22, 1991, and notified Bayer on December 6, 1991. See *id.* at 194. Bayer sued Barr for patent infringement on January 16, 1992, and in November 1992, both parties agreed to extend the thirty-month stay until patent litigation was resolved. See *id.* at 194-95. While waiting for the trial to commence, Barr entered into agreements with Hoechst, The Rugby Group, Inc. (“Rugby”) and Watson Pharmaceuticals, Inc. (“Watson”) concerning the eventual production and marketing of generic Cipro. See *id.* at 195. Just prior to the trial, Bayer and Barr settled their patent dispute, and, subsequently, all four parties entered into a supply agreement and a settlement agreement along with some other ancillary parties. See *id.* at 195-96. Essentially, the agreements barred the generics from manufacturing Cipro until either Bayer’s patent on Cipro expired or another party successfully challenged the Cipro

plaintiffs in *Cipro* comprised a class of direct and indirect purchasers of Cipro as well as individual non-class plaintiffs.<sup>145</sup> Defendants were a brand-name manufacturer, Bayer, and a collection of generic manufacturers.<sup>146</sup> The plaintiffs alleged that the drug manufacturers entered into agreements to prevent competition for Cipro in violation of federal and state antitrust laws.<sup>147</sup> While the court in *Cardizem CD III* summarily dismissed defendants' arguments against *per se* designation<sup>148</sup>—namely, that the Act's scheme created a “novel” area of law,<sup>149</sup> that the Agreement was an attempt to enforce patent rights<sup>150</sup> and that the Agreement was an interim settlement<sup>151</sup>—the *Cipro* court thoroughly analyzed all three issues,<sup>152</sup> concluding that these circumstances “pose significant obstacles”<sup>153</sup> to designating an agreement in this area as deserving of *per se* treatment.

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patent. *See id.* at 196. In the interim, Bayer agreed to supply Barr with Cipro for marketing under a generic name or, alternatively, to make quarterly payments of approximately \$16 million to the generics. *See id.* Since the agreement's inception, through December 2003, Bayer has paid nearly \$400 million to the generics. *See id.* While the parties submitted a consent decree to the judge indicating their resolution of the patent litigation, the consent decree lacked information concerning Bayer's payment to the generics and the arrangement of payments in lieu of supplying Cipro. *See id.* at 196-97.

145. *Compare id.* at 191 (describing plaintiffs involved in litigation), with *In re Cardizem CD Antitrust Litig.* (Cardizem CD I), 105 F. Supp. 2d 618, 625-27 (E.D. Mich. 2000) (describing plaintiffs involved in litigation).

146. *Compare Cipro*, 261 F. Supp. 2d at 191, with *In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896, 899 (6th Cir. 2003) (demonstrating defendants are in similar market positions in both cases, namely, brand-name defendant and generic manufacturer defendant).

147. *Compare Cipro*, 261 F. Supp. 2d at 191-92, with *Cardizem CD III*, 332 F.3d at 900, 904 (demonstrating plaintiffs in both cases allege violation of state and federal antitrust laws).

148. For a complete discussion on the arguments presented to the *Cardizem CD III* court, see *supra* notes 121-31 and accompanying text.

149. *See Cardizem CD III*, 332 F.3d at 908.

150. *See id.*

151. *See id.*

152. *See Cipro*, 261 F. Supp. 2d at 233-34 (outlining court's rationale in deciding relevant factors in determining whether to apply rule of reason or *per se* treatment to agreements). The court stated:

This case involves the rights of a patent holder whose patent . . . has never been found invalid. This case also involves the Hatch-Waxman Amendments—a new statutory scheme creating a novel, low-cost method for challenging the validity of drug patents. Lastly, this case involves settlement agreements, the type of agreements, generally speaking, encouraged by the legal system and entered into with great frequency. These circumstances pose significant obstacles to *per se* treatment of the challenged agreements.

*Id.*

153. *See id.*



Unlike the *Cardizem CD Litigation* courts that dismissed the effects that a valid patent imposes on evaluating anticompetitive effects,<sup>154</sup> the court in *Cipro* evaluated the rights granted to a patent holder under the law and their implications with respect to alleged antitrust violations.<sup>155</sup> In its evaluation, the *Cipro* court concluded, as a matter of law, that the proper course of action entails an analysis of the exclusionary effects of a valid patent prior to a determination of the propriety of designating an agreement *per se* illegal.<sup>156</sup> The *Cipro* court was highly critical of the analysis used by the court in *Cardizem CD II*, going so far as to comment: "It is *fairly evident* that the district court[ ] in *Cardizem* . . . did not employ this analysis and, instead, *immediately* labeled the challenged restraint [a] *per se* illegal horizontal market allocation agreement[ ]."<sup>157</sup>

The *Cipro* court then examined the effect the Act had on settlements in patent litigation,<sup>158</sup> holding that the Act created a unique situation where reverse payments—which are normally condemned—are actually a "natural by-product" of its statutory scheme.<sup>159</sup> This holding was in direct contrast to *Cardizem CD II*, which condemned the Agreement's reverse

154. Compare *id.* at 247-49 (analyzing effects of patent protections as they relate to antitrust violations), with *In re Cardizem CD Antitrust Litig.* (*Cardizem CD II*), 105 F. Supp. 2d 682, 701 (E.D. Mich. 2000) (failing to address patent issue), and *Cardizem CD III*, 332 F.3d at 908 (agreeing with *Cardizem CD II* conclusion, which found unpersuasive defendants' argument that patent rights avoid *per se* treatment). In a twenty-four-page opinion, the district court in *Cardizem CD II* devoted one sentence to analyzing the impact of Hoechst's patent: "The anti-competitive effects of [Hoechst's] patent are . . . not at issue." *Cardizem CD II*, 105 F. Supp. 2d at 701. Amazingly, the Sixth Circuit actually said: "As can be explained in *greater detail* in the district court's opinion, . . . the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights . . ." *Id.* (emphasis added). This lack of analysis was one of the reasons the *Cipro* court declined to follow *Cardizem CD II*. See *Cipro*, 261 F. Supp. 2d at 247 ("Accordingly, this court declines . . . to follow the reasoning in *Cardizem* . . . and to find the [agreements] in this case *per se* illegal without a more elaborate inquiry into the effects of Bayer's patent monopoly on the conduct at issue.").

155. See *Cipro*, 261 F. Supp. 2d at 248-49 (examining development of law with respect to exclusion rights of patent holder and implication in antitrust context and finding scope of patent protection must be examined); see also HOVENKAMP, *supra* note 8, § 5.6b, at 252 (examining different scenarios requiring rule of reason versus *per se* treatment and concluding alleged monopolization involving innovation policies of firm would require rule of reason analysis).

156. See *Cipro*, 261 F. Supp. 2d at 249 (stating proper analysis where patent is at issue). The court stated:

Accordingly, when patents are involved, case law directs that the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal. Therefore, the proper analysis in this case is whether the plaintiffs have proven as a matter of law that the challenged agreements restrict competition beyond the exclusionary effects of the [patent].

*Id.*

157. *Id.* at 249 n.62 (emphasis added).

158. See *id.* at 249-52 (examining settlement agreements in context of Act's statutory scheme).

159. See *id.* at 252 (stating effect of Act on settlements). The court stated:

structure of settlement payments,<sup>160</sup> and *Cardizem CD III*, which held that *per se* treatment applied despite the novelty of the Act.<sup>161</sup> The court in *Cipro* looked to the normal state of affairs for entering a market controlled by a patent holder and found that in a traditional patent settlement scenario consideration would flow from the generic manufacturer to the patent holder.<sup>162</sup> Under the Act, however, the court noted that the normal cost and risk assessments of the parties are drastically changed,<sup>163</sup> and the result is that “consideration flows from the patent owner . . . to the challenger . . . and not vice versa, as in a traditional context.”<sup>164</sup> The *Cipro* court held that because of the statutory scheme of the Act, a *per se* condem-

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[B]ecause of the generic manufacturer’s entitlement under the Hatch-Waxman Amendments to institute patent litigation merely by filing an ANDA IV, the statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits. Accordingly, so-called reverse payments are a natural by-product of the Hatch-Waxman process . . . .

*Id.*

160. *See In re Cardizem CD Antitrust Litig.* (Cardizem CD II), 105 F. Supp. 2d 682, 704 n.14 (E.D. Mich. 2000) (“If the patent owner pays the infringer, and if the infringer settles by . . . agree[ing] to abandon the field, scrutiny is warranted.”) (quoting Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 FED. CIR. B.J. 113, 123 (1998)) (alteration and omission added).

161. *See In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896, 908 (6th Cir. 2003) (holding novelty does not preclude *per se* application). The court stated:

Nor does the fact that this is a “novel” area of law preclude *per se* treatment. To the contrary, the Supreme Court has held that “whatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.”

*Id.* (internal citations omitted).

162. *See Cipro*, 261 F. Supp. 2d at 251 (explaining general situation involving one party attempting to enter market protected by patent). The court essentially stated that to enter a protected drug market in a non-Act situation, a generic company would incur costs of research, manufacturing and marketing. *See id.* Once the drug is on the market, the patent holder’s sales would have dropped, and it is likely the patent holder would sue for lost profits and willful infringement. *See id.* The court found that a settlement between the two, assuming a valid patent, would result in money flowing from the generic manufacturer to the patent holder. *See id.*

163. *See id.* (noting how Act distorts commonly held legal principles regarding settlements). The court stated:

By contrast, in creating an artificial act of infringement (the ANDA IV filing), the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales. This statutory scheme affects the parties’ relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, Barr’s exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but an enormous downside—losing its patent.

*Id.*

164. *Id.* at 251-52.

nation of reverse payments in a patent settlement context was not appropriate,<sup>165</sup> contrary to the determinations made in *Cardizem CD II* and *Cardizem CD III*.<sup>166</sup>

### 3. *Uneven Application of Supreme Court Precedent: Absence of Key Factors*

The *Cardizem CD III* court's analysis of Supreme Court precedent,<sup>167</sup> guiding its decision to find the Agreement *per se* illegal, failed to apply the rationale behind the High Court's holdings. Specifically, the court failed to take into account the FTC's findings on the Agreement and the "novelty" of the Act in relation to whether the court had the necessary experience to conclusively determine the Agreement was *per se* invalid.

The court cited *Broadcast Music, Inc. v. Columbia Broadcast System, Inc.*<sup>168</sup> for support in applying a *per se* rule to the Agreement.<sup>169</sup> Dealing with a copyright antitrust claim in that case, the Supreme Court stated that although it was not bound by an executive agency determination,<sup>170</sup> and a favorable agency determination would not necessarily immunize defendants from private action,<sup>171</sup> courts must take into account the fact that an

165. *See id.* at 252 (stating that because of Act's process, reverse payments present in agreement are not so nefarious as to warrant *per se* treatment).

166. *See Cardizem CD III*, 332 F.3d at 915 (affirming both district court's denial of motion to dismiss by defendants and grant of partial summary judgment to plaintiffs because Agreement constituted *per se* illegal violation of Sherman Act); *In re Cardizem CD Antitrust Litig. (Cardizem CD II)*, 105 F. Supp. 2d 682, 706-07 (E.D. Mich. 2000) (granting plaintiffs' motion for partial summary judgment because Agreement constituted *per se* illegal violation of Sherman Act).

167. *See Cardizem CD III*, 332 F.3d at 906-09 (citing *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982), nine times where Court, by 4-3 vote, condemned maximum price-fixing arrangement by group of doctors as *per se* illegal); *id.* at 906 (citing *State Oil Co. v. Khan*, 522 U.S. 3 (1997), three times where Court, by unanimous decision, held that vertical price-fixing arrangements are not *per se* illegal); *id.* at 906-07 (citing *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984), two times where Court, by 7-2 vote, held that NCAA had unreasonably restrained trade, but that its actions were not subject to *per se* rule); *id.* at 907 (citing *United States v. Topco Associates, Inc.*, 405 U.S. 596 (1972), two times where Court, by 6-1 margin with Justice Blackmun concurring, condemned arrangement between cooperative of small grocery stores as *per se* illegal); *id.* at 906 (citing *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1 (1979), where Court, by 8-1 vote, found that blanket copyright licensing arrangement was not subject to *per se* rule, nor was it illegal restraint of trade).

168. 441 U.S. 1 (1979).

169. *See Cardizem CD III*, 332 F.3d at 906 ("[A] *per se* rule is applied when 'the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.'" (quoting *Broad. Music*, 441 U.S. at 19-20)).

170. *See Broad. Music*, 441 U.S. at 16 (stating Supreme Court is not bound by views of DOJ).

171. *See id.* at 13 ("[A] consent judgment, even one entered at the behest of the Antitrust Division, does not immunize the defendant from liability for actions, including those contemplated by the decree, that violate the rights of nonparties.").

executive agency scrutinized the arrangement.<sup>172</sup> The alternative, noted the Court, would be that an “unthinking application of the *per se* rule might upset the balancing of economic power and of procompetitive and anticompetitive effects presumably worked out in the decree” between the defendants and the executive agency.<sup>173</sup>

On March 16, 2000, the FTC filed a complaint against Hoechst and Andrx.<sup>174</sup> The complaint alleged that the Agreement was an unreasonable restraint of trade.<sup>175</sup> The *Cardizem CD II* decision filed on June 6, 2000, examined the FTC complaint; however, because the administrative hearing was set for November 14, 2000, the court was unable to significantly evaluate its impact.<sup>176</sup> On April 2, 2001, the FTC, Hoechst and Andrx entered into a consent agreement.<sup>177</sup> The Sixth Circuit decided *Cardizem CD III* on June 13, 2003, over two years after the FTC consent decree, yet not a single mention of the decree appears in the court’s opinion.<sup>178</sup> Significantly, the FTC stated:

Based on the FTC’s investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.<sup>179</sup>

It is difficult to rationalize the court’s application of the *per se* rule in light of the Supreme Court’s instruction to examine agency determinations, es-

172. *See id.* (“[I]t cannot be ignored that the Federal Executive and Judiciary have carefully scrutinized ASCAP and the challenged conduct . . . [T]he decree is a fact of economic and legal life in this industry, and the *Court of Appeals should not have ignored it completely in analyzing the practice.*”) (emphasis added).

173. *Id.* at 13 n.24.

174. *See* Complaint of FTC, *In re* Hoechst Marion Roussel, Inc., No. 9293, 2000 WL 288452 (F.T.C. Mar. 16, 2000), available at <http://www.ftc.gov/os/2000/03/hoechstandrxcplmain.htm> [hereinafter FTC Complaint].

175. *See* FTC Complaint ¶ 29. Although the FTC alleged illegal restraint of trade in violation of only 15 U.S.C. § 45, the Federal Trade Commission Act, the Supreme Court has stated “the FTC Act’s prohibition of unfair competition and deceptive acts or practices . . . overlaps the scope of § 1 of the Sherman Act . . . aimed at prohibiting restraint of trade.” *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 763 n.3 (1999).

176. *See In re* Cardizem CD Antitrust Litig. (Cardizem CD II), 105 F. Supp. 2d 682, 690 (E.D. Mich. 2000) (stating general allegations of FTC complaint and noting hearing date of November 14, 2000).

177. *See In re* Hoechst Marion Roussel, Inc., No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (decision and order), available at <http://www.ftc.gov/os/2001/04/hoechstpdo.pdf> [hereinafter FTC Consent Decree].

178. *See In re* Cardizem CD Antitrust Litig. (Cardizem CD III), 332 F.3d 896, 901-09 (6th Cir. 2003) (lacking any mention of FTC complaint or FTC consent decree in both recitation of facts and legal analysis).

179. *Hoechst Marion Roussel, Inc.*, 66 Fed. Reg. 18,636 (FTC Apr. 10, 2001), available at <http://www.ftc.gov/os/2001/04/hoechstanalysis.pdf>. (providing analysis to aid public comment).

pecially considering this particular determination found no delay in generic entry to the Cardizem CD market.<sup>180</sup>

Finally, while the court determined it apparently had the “considerable experience” required by the Supreme Court to properly characterize the Agreement as *per se* illegal, it is unclear that that determination was accurate.<sup>181</sup> First, the Supreme Court itself, in a unanimous decision in *Broadcast Music*, held that it did not have the experience necessary in copyright law to find a *per se* rule applicable in the area of blanket licensing.<sup>182</sup> Second, the court in *Cipro*, facing a situation identical to *Cardizem CD III*, undertook a detailed analysis of the rights of patent holders<sup>183</sup> and the interactions of parties within the Act,<sup>184</sup> rather than concluding with cursory analysis that a *per se* designation was warranted.

#### IV. STRONG PRO-INNOVATION POLICY NEEDED

Consumers and innovators both deserve proper protection; the difficult issue is striking a balance that spurs competition in the marketplace while encouraging continued investment in innovation.<sup>185</sup> Recently, however, consumer protection has come at the expense of the innovator, particularly in the pharmaceutical industry.<sup>186</sup>

Opponents of “big-pharma” frequently cite high prices for brand-name drugs, upward increases in the percentage of health care costs spent on drugs and large industry bottom lines as evidence of an industry with a

180. Compare *Morse*, *supra* note 2, at 392 (“If [the FTC found] no delay in entry by either Andrx or any other potential manufacturer, it is difficult to understand how the agreement diminished competition.”), with *Cardizem CD III*, 332 F.3d at 907 (“By delaying Andrx’s entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx’s 180-day period of marketing exclusivity . . .”).

181. Compare *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 344 (1982) (“Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.”), with *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607-08 (1972) (“It is only after considerable experience with certain business relationships that courts classify them as *per se* violations of the Sherman Act.”) (emphasis added).

182. See *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 9-10 (1979) (commenting on novelty of copyright and antitrust issue). The Court stated: “We have never examined a practice like this one before; indeed, the Court of Appeals recognized that ‘[i]n dealing with performing rights in the music industry we confront conditions both in copyright law and in antitrust law which are *sui generis*.’” *Id.* at 10. (internal citations omitted).

183. See *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro)*, 261 F. Supp. 2d 188, 247-49 (E.D.N.Y. 2003) (analyzing federal law for effects of patent law with respect to *per se* designation in antitrust law).

184. See *id.* at 250-52 (analyzing effect of “novel” statutory scheme in Act with respect to antitrust condemnation of “reverse payments”).

185. See *Anthony*, *supra* note 24, at 3, 37-38 (commenting on crucial balance necessary for ensuring competitive market and protecting patent rights).

186. For a discussion on the impacts of congressional and FTC action towards the pharmaceutical industry, see *supra* notes 1-2, 6-7 and accompanying text.

monopolistic drive to maximize profits and stunt competition.<sup>187</sup> The facts, however, indicate otherwise. Only about a dime out of every health care dollar is spent on drugs, including generics.<sup>188</sup> Right now, the process of bringing a drug to market costs \$800 million and takes almost fourteen years of testing and approval.<sup>189</sup> Out of five thousand potentially viable compounds tested on animals, only five make it to the human clinical testing stage, and of that five, only one makes it to market.<sup>190</sup> Once on the market, only about one out of five drugs will ever recoup its initial investment and become profitable for a firm.<sup>191</sup> Pharmaceutical companies also reinvest their profits into research and development more

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187. See O'Reilly, *supra* note 1, at 430, 432 (providing political suggestion on how Congress should handle lobbying effort of big pharmaceutical companies); *Generic Drugs*, *supra* note 9, at 36 (providing economic overview of problems with big-pharma); see also Lobanoff, *supra* note 2, at 1331, 1337-38 (claiming brand-name pharmaceutical companies are only ones to blame for problems in Act). *Consumer Reports* writes: "Protect the monopoly has become the innovators' mantra." *Generic Drugs*, *supra* note 9, at 36. The report continues to implicate big-pharma, declaring: "Despite industry claims that it needs extraordinary profits to finance risky, expensive research and development, the 11 companies in the Fortune 500 spent just 12 percent of revenues on R&D and 30 percent on marketing and administration; they took 17 percent as profits." *Id.* O'Reilly implicates Congress as the primary source of the problem of prescription drug funding, stating: "Instead of focusing on the pioneer drug industry's lucrative lobbying efforts, Washington should turn its attention to the sick and elderly, whose funds pay for prescription drugs." O'Reilly, *supra* note 1, at 432. O'Reilly goes on to state:

The principal sponsor of the [Act] criticized the "collusion" efforts of pioneers, saying that it was "thoroughly at odds with the interests of American consumers." . . . However, the amount of profits available under the current scheme are so huge, that lobbyists for the innovative companies oppose any changes to what was put in place seventeen years earlier. These lobbyists still want more concessions from Congress.

*Id.* at 430.

188. See Alan F. Holmer, President & CEO, PhRMA, The Case for Innovation: The Role of Intellectual Property, Address Before the Economist's Second Annual Pharmaceuticals Roundtable (Nov. 20, 2002), available at <http://www.phrma.org/publications/publications/20.11.2002.629.cfm> [hereinafter Holmer Speech] ("Prescription medicines make up about ten cents of each health care dollar.").

189. See JAMES W. HUGHES ET AL., NAT'L BUREAU OF ECON. RESEARCH, "NAPSTERIZING" PHARMACEUTICALS: ACCESS, INNOVATION, AND CONSUMER WELFARE 7 (Oct. 2002), available at <http://www.nber.org/papers/w9229> [hereinafter NBER PAPER] ("The average drug takes twelve years to develop and test, with up to an additional two years for FDA approval.").

190. See *id.* at 8.

191. See Nancy Duvergne Smith, *Pharmaceutical Industry Balances High Profits, Moral Ground*, IMPACT (Winter 2003), at [http://web.mit.edu/ctpid/www/impact11\\_lectures.html](http://web.mit.edu/ctpid/www/impact11_lectures.html) (last visited Apr. 6, 2004) (statement of Franz Humer, Chairman and CEO of Rouche Holding Ltd.) ("Of 10,000 compounds in the test tube, only ten make it to human testing. Only one makes it to market. And only one of four that make it to market returns its investment."); PhRMA, *Fact Sheet: Pharmaceutical Patent Incentives*, at <http://www.phrma.org/publications/publications/17.06.2003.746.cfm> (last visited Jan. 14, 2004) ("Seven out of every ten medicines approved by FDA do not generate sufficient sales to cover average research and development costs."); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro), 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) ("[O]nly 30% or less of mar-

than all other industries combined—an estimated \$32 billion alone in 2002.<sup>192</sup> Additionally, drug consumers are not all being impacted to the extent that is being reported. A study by the Agency for Healthcare Research and Quality and the National Center for Health Statistics found that the top twenty percent of all drug purchasers pay over eighty-six percent of all drug costs.<sup>193</sup> Eighty percent of all drug purchasers in this country spend, on average, just \$66 on drugs per year, out of a total health care budget of \$1,160.<sup>194</sup>

Another issue that arises when discussing the need to protect consumers is the definition of “consumer” and whether any duty is owed to the future consumers and their right to receive life-saving drugs.<sup>195</sup> A recent paper by the National Bureau of Economic Research (“NBER Paper”) has shown that pharmaceutical patents have been considerably weakened, with an effective market life of only 6.5 years.<sup>196</sup> Additionally, the NBER Paper concluded that if the current trend of pharmaceutical patent erosion continues in favor of consumer protection, this country will suffer a future consumer loss of \$3 for every \$1 of current consumer gain by faster generic entry into the market.<sup>197</sup> Yet Congress and the FTC, rather than

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keted drugs produce revenues that that equal or exceed their average R&D costs.”).

192. See PhRMA, *Patent Incentives for Discovery of New Medicines Must Be Maintained, PhRMA Tells Lawmakers* (June 17, 2003), at <http://www.phrma.org/mediaroom/press/releases/17.06.2003.747.cfm> (noting organization’s members invested estimated \$32 billion in research and development).

193. See PhRMA, *Who Is Cared for with Prescription Medicines? Characteristics of Individuals with High Prescription Drug Expenses in 2000* (Summer 2003), at <http://www.phrma.org/publications/twopager/2003-09-04.847.pdf> (last visited Apr. 6, 2004) (citing data reported in 2000 Medical Expenditure Panel Survey).

194. *See id.*

195. *See* NBER PAPER, *supra* note 189, at 3-4 (stating policy implications of result of study). The authors conclude that the “sub-optimal” patent protection afforded pharmaceuticals is the result of public policies being influenced by consumer groups that are identifiable and well organized. *See id.* Because of this influence, there is a risk that actual consumers of prescription drugs have a greater voice in determining the public policy than the unknown potential consumer, who is either waiting for a drug to be invented that is not yet on the market or has not yet contracted the specific ailment requiring drug therapy. *See id.* at 4.

196. *See id.* at 5 (examining pharmaceutical patents and exclusivity periods from 1997-2001 and finding average of 6.5 years in 2001).

197. *See id.* at Abstract (concluding weakened pharmaceutical patents result in three dollars of future consumer loss for one dollar of present day gain). The authors state:

We find that providing greater access to the current stock of prescription drugs yields large benefits to existing consumers. However, realizing those benefits has a substantially greater cost in terms of lost consumer benefits from reductions in the flow of new drugs. Specifically, the model yields the result that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value from reduced future innovation.

*Id.*

strengthening pharmaceutical patent protection, have chosen to single out the pharmaceutical patent and weaken it further with the short-sighted goal of lowering current drug prices.<sup>198</sup> If one considers the consumer as a continuous entity, then the need for a strong pro-innovation policy becomes self-evident; without such a policy, the future consumer will suffer for the short-term benefit of the current consumer.<sup>199</sup>

## V. CONCLUSION

In *Cardizem CD III*, the Sixth Circuit, apparently relying on Supreme Court precedent condemning horizontal market allocations under the Sherman Act,<sup>200</sup> characterized the Agreement as a *per se* illegal restraint of trade.<sup>201</sup> The court, however, did not analyze critical factors specific to the Agreement within the context of the pharmaceutical industry, calling into question whether the court had the “considerable experience” necessary to make a *per se* determination and whether its holding should be given any weight.<sup>202</sup> Specifically, the court failed to address the FTC’s finding in its investigation of the Agreement, the effects of patent rights as an exclusionary market force and the unique framework of the Act as it pertains to settlement agreements in patent infringement actions.<sup>203</sup> While consumers deserve access to affordable health care and protection from illegal antitrust conduct, both the courts and Congress need to come to a more thorough understanding of the importance of the pharmaceutical industry in ensuring the health and well-being of current and future

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198. For a discussion on the impacts of congressional and FTC action towards the pharmaceutical industry, see *supra* notes 1-4, 6-7 and accompanying text.

199. See O’Reilly, *supra* note 1, at 415 (stating that patent protection must remain strong for social benefit). O’Reilly states:

There is no dispute that innovators need to be able to recoup their investment at a profit, so that future financial investment in socially beneficial pharmaceutical research will continue. Innovators in the pharmaceutical field are bound by extremely complex and demanding controls established for public protection. The “new drug application” process is remarkably expensive and thorough, therefore the innovator’s costs to be recouped during the patent period include not only costs related to discovery, but also the costs associated with regulatory approvals.

*Id.*

200. See *In re Cardizem CD Antitrust Litig.* (Cardizem CD III), 332 F.3d 896, 907 (6th Cir. 2003) (citing four Supreme Court cases for general proposition that horizontal market allocations are naked restraints of trade and, thus, *per se* illegal).

201. See *id.* at 908 (holding Agreement was horizontal market allocation to grant Hoechst entire U.S. market for diltiazem hydrochloride).

202. See Morse, *supra* note 2, at 399 (noting that *Cardizem CD III* holding should not be “overread”). For a discussion and analysis of the use and application of Supreme Court precedent by the *Cardizem CD III* decision, see *supra* notes 167-84 and accompanying text.

203. For a complete analysis of the factors employed by the court in *Cipro*, as compared to the *Cardizem CD III* court, see *supra* notes 144-66 and accompanying text.



generations.<sup>204</sup> If pharmaceutical companies are dissuaded from continuing to invest in breakthrough drugs, ultimately the consumer suffers.<sup>205</sup> Moreover, if a constant production of breakthrough drugs is not maintained, the generic drug industry that will be left without a continuing

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204. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro), 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (stating that policy favoring application of rule of reason analysis over *per se* analysis encourages risk-taking and R&D investment). The court stated:

[A] rule that makes it *per se* illegal to settle a Hatch-Waxman lawsuit . . . limits the options available to both generic and brand-name manufacturers. If brand-name manufacturers are unable to control or limit their risk by settling Hatch-Waxman litigation, they, like generic manufacturers, may be less inclined to invest the research and development (“R&D”) costs associated with bringing new drugs to market. The pharmaceutical industry depends greatly on R&D and the economic returns to intellectual property created when a successful new drug is brought to market. A rule prohibiting settlements of Hatch-Waxman patent litigation can have . . . extremely large effect[s] on the economic welfare and medical well-being of US customers. The pharmaceutical industry in the US spent \$26 billion on R&D in 2000 with the average cost of developing a new drug now estimated at \$802 million. Yet only 30% (or less) of marketed drugs produce revenues that equal or exceed their average R&D costs. If incorrect judicial determinations are made that decrease the value of the intellectual property, expected returns on R&D will decrease and new drug innovation in the US will decrease. The results will be fewer drugs that led in the past to healthier and more productive lives for US customers and large gains to the US economy.

Although a policy in favor of settlement of litigation cannot save a *per se* violation from the scriptures of the *Sherman Act*, a rule that too quickly condemns actions as *per se* illegal, potentially chilling efforts to research and develop new drugs and challenges the patents on brand-name drugs, does competition—and thus, the *Sherman Act*—a disservice. Application of the rule of reason will permit the court, in light of the evidence presented by the parties, to balance the anticompetitive effects of the [agreement] against the benefits of allowing brand-name drug companies to invest in R&D with some degree of confidence that they will be able to control patent litigation when they introduce new drugs. In weighing these competing policy concerns under a rule of reason analysis, the court will be able to take into account a variety of factors affecting the degree of anticompetitive impact caused by the agreements.

*Id.* (internal citations omitted).

205. See Holmer Speech, *supra* note 188 (discussing importance of maintaining strong incentives for discovering new medicines). Mr. Holmer first described a scenario in 2050, where this country had strong patent protections for its drugs. See *id.* In this scenario, life expectancy has increased and disability rates have dropped. See *id.* Drug advances have made communicable diseases a thing of the past; as a result, “[e]conomic productivity is up, sick days are on the decline, and people [are] contribut[ing] to society well into their 80’s.” *Id.* This, he says, are the human and economic realities of pharmaceutical patent protection. See *id.* In scenario two, patent rights are weakened causing most pharmaceutical companies to copy each other or older drugs. See *id.* Alzheimer’s disease is rampant and nursing homes are full, representing the fastest growing health care cost. See *id.* In order to fund the exorbitant health care costs, Congress has “raised taxes and cut funding to other programs.” *Id.* Families are forced to expend large portions of their budget caring for their sick or elderly parents and grandparents. See *id.* He asks us to choose scenarios: “Where will you spend your 85th birthday?” *Id.*

supply of pioneer drugs to copy and bring to market.<sup>206</sup> The best way to protect against these potential unfortunate happenings is to prevent the erosion of patent rights for pharmaceutical companies and apply a rule of reason analysis to agreements made within the pharmaceutical industry.

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206. See NBER PAPER, *supra* note 189, at 19 (demonstrating graphically how, when no new drugs are invented due to weakened patent rights, generic manufacturers suffer loss of product to mimic).

