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## ARTICLES

# CORNERING THE MARKET IN A POST-9/11 WORLD: THE FUTURE OF HORIZONTAL RESTRAINTS

DANIEL GOLDBERG\*

### INTRODUCTION

In the next few years, several widely prescribed drugs, such as Prozac and Prilosec, will lose their patent protection,<sup>1</sup> allowing equivalent generic drugs to penetrate the pharmaceutical drug market. To extend their exclusive position in the market, brand drug manufacturers have begun entering into agreements with generic drug producers to delay the latter's entry into the market. The Federal Trade Commission (FTC) has expressed concern that such agreements are plainly anticompetitive horizontal restraints that violate Section 1 of the Sherman Antitrust Act.<sup>2</sup> The FTC has

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1. See, e.g., "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements", Prepared Statement of the Federal Trade Commission before the Senate Judiciary Committee, May 24, 2001, available at <http://www.ftc.gov/os/2001/05/pharmtstmy.htm> (last visited Mar. 3, 2003) [hereinafter "FTC Statement"] (noting that "[w]ithin the next five years, patents on brand-name drugs with combined U.S. sales approaching \$20 billion will expire"). See also *Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, available at <http://www.cbo.gov> (last visited Mar. 29, 2002) (hereinafter "CBO Report") (same); *Purple Pill Patents*, (National Public Radio audio broadcast, Apr. 18, 2002) (describing the Prilosec manufacturer's (AstraZeneca) efforts to prevent generic entry into the market); *A pill that changed the world; Generic Drugs*, THE ECONOMIST, Aug. 3, 2001, at 1 (discussing Eli Lilly's dilemma with Prozac's impending off-patent status).

2. See FTC Statement, *supra* note 1, at 4 (surveying several cases in which "the Commission alleged that as part of a [patent] settlement agreement, the branded firm made payments to the generic firm in exchange for delayed entry"). These cases are explained in greater detail in Part II.B. In addition, the FTC released a report on July 30, 2002, detailing its specific recommendations for changes to the Hatch-Waxman Act, which regulates generic drug production. See Federal Trade Commission News Release,

filed several lawsuits and entered into several consent agreements with brand drug manufacturers to curb the use of these agreements.<sup>3</sup>

Underlying all of this is the complex relationship between patents and antitrust law. Some brand drug manufacturers have filed patent infringement lawsuits against generic drug producers.<sup>4</sup> Under the Hatch-Waxman Act,<sup>5</sup> the statute principally responsible for regulating generic drug production, filing a patent infringement lawsuit delays generic drug entry into the market for as long as two and a half years.<sup>6</sup> Moreover, in the course of this litigation, the parties often settle, and, as part of the settlement, the generic drug producer agrees to delay entry into the market for a further specified period of time.<sup>7</sup> Concerned about this behavior, the FTC has initiated legal action and has made detailed recommendations for changing the current legal regime to prevent such agreements.<sup>8</sup>

This article examines the legality of agreements between brand drug manufacturers and generic producers that delay generic drug entry into the relevant market. More specifically, this article explores the connection between patents, pharmaceuticals, and antitrust policy in a post 9/11-world facing an increased need for affordable pharmaceuticals to combat potential acts of bio-terrorism. The 9/11-aspect is crucial to

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*FTC Recommends Legislative Changes to Hatch-Waxman Act*, available at <http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm> (last visited Mar. 4, 2003). See also *infra* Part IV.B (discussing FTC recommendations for legislative changes).

3. *Id.*

4. See, e.g., *id.* (explaining why brand drug manufacturers often initiate patent infringement litigation against generic manufacturers in order to forestall generic drug entry). See also *Altman v. Bayer Corp.*, 125 F. Supp. 2d 666, 668-69 (S.D.N.Y. 2000) (discussing Bayer's initiation of a patent infringement lawsuit against a generic drug producer regarding the antibiotic Cipro).

5. Act of Sept. 24, 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1998) (codified at 21 U.S.C. §§ 355, 360cc & 35 U.S.C. §§ 156, 271, 282 (2000)).

6. See discussion *infra* Part II (explaining the framework the Hatch-Waxman Act creates).

7. See, e.g., *Altman*, 125 F. Supp. 2d at 669 (stating that the brand drug and generic manufacturers entered into a settlement in which the generic producer, Barr Laboratories, "agreed not to market its Cipro generic equivalent in the United States or otherwise trigger the 180 day exclusivity period in exchange for [the brand drug producer]'s promise to pay \$24.5 million . . . to Barr. . .").

8. See *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, available at <http://www.ftc.gov/opp/intellect/index.htm> (last visited Mar. 4, 2003) (exploring the interrelationship of patents, intellectual property in biotechnology, and antitrust concerns). See also FTC Report, *supra* note 1 (describing the study conducted by the FTC).

understanding the evolutionary nature of antitrust because, in a dialectical sense, 9/11 changed the thesis of antitrust enforcement in the pharmaceutical market. This change is most clearly illustrated with respect to the antibiotic Ciprofloxacin (Cipro), the anti-anthrax drug that became a household name for unfortunate reasons following 9/11. The Cipro debate, detailed in Part III, which has taken on great importance since 9/11,<sup>9</sup> provides a useful case study of the relationship between patent law, brand name drugs, generic counterparts, and antitrust enforcement in the general pharmaceutical market.

The horizontal restraints at issue here are relatively recent phenomena and the FTC did not file its first complaint challenging such conduct until May of 2000. Furthermore, the cases that have been filed have had little time to develop through the judicial system. Thus, instead of surveying case law, this article focuses on the total context surrounding generic drug competition specifically as it relates to Cipro. This article will survey all relevant phenomena bearing on the generic drug competition issue, including, but not limited to, the legislative, executive, political, historical, economic, and judicial factors that inform the question. The idea is to treat a question of antitrust policy as an historical phenomenon that cannot be assessed solely in terms of doctrine, but in view of the legal and social context the issue arises within.<sup>10</sup>

In assessing the legality of agreements that delay generic entry into the market, this article addresses two questions. The first question is whether patents on pharmaceuticals encourage or discourage competition in the relevant market or markets. The second question is whether courts will be more or less willing to find antitrust violations by brand drug manufacturers in the post-9/11 world.

To answer these two questions, this article will first contrast the Hatch-Waxman Act's intent, history, and effects with the philosophy behind patent protections in the pharmaceutical industry. The article will then conduct an economic analysis of pharmaceutical markets in relation to patents and generic drug entry. Finally, the article provides a historical analysis of antitrust enforcement as applied to the Cipro litigation in a post-9/11 legal culture.

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9. See James Surowiecki, *No Profit, No Cure*, THE NEW YORKER, Nov. 5, 2001, at 46 (rejecting emphatically DHHS Secretary Tommy Thompson's threat "to break Bayer's patent on [Cipro]" if Bayer did not agree to sell the drug to the U.S. at a below-market price).

10. See discussion *infra* Part IV.B (detailing the historical approach to antitrust).

## I. THE HATCH-WAXMAN ACT: A PRECARIOUS BALANCE

### A. Background & Objectives of the Act

Any analysis of pharmaceuticals, patents, and competition must begin with the 1984 Hatch-Waxman Act, which “was an unprecedented attempt [by Congress] to achieve two seemingly contradictory objectives, namely, 1) to make lower-costing generic copies of approved drugs more widely available and 2) to assure that there were adequate incentives to invest in the development of new drugs.”<sup>11</sup>

Conceptually speaking, there is obvious tension behind the purposes of the federal patent system, and antitrust policy. “The intersection of the patent and antitrust laws presents a formidable paradox. The patent laws increase invention and innovation by offering inventors a right to exclude. The antitrust laws foster competition, sometimes through the condemnation of such exclusion.”<sup>12</sup> Thus, “[a]ctivity that may be encouraged under the patent system frequently raises the suspicion of the antitrust laws by reducing competition.”<sup>13</sup>

The Hatch-Waxman Act is controversial because it attempts to accomplish both of these seemingly mutually exclusive goals at the same time. As prescription drug prices continue to rise and as the post-9/11 world faces the all-too-real specter of bioterrorism, one cannot overstate the importance of encouraging both competition between pharmaceuticals and research and development.

The power play between the generic and brand-name pharmaceutical markets is clearly illustrated by the Act's legislative process. As Professor Engelberg notes, “Each of the patent provisions of the [1984] Act was born as part of a unique legislative process which, in reality, was a congressionally supervised negotiation between the generic and brand-name pharmaceutical industries in which the parties were compelled to reach a compromise by the legislature.”<sup>14</sup> This history lends itself to understanding how the Act has developed and its effects on the rudiments of patent protection.

However, as Professor Engelberg argues, there is no connection between patent protections and commercial benefits because commercial benefit depends on a host of factors

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

12. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 762-63 (2002).

13. *Id.* at 769.

14. Engelberg, *supra* note 11, at 391.

extraneous to the existence and scope of patent protections.<sup>15</sup> Thus, “there [is] no legal or logical relationship between the life of a patent and the commercial life of any product claimed in a patent.”<sup>16</sup> This is the basis of Professor Engelberg’s conclusion that the special patent protections codified in the Act are unwarranted and that patent law should not provide “corporate welfare” to pharmaceutical manufacturers.<sup>17</sup>

Prior to 1984, drug companies often sought FDA approval for the manufacture of generic drugs “before the relevant patents expired, even though it was necessary to make and use the patented invention and thus commit acts amounting to literal infringement as part of the process of seeking FDA approval.”<sup>18</sup> Curiously, no cases exist prior to 1984 where a brand drug manufacturer sued a generic drug producer for patent infringement when the latter sought FDA approval.<sup>19</sup> Furthermore, prior to 1984, the federal government provided no clear process for FDA approval of generic drugs. “[B]y the early 1980s the approval of generic versions of existing drugs was an uncertain process. The patents on many important drugs had expired or were about to expire, and the prospect of competition in the sale of those products and of inevitably lower prices for consumers was dim.”<sup>20</sup>

### B. Nuts & Bolts of the Act

In 1984, after successful negotiations between the generic and

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15. *See id.* (arguing that “[c]ommercial success actually depends upon a multitude of other factors including the commercial practicality of the invention, the state of development, [and] the existence of a market. . .”).

16. *Id.* at 394.

17. Though the author sympathizes with Professor Engelberg’s conclusion, his inferences are not entirely convincing. His argument ignores the possibility that patent protections may be necessary yet not sufficient to effect commercial success. While the provisions of a patent obviously do not guarantee commercial success, it is not implausible to suggest that without such protection, the willingness to innovate is at least dampened, and at most derailed, due to the loss of the profit incentive. In the case of drugs like Cipro that have become, at least popularly, vital in a post-9/11 world, curbing innovation even slightly could have serious repercussions. In any case, I am not here rejecting Professor Engelberg’s argument, but only suggesting that his premises do not seem unassailable. I will return to this perspective in detail later in the Article. For now, it will suffice for the reader to understand that one reason the Act is controversial is because some do perceive it as a kind of corporate welfare, rather than as a necessary safeguard for drug research and development.

18. Engelberg, *supra* note 11, at 395.

19. *Id.*

20. *Id.* at 397.

brand name pharmaceutical industries,<sup>21</sup> Congress passed the current form of the Hatch-Waxman Act.<sup>22</sup> President Reagan signed the bill into law on September 24, 1984.<sup>23</sup>

There are several important provisions of the Act. First, the Act enables brand drug manufacturers to apply for "an extension of their patent term. . . [These] extensions . . . equal half of the time the drug spent in clinical testing (usually a total of six to eight years) plus all of the time it spent having the FDA review its new drug application (usually about two years)."<sup>24</sup> Congress intended for these patent extensions to offset the acts of infringement that occur during the approval process.<sup>25</sup>

Second, the Act contains provisions aside from patent extensions that work to postpone generic entry. To obtain FDA approval, a putative generic drug producer must file an abbreviated new drug application (ANDA).<sup>26</sup> "Under the abbreviated procedure, an ANDA applicant that demonstrates bioequivalency [sic] with a pioneer drug may rely upon FDA findings of safety and efficacy."<sup>27</sup> The FDA requires an ANDA applicant to make one of four possible certifications regarding the brand drug manufacturer's patent protections.<sup>28</sup> This Article (and the FTC) is concerned only with certification IV.

A certification under paragraph IV requires the ANDA applicant to give notice of the ANDA filing to the patent owner and the firm that obtained the new drug approval for the listed drug (typically the pioneer manufacturer). This notice must include a detailed

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21. Engelberg, *supra* note 11, at 405. Professor Engelberg explains that [b]y early August 1984, it became clear that no law would be enacted unless a compromise could be negotiated directly between the generic and brand-name factions. Accordingly, Senator Hatch placed heavy pressure on representatives of the two sides to reach agreement and ultimately acted as a referee and arbitrator on the final points of disagreement.

*Id.*

22. *Id.* at 406.

23. *Id.* at 407.

24. CBO Report, *supra* note 1, at xiii-xiv.

25. *See id.* at 4 (citing 35 U.S.C. § 156(c) (2000)).

26. *See* FTC Statement, *supra* note 1 (noting that ANDA is designed to protect companies' innovations while encouraging competition). *See also* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676-78 (1990) (tracing the framework imposed by the Hatch-Waxman Act); Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130, 1131-32 (Fed. Cir. 1995) (same).

27. FTC Statement, *supra* note 1 (citing 21 U.S.C. § 355(j)(2) (1994)). The alert reader will no doubt have noticed the free-rider problem lurking in the statutory scheme insofar as imitators are free to rely on the brand drug manufacturers' investments in proving safety and efficacy. For discussion of the implications of the free-rider problem as to pharmaceuticals, and the role patent protections play in reducing the problem, see Part III.A.

28. 21 U.S.C. § 355(j)(2)(A)(vii) (2000).

statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not invalid, is unenforceable, or will not be infringed.<sup>29</sup>

Once a would-be generic drug manufacturer files a paragraph IV certification with the FDA, two provisions at the heart of the current FTC concern become relevant. First, if the patent owner brings a patent infringement lawsuit against the ANDA applicant within forty-five days of receiving notice of the paragraph IV certification, the FDA may not approve an ANDA for thirty months. The only exception to this time period occurs if a court gives a final order as to the infringement suit, or if a court orders a longer or shorter period.<sup>30</sup> Second,

[t]he Act grants to the first ANDA filer a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. The 180-day exclusivity period begins running on the earlier of (1) the date the first ANDA filer begins commercial marketing of the generic drug, or (2) the date a court decides the patent addressed by the paragraph IV certification is invalid or not infringed.<sup>31</sup>

Perhaps most importantly, "[n]o other generic manufacturer may obtain final FDA approval to market its version of the relevant product until the first filer's 180-day exclusivity period has expired."<sup>32</sup> Understanding how the statutory provisions work is made easier by considering several fact patterns. The following section describes scenarios that apply the Act's provisions.

### C. Cases & Controversies

Generally, the FTC disapproves of abuses by petitioners during the paragraph IV certification process. Consider the following hypothetical.

At  $T_1$  (Time One), a putative generic drug producer files an ANDA with paragraph IV certification. The patent owner and the firm that obtained the new drug approval receive the requisite notice at  $T_2$ . Within forty-five days of receiving this notice, at  $T_3$ , the brand drug manufacturer files a patent infringement lawsuit, essentially disputing the paragraph IV certification. This delays any generic entry into the market for thirty months, unless a court decides the matter in the interim. Finally, at  $T_4$ , as part of the "settlement" agreement, the ANDA filer agrees not to market a

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29. FTC Statement, *supra* note 1. See also 21 U.S.C. § 355(j)(2)(B) (2000) (giving applicant notice requirements); 21 C.F.R. § 314.95(c)(6) (2002) (requiring a detailed statement of facts and law from the applicant).

30. 21 U.S.C. §§ 355(c)(3)(c), 355(j)(5)(B)(iii) (2000).

31. FTC Statement, *supra* note 1, at 4.

32. See *id.* (citing 21 U.S.C. § 355(j)(5)(B)(iv) (2000)).



generic version of the brand drug for some indefinite period of time in exchange for compensation. Part of this settlement agreement includes the ANDA filer's agreement not to transfer or assign its 180-day exclusivity rights under the Act.

Under this set of facts, the brand drug manufacturer has essentially insured that no generic version of its pharmaceutical will enter the market. First, the initiation of the patent infringement lawsuit prevents the FDA from approving the ANDA for two and a half years. Given that brand drugs enjoy market exclusivity for the duration of the patent, an extra two and half years with no competition is significant. Second, and more important, if the initial ANDA filer agrees not to market its generic drug, *no other generic version can legally enter the market*. This result follows because the 180-day exclusivity period grants the initial ANDA filer the right to market its generic drug for 180 days without any other generic drug competition, as to the specific drug sought to be produced under the ANDA. The exclusivity period does not begin to run until either the generic drug producer markets its drug or a court decides against the patent owner on the infringement claim. The settlement agreement ensures that neither of the two ways that the exclusivity period can begin to run will ever come to fruition. By settling, the generic drug producer agrees not to market its drug, the first way the exclusivity period may begin to run, and the brand drug manufacturer obviously avoids an unfavorable judicial disposition, the second way the exclusivity period begins to run. It is as if the generic market for the drug at issue is in suspended animation, with the exclusivity period permanently tolled. So long as the brand drug manufacturer settles with the initial ANDA filer, the exclusivity period will never begin to run, effectively removing generic drug competition from the market.

This phenomenon is certainly not hypothetical. The FTC filed three complaints in the last three years challenging very similar fact patterns to the scenario described above. The FTC filed the first of these in May of 2000 against Abbott Laboratories and Geneva Pharmaceuticals.<sup>33</sup> "The complaint charged that Abbot[t] paid Geneva approximately \$4.5 million per month to keep Geneva's generic version of Abbot[t]'s proprietary drug (Hytrin) off the U.S. market. . . ."<sup>34</sup> The complaint further alleged that Geneva agreed not to enter the market until either the final resolution of the patent infringement litigation or the entry of another generic Hytrin product.<sup>35</sup> Geneva also agreed not to transfer or assign its

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33. *Id.*

34. *Id.*

35. *Id.*

exclusivity rights as the first ANDA filer.<sup>36</sup> “These provisions ensured that no other company’s generic version of Hytrin could obtain FDA approval and enter the market during the term of the agreement, because Geneva’s agreement not to launch its product meant the 180-day exclusivity period would not begin to run.”<sup>37</sup> Subsequent to the complaint, Abbott and Geneva signed a consent decree essentially invalidating the agreement.<sup>38</sup>

The two other cases in which the FTC filed a complaint both involved a similar kind of settlement, arising out of patent infringement litigation, entered into by the brand drug manufacturer and the generic producer.<sup>39</sup> In each of these cases, the brand drug manufacturer compensated the generic drug producer in exchange for the latter’s agreement to delay entry into the relevant pharmaceutical market.<sup>40</sup>

The Cipro litigation follows the same pattern. Bayer Corporation, the manufacturer of Cipro, filed a patent infringement lawsuit against the initial ANDA filer, Barr Laboratories.<sup>41</sup> During the pendency of the litigation, the FDA tentatively approved of Barr’s ANDA application, which meant that Barr was legally entitled to market its generic if the patent litigation was resolved in its favor.<sup>42</sup> Prior to a final judicial resolution, Bayer agreed to pay Barr \$24.5 million in exchange for the latter’s promise “not to market its Cipro generic equivalent in the United States or otherwise trigger the 180 day exclusivity period.”<sup>43</sup> The result, as in the cases described above, “was to foreclose any Cipro generic equivalent competition from entering the market.”<sup>44</sup>

A *prima facie* analysis shows that the agreements described above all act as horizontal restraints because the agreement between the generic drug producer and the brand drug manufacturer serve to keep the generic version off the market. Presumably, once the generic enters the market, the supply of the drug in question will increase, depressing prices. The plaintiff in *Altman* sued under precisely this theory of the case—that

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36. *Id.*

37. *Id.*

38. *Id.*

39. In re Hoechst Marion Roussel, Inc.; Carderm Capital L.P.; and Andrx Corp., Docket No. 9293 (Apr. 2, 2001); In re Schering-Plough Corp. et al., Docket No. 9297 (Mar. 16, 2000).

40. See FTC Statement, *supra* note 1, at 4 (explaining how the brand drug manufacturers paid the generic drug producers to delay the latter’s access into the market).

41. *Altman v. Bayer Corp.*, 125 F. Supp. 2d 666, 669 (S.D.N.Y. 2000).

42. *Id.*

43. *Id.*

44. *Id.*

consumers “were injured by paying prices for Cipro that were ‘supracompetitive,’ i.e., substantially higher than the prices that Plaintiff and members of the Class would have paid absent the allegedly deceptive and misleading stipulation.”<sup>45</sup>

However, as the Supreme Court has observed numerous times, the mere existence of high prices is insufficient to establish a Section 1 violation.<sup>46</sup> Rather, the analysis must focus squarely on the effects of the restraint in question.<sup>47</sup> Though it seems difficult to discern, at first glance, how an agreement to restrict output of a given product has largely pro-competitive effects, appearances can be misleading. First, there is a question as to the cross-elasticity of demand as to brand drug prices versus prescription drug prices.<sup>48</sup> Second, the agreements at issue merely extend the brand drug’s market exclusivity. This is precisely what patent protections are designed to do, bestow upon the patent owner the right to exclude others from using the invention for the life of the patent.<sup>49</sup> Is such market exclusivity inherently anticompetitive? The pharmaceutical industry emphatically answers in the negative, and holds instead that the protections codified in the Hatch-Waxman Act are pro-competitive to the extent they encourage research and development.<sup>50</sup>

Sufficient analysis of the effects of agreements that delay generic entry into the market necessitates economic inquiry into the pharmaceutical industry. Fortunately, in 1998, the nonpartisan Congressional Budget Office (CBO) completed a detailed economic analysis of the effects of generic drug entry into pharmaceutical markets.

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45. *Id.* at 673.

46. *E.g.*, *Theatre Enterprises, Inc. v. Paramount Film Distrib. Corp.*, 346 U.S. 537, 541 (1954) (holding that high prices alone do not establish anti-competitive activity).

47. *See, e.g.*, *Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) (providing the famous aphorism that “[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.”)

48. *See infra* notes 72-80 (elaborating on market segmentation and demand elasticity).

49. *See Engelberg, supra* note 11, at 393 (striking a balance between the wide spread availability of low cost generic drugs and incentive to invest in research for new medications).

50. *See discussion infra* Part IV.A (discussing the procompetitive nature of patents).

## II. THE ECONOMICS OF GENERIC DRUG ENTRY

### A. Pricing Objectives & a Free-Rider Problem

The federal government has two competing policy objectives with respect to the pricing of prescription drugs. On the one hand, it wants to ensure that companies have enough incentive to invest in researching and developing innovative drugs. On the other hand, it wants to discourage them from charging excessively high prices. In general, the government achieves the first goal through a patent system that grants market exclusivity for a limited period of time, allowing companies to recoup their investment in [research and development]. For the second goal, it relies on competition between similar drugs to hold prices down.<sup>51</sup>

According to Professor Engelberg, these goals are consistent with the legislative purpose underlying the Hatch-Waxman Act.<sup>52</sup> However, a free-rider problem is implicit in the tension between these goals, particularly in industries where innovation is crucial.

Conducting research and development and bringing an invention to market often are lengthy and expensive processes, with no guarantees of success at the end of the tunnel. And on those occasions where success is achieved, 'free riders' who did not make any such investments might imitate the hard-earned innovation and appropriate its value for themselves.<sup>53</sup>

Brand drug manufacturers perceive federal patent protections as the chief weapon in reducing the free-rider problem. In economic terms,

intellectual property is a public good. That is, it is nonrival (consumption by one person does not leave any less of the good to be consumed by others) and nonexclusive (others cannot be excluded from consuming it). As a result . . . public goods tend to be . . . subject to free riders, who are tempted to imitate the invention after it has been developed.<sup>54</sup>

The patent extensions and market exclusivity provisions of the Hatch-Waxman Act are intended to reduce the free rider problem insofar as the Act tempers generic producers' ability to imitate (or delay) the invention after it has been developed. This

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51. CBO Report, *supra* note 1, at 13. Though the author does not have the requisite background to judge the methodological worth of this study, it is the most comprehensive study of the effects of generic drug entry on pharmaceutical pricing the author has located.

52. See Engelberg, *supra* note 11, at 389 (stating that the legislation attempted to achieve increases in both the availability of generic drugs and incentives to develop new drugs).

53. Carrier, *supra* note 12, at 766-67.

54. *Id.* at 767 (footnotes omitted).

objective is all the more important in the pharmaceutical paradigm because, as Professor Carrier points out, “once [a] drug is developed, it is easy for free-riding competitors to replicate this work.”<sup>55</sup> The free riding problem is legitimate and is at the core of brand drug manufacturers’ claims that firms in the market will correct for the free riding problem in the most efficient manner. When left to its own devices, the brand drug producer (“A”) will negotiate with the generic producer (“B”) to keep the generic drug off of the market. Doing so eliminates some competition, thereby eliminating at least one imitator’s ability to free ride on, e.g., A’s safety and efficacy findings. Free rider or not, B’s legal right to compete is valuable, and A compensates B for B’s relinquishment of it. In any case, the scenario is *pareto optimal*. Both A and B are better off, and neither are worse off.

Understanding why an effective balance of the two aims of federal drug pricing policy is so difficult to attain requires a deeper analytic and economic comprehension of generic drug entry and its effects on brand drug pricing. Before moving to the CBO’s analysis of the effect of generic entry on brand drug pricing, it is first necessary to survey some important characteristics of the overall pharmaceutical industry and its relevant markets.

### B. Managed Care & Pharmaceutical Market Analysis

The structure of the managed care industry is designed to exert downward pressure on pharmaceutical prices. Managed care organizations’ (MCOs) use pharmacy benefit manager (PBMs) to exert this pressure.<sup>56</sup> MCOs subcontract with PBMs to negotiate superior prescription drug prices, and extends the right to the PBM to do so for the MCOs entire patient network.<sup>57</sup> “In return for channeling their patient base to particular pharmacies, they arrange to pay lower retail prices for drugs at those pharmacies.”<sup>58</sup>

“PBMs are able to negotiate rebates from manufacturers of brand-name drugs based on their ability to steer their members towards a particular drug . . . .”<sup>59</sup> These rebates are one way PBMs achieve savings on prices ultimately paid by the MCOs for its members. The second way is the lower retail prices achieved by the PBMs enhanced bargaining power.<sup>60</sup> Yet a third way PBMs force drug prices down is through generic drug substitution.<sup>61</sup>

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55. *Id.* at 836.

56. CBO Report, *supra* note 1, at 8.

57. *Id.* at 6.

58. *Id.*

59. *Id.* at 6-7.

60. See *supra* notes 57-60 and accompanying text (stating how MCOs use PBMs to negotiate lower prices).

61. CBO Report, *supra* note 1, at 8.

PBMs often provide financial incentives to pharmacists for using generic drugs and encourage consumers to request generic drugs.<sup>62</sup> PBMs do so “by charging a higher copayment for . . . brand-name drugs chosen over generic substitutes.”<sup>63</sup>

The essential point is that the structure of managed care exerts downward pressure on drug prices. The overall effect of this pressure may be doubted, given the ever-rising drug prices, but the pressure exists, at least in theory. This is important because it gives credence to brand drug manufacturers’ claims that market forces are arrayed against increasing prescription drug prices over the long term. Moreover, given PBMs’ use of generic drugs as a weapon in depressing drug prices, the relevance of the brand drug producers’ contentions that generic drugs depress drug prices and thereby stifle innovation is obvious. In other words, the structure of the managed care industry facilitates generic drug entry into the market.<sup>64</sup>

Furthermore, as in any antitrust analysis, the relevant market must be defined. A preliminary analysis indicates that the pharmaceutical market is not highly concentrated.<sup>65</sup> “The four largest manufacturers of innovative drugs each accounted for only 6 percent to 7 percent of total U.S. pharmaceutical sales in 1994. And the top 10 companies together shared just 56 percent of the market.”<sup>66</sup> However, these statistics are misleading. It is difficult to understand, for example, how a drug used to correct heart arrhythmia competes with a drug used to treat asthma. Obviously an individual cannot use one drug to treat both conditions (assuming the drug is only efficacious as to one of the conditions).

A more accurate assessment, then, requires segmenting the pharmaceutical industry into related classes of drugs. “When pharmaceutical sales are divided into narrower submarkets, in which products are grouped only with their immediate competitors, much higher concentration becomes apparent.”<sup>67</sup> Figure 1 represents this assessment.<sup>68</sup> The CBO surveyed sixty-six therapeutic classes.<sup>69</sup> “In just over half of those classes, the top

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62. *Id.*

63. *Id.* at 9 (footnote omitted).

64. *See id.* (footnote omitted) (noting that some HMOs actually require generic drug substitution for brand drugs, if available).

65. *Id.* at 22.

66. *Id.* (footnote omitted).

67. *Id.* *See also* Richard G. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do? An Accurate Understanding of Price Differences Is Essential to the Crafting of Sound Prescription Drug Policies*, HEALTH AFFAIRS, Mar.-Apr., 2001, at 121 (analyzing differential prescription drug prices by defining the relevant market based on therapeutic segments).

68. CBO Report, *supra* note 1, at 23, fig. 5.

69. *Id.* at 22.

three innovator drugs accounted for 80 percent or more of retail pharmacy sales in their class. In only nine of the classes did the top three innovator drugs make up less than 50 percent of their pharmacy market.<sup>70</sup> (Figure 1).

A 1997 study preceded the CBO's analysis as to segmentation of pharmaceutical markets, reaching similar conclusions.<sup>71</sup> Professor Manning's analysis also goes to an important indicator of market definition, elasticity of demand. He observes that

[o]n the one hand, it is possible that generics compete directly with brand name drugs, thus increasing the elasticity of demand for and reducing the price of branded products. On the other hand, it is possible that generic substitutes create segmented markets. The seller of a branded product may face a smaller but more inelastic demand. Consequently, price may be higher than it would be in the absence of generic substitutes.<sup>72</sup>

This analysis is important for several reasons. First, Professor Manning concludes that "the market segmentation argument applies in the United States."<sup>73</sup> Second, and more importantly, is the notion that brand drugs may not compete directly with generic substitutes, but enjoy greater inelastic demand in smaller, more segmented markets.<sup>74</sup> It follows from this that generic drug entry actually causes brand drug prices to rise: "generics raise branded drug prices."<sup>75</sup> CBO's analysis confirms Professor Manning's results, and explains the mechanism by which this occurs.

"[P]rices of brand-name drugs do rise faster than inflation for many purchasers after generic entry . . . ."<sup>76</sup> How is this possible? Once generic drugs enter the market, price-sensitive consumers will switch to the generic version.<sup>77</sup> As this occurs, "demand for the original brand-name drug declines and may become less sensitive to price. If that happens, the price of the brand-name drug could theoretically rise more quickly over time than it would have without generic competition."<sup>78</sup> CBO's analysis does show that brand drug manufacturers increase discounts to retailers after generic entry, leading to the conclusion that though brand drug prices continue to increase at a hyperinflationary rate even

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70. *Id.* at 22-23 (footnote omitted).

71. Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 214-15 (1997).

72. *Id.*

73. *Id.* at 217.

74. *Id.* at 214-15.

75. *Id.* at 217.

76. CBO Report, *supra* note 1, at 29.

77. *Id.*

78. *Id.*

after generic entry, “some purchasers pay less for those drugs after generic entry.”<sup>79</sup>

This point is crucial, as it undermines a superficially reasonable thesis: that generic drug competition lowers brand drug prices. Indeed, this is precisely the claim that the plaintiffs made in *Altman v. Bayer Corp.*<sup>80</sup> However, this analysis presents something of an enigma. Namely, if generic competition does not lower brand drug prices, why are brand drug manufacturers driven to enter into agreements with generic drug producers to delay generic entry into the market? If CBO and Professor Manning are correct, proper economic analysis dictates that brand drug manufacturers ought to encourage generic drug entry, because such entry raises brand drug prices.

There are several answers to this question. The first answer involves pricing of generic drugs, as opposed to brand drugs. “As generic drugs are substituted for their more expensive brand-name counterparts, the average price of a prescription falls . . . . [G]eneric substitution lowered the average cost for a multiple-source prescription by \$11.”<sup>81</sup> The fact that brand drug prices rise after generic entry does not alter the intuitive, empirically correct notion that generic drugs are far cheaper than brand name drugs.<sup>82</sup>

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79. *Id.*

80. 125 F. Supp. 2d 666, 669 (S.D.N.Y. 2000).

81. CBO Report, *supra* note 1, at 28.

82. *Id.* See also Melissa K. Davis, Note and Comment, *Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357, 365 (1995) (imparting that “switching from a brand-name drug to a generic drug results in a savings of between thirty and fifty percent”); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?* 43 J.L. & ECON. 311, 312 (2000) (“Generic competition on off-patent drugs offers the potential for significant savings to consumers.”). Danzon & Chao report a marked effect on prescription drug prices overall in the United States: “[t]he price elasticity with respect to the number of generic competitors in the United States is -.50.” Danzon & Chao, *supra*, at 339. The authors of the study are primarily interested in showing that more regulated pharmaceutical markets produce a steeper decline of price. . . . Generic competition has a significant negative effect on price for the United States and other countries with relatively free pricing . . . whereas for the countries with strict price regulation . . . the number of generic competitors has either no effect or a positive effect on prices.

*Id.* at 354-55.

More recently, the FTC confirmed the price effects of generic drugs in a report released on July 30, 2002. The FTC cited a 1997 study showing “higher prices for brand-name prescription drugs (in light of factors such as inelastic demand among users of brand-name products), but large decreases in the prices of corresponding generic drugs.” Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>, at 9 (last visited Aug. 12,



Furthermore, generic drugs rapidly gain market share when introduced to the market formerly occupied exclusively by a patented brand name drug.<sup>83</sup> CBO studied twenty-one brand name drugs that faced competition from generic drugs between 1991 and 1993.<sup>84</sup> “For seven of [these] drugs . . . generics had gained 65 percent or more of the innovator’s market by 1994.”<sup>85</sup> Furthermore, CBO’s data indicates that “[i]n 1980, generic drugs accounted for only around 13 percent of the total quantity of prescriptions sold for multiple-source drugs . . . fourteen years later, they constituted 58 percent of the total quantity of multiple-source prescriptions dispensed . . . .”<sup>86</sup> This is obviously a marked gain in market share. (Figure 2). It makes sense, then, that brand drug manufacturers are concerned enough with generic competition to horizontally restrain prescription drug output by delaying generic entry into the market.

A producer, for example, may invest twenty-five dollars in developing widgets. He may decide to sell widgets for fifty dollars. However, if he sells a widget to only five consumers, his returns are not as valuable as a producer who charges twenty-five dollars but reaches (sells to) ninety-five consumers. The fact that prescription drug prices may increase at a hyperinflationary rate does not alter the brand drug manufacturers’ concern that their returns decrease in rough proportion to their market share.<sup>87</sup>

The second reason brand drug manufacturers want to restrain generic drug entry turns to brand drug manufacturers’ chief ammunition in defending the pro-competitiveness of brand drug exclusivity: returns on innovation. Specifically, CBO analysis indicates that “the increase in generic market share since 1984 has decreased the total returns from marketing a new drug by about \$27 million, on average.”<sup>88</sup> “Expressed as a percentage, the \$27 million decline in returns equals roughly 12 percent of the total average returns from marketing a new drug.”<sup>89</sup> Nevertheless, the patent extensions provided for by the Hatch-Waxman Act help

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2002) (citing Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75-90 (1997)).

83. CBO Report, *supra* note 1, at 28.

84. *Id.*

85. *Id.* (emphasis added).

86. *Id.* at 37.

87. See Jith Jayaratne & Phillip E. Strahan, *Entry Restrictions, Industry Evolution, and Dynamic Efficiency: Evidence from Commercial Banking*, 41 J.L. & ECON. 239, 242 (1998) (observing that the easing of entry barriers caused some banks to lose profits and market share to more efficient producers).

88. CBO Report, *supra* note 1, at 38.

89. *Id.*

offset the decline to some extent.<sup>90</sup> “On average, therefore, the returns from marketing a new drug would probably still fully cover the capitalized costs of [research and development] despite the increase in generic sales since 1984.”<sup>91</sup>

The decline in returns is obviously of concern to brand drug manufacturers for economic reasons. However, brand drug manufacturers assert that the decline in returns is a social and medical problem, rather than simply a competitive challenge to the respective business model. “Although the Act specifically purports to promote new [research and development] investment, this report implies that its effects may in fact deter [research and development] development by lowering returns on an already risky investment.”<sup>92</sup>

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90. *Id.*

91. *Id.* at 47.

92. Nicholas Groombridge and Ruth Atherton, *The Hatch-Waxman Act: Bonus for Brand Names or Godsend for Generics*, available at <http://www.corporateintelligence.com/issues.cfm?story=43584&author=Groombridge> (last visited Mar. 27, 2002). See also PhRMA Industry Profile 2002, available at <http://www.phrma.org/publications/publications/profile02/index.cfm>, at 17 (last visited May 1, 2002) (explaining that drug development is a “long, risky, and expensive” process) [hereinafter “PhRMA Report”]. *But cf.* CBO Report, *supra* note 1, at 47 (noting that only the few drugs that were barely profitable to begin with are no longer profitable after generic entry). To the extent CBO is correct, it seems that allocative efficiency is better served by facilitating generic entry into the market: resources will not be wasted on drugs that society does not demand enough to render the drugs profitable.

At least one commentator goes further than CBO and argues that proper economic analysis demonstrates that the economic behavior of the brand drug manufacturers themselves that reduces returns on R&D. F.M. Scherer argues:

A robust pattern persists. Combined with evidence that profit rates of return on pharmaceutical industry R&D investments tend to exceed risk-adjusted capital costs by only modest amounts, the pattern suggests that pharmaceutical industry R&D is best described by a virtuous rent-seeking model. That is, as profit opportunities expand, firms compete to exploit them by increasing R&D investments, and perhaps also promotional costs, until the increases in costs dissipate most, if not all, supranormal profit returns. If this is a correct interpretation of the industry’s behavior, it has self-evident implications for policy interpretations aimed at reducing industry prices and profits.

F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending; An Analysis That Answers the Question: What Does the Pharmaceutical Industry Really Do With Its Profits?*, HEALTH AFFAIRS, Sept.-Oct. 2001, 216, 220 (footnote omitted).

Professor Scherer’s analysis here suggests that firms increase R&D investments where the economic forecast may allow a favorable return on investment. Such increase in capital expenditures decreases the firm’s margin and decreases returns on the R&D investment. If this is correct, it casts some doubt on the accuracy of the brand drug producers’ claims that it is the behavior of generic producers (rather than their own rent-seeking behavior)

To recapitulate, the economic analysis illustrates the following:

- On the demand side, managed care exerts downward pressure on prescription drug prices;
- The relevant pharmaceutical market must be segmented by therapeutic class;
- Market analysis illustrates that generic entry actually raises brand drug prices (brand drug price demand is inelastic);
- Generic drugs rapidly gain substantial market share subsequent to entry into the relevant market;
- Generic drug entry lowers returns on brand drugs, but brand-drug manufacture remains profitable, albeit at a lower margin.

Where does this economic analysis leave us? First, on the macro level, one must not forget that prescription drug prices, both generic and brand drug, continue to rise.<sup>93</sup> Second, to the extent brand drug prices are higher *after* generic entry, it makes little sense for brand drug manufacturers to delay generic entry in order to charge supracompetitive prices. Third, brand drug manufacturers face competition from generic drugs in terms of the latter's rapid gain of market share after entry into the market. Fourth, brand drug manufacturers continue to fully capitalize on the costs of research and development for all but the most marginal of pharmaceuticals.

### III. ANTITRUST ENFORCEMENT: A HISTORICAL APPROACH

#### A. *Patent Protections Have Pro-competitive Effects*

The first step in the legal analysis of the economic data canvassed above is to return to the question that necessitated economic inquiry: do patents generally have pro-competitive or anti-competitive effects? Though there are some, such as

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that decreases R&D returns. See Margaret A. Peteraf & Randal Reed, *Pricing and Performance In Monopoly Airline Markets*, 37 J.L. & ECON. 193, 197 (1994) (observing that "[s]trategic models of dominance suggest that incumbents may invest in assets that cannot be replicated easily without significant lags and/or sunk expenditures.").

The economic data is thus somewhat inconsistent on the nature and cause of declining R&D returns. Nevertheless, even given Professor Scherer's point, CBO's analysis, as well as the obviously biased brand drug producers' analysis, suggests that generic competition plays *some* role in decreasing returns on R&D. More detailed and thorough economic analysis is required to delineate the extent of generic competition's effect.

93. See Engelberg, *supra* note 11, at 391 (noting that the price of prescription drugs increased 10.1 percent).

Professor Engelberg, who feel that the patent extensions and market exclusivity of the Hatch-Waxman Act are unnecessary,<sup>94</sup> CBO's analysis suggests that such protections offset the effect of generic gains in market share after generic entry.<sup>95</sup> In turn, it follows from this that the right to exclude generics from the market is at least relevant to brand drug manufacturers' ability to capitalize on the costs of research and development. This, of course, is one of the purposes of the Hatch-Waxman Act, and is inextricably linked with the purpose of patent protection.

To the extent patents do provide some incentive to expend capital on research and development, even if the effect is not as substantial as brand drug manufacturers would contend, patents do have pro-competitive effects in the pharmaceutical industry. Contrary to Professor Engelberg's argument, it does not follow from the fact that patents are insufficient to guarantee commercial success that patents are not necessary as an incentive to expend capital on research and development. This is all the more true in an economic climate in which the returns on brand drugs are shrinking, at least insofar as generic drugs enter the given market. Insofar as patents encourage more and varied pharmaceutical manufacturers to innovate and allocate resources to research and development, there is undoubtedly some pro-competitive effect from patents and the market exclusivity provisions of the Act.

This, however, is just the beginning of the inquiry. The fact that the protections benefiting brand drug manufacturers in the Act may have some pro-competitive effects does not mean that agreements to delay generic entry into the market are either legal or desirable. The fact remains that agreements between generic and brand drug producers to delay generic entry into the market are hardly the legal equivalent of patent extensions enshrined in statutory law. The effect of each may be to ensure market exclusivity, but the entire point of patent protection, and of the Hatch-Waxman Act, is to achieve an appropriate balance between competition and enabling an innovator manufacturer to capitalize on its investment.<sup>96</sup>

Horizontal restraints of the type that concern the FTC surely advance one of these two goals—increasing the brand drug manufacturers' margin—but arguably at the expense of restricting

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94. See *supra* notes 15-17 and accompanying text (noting that a patent protection does not guarantee commercial success).

95. See *supra* note 92 and accompanying text (noting that returns from the sale of new drugs would diminish and would no longer provide incentive for research and development).

96. See Carrier, *supra* note 12, at 762-63 (discussing the objectives of the Drug Price Competition and Patent Term Restoration Act).

consumers' ability to purchase cheaper generic drugs in a competitive market. Recall the point that the two goals of the Hatch-Waxman Act are at the very least mutually inconsistent and are possibly mutually exclusive.<sup>97</sup> Thus, the antitrust question of brand drugs versus generic drugs becomes one of prioritization: should society place more weight on brand drug manufacturers' right (and society's need) to capitalize on its research and development, or on consumers' rights to purchase cheaper generic drugs in a more competitive market?

The Cipro case is useful to answer this question. Why Cipro? First, it is timely and intriguing. Second, in the wake of 9/11, society's need for the drug reached urgent levels—lending ammunition to the brand drug manufacturers' claims that innovation needed to produce new and superior drugs, particularly antibiotics, are directly linked to returns on research and development that are diminished by generic entry.<sup>98</sup> Third, any proper antitrust analysis cannot be viewed in a vacuum, divorced from context. Antitrust law is best perceived as an evolutionary doctrine, and understanding a particular antitrust question is impossible outside of an understanding of the context the issue arises in. The Cipro debate frames this point neatly.

### B. *The Historical Approach to Antitrust Analysis*

The Sherman Act and its companion regulations are beautiful in their sparse simplicity. The interpretation of competition protection has largely been left in the hands of judges and regulators, who have relied over time on economists' analyses of how competition operates in particular markets and, correspondingly, on popular perceptions of what competition protection means.<sup>99</sup>

Professor Swanson's point is that the fluid, evolutionary

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97. See *supra* notes 12-14 and accompanying text (illustrating the conflicting goals of antitrust law and patent protection).

98. See Surowiecki, *supra* note 9, at 46 (arguing that after 9/11 patents may be broken with ease). Indeed,

[n]ow more than ever we want to encourage drug companies to devote their considerable resources to antibiotic R & D, rather than to another treatment for baldness or impotence. Is this the moment to inform them that if they come up with something of genuine worth, something we vitally need, we may just decide to break their patent?

*Id.* See also Joseph P. Reid, Note, *A Generic Drug Price Scandal: Too Bitter A Pill For the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 339 (1999) (concluding that "society must accept that, despite the cost, it will only be medically prepared for the new millennium by encouraging the pioneer industry to expand research and development.").

99. Carol B. Swanson, *Antitrust Excitement in the New Millennium: Microsoft, Mergers, and More*, 54 OKLA. L. REV. 285, 325 (2001).

nature of antitrust law stems from the sparse statutory language itself. “[A]ntitrust law has been a fluid—and often controversial—concept since its birth in the late nineteenth century’s industrial age. Its substantive application has shifted radically over time due to changes in the economy, the political climate, popular views of ‘big business’, and developments in economic theory.”<sup>100</sup>

It is not particularly fruitful to attempt to understand a particular antitrust question purely in terms of doctrine, precedent, or theory. “If we want to know how antitrust has affected us, we should look to history and not to theoretical critiques of particular decisions.”<sup>101</sup> Understanding the controversy between generic drugs and brand drugs requires more than a mere examination of the economic or theoretical effects of generic drug entry on pricing. Rather, one must understand the particular question’s locus on the historical continuum, the context in which the issue arises. “A historical approach to evaluating the economic impact of antitrust law must look at the evolution of an industry or the economy as a whole. The historical approach evaluates antitrust’s role in the broader context of economic development.”<sup>102</sup>

### C. *The Intragovernmental Discourse Regarding Generic Drug Competition*

The Cipro debate operates as a superb prism for viewing the conflict between generic drugs and brand drugs in a historical context. This is because the nature of the issue changed dramatically in the space of several months. The historical analysis posits that federal enforcement moves in cycles.<sup>103</sup> Understanding the potential for antitrust enforcement requires comprehension, *inter alia*, of a particular administration’s competition philosophy.

For example, Franklin Delano Roosevelt “declared war on cartels and monopolies across the economy.”<sup>104</sup> In contrast, President Reagan’s administration adopted “the Chicago School’s approach,” and antitrust enforcement approached dormancy during the 1980s.<sup>105</sup> President G.H.W. Bush to some extent, and President Clinton to a greater extent, each revived antitrust

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100. *Id.* at 287.

101. Peter C. Carstensen, *How to Assess the Impact of Antitrust on the American Economy: Examining History or Theorizing?*, 74 IOWA L. REV. 1175, 1194 (1989).

102. *Id.*

103. See, e.g., Swanson, *supra* note 99, at 291 (describing the cycles of antitrust enforcement since the Sherman Antitrust Act was enacted).

104. *Id.* at 293.

105. *Id.* at 294-95.

enforcement as an important aspect of overall consumer welfare.<sup>106</sup> Current President G.W. Bush generally “indicates a preference for deregulation, but does support government intervention to break up monopolies.”<sup>107</sup>

Given the pro-deregulation, *laissez faire* approach of the current administration, it is doubtful that many antitrust scholars would have predicted in August of 2001 that a member of the President’s Cabinet would threaten to break a brand drug manufacturer’s patent if it did not reduce its prices on a particular drug. To term such a phenomenon the epitome of aggressive government involvement seems an understatement. Aggressive antitrust enforcement is often measured by the number of DOJ lawsuits or FTC complaints filed. More drastic action occurred in late October 2001, when the Secretary of Health and Human Services (HHS), Tommy Thompson, threatened “to break Bayer [Corporation’s] patent on” Cipro if it did not agree to reduce the price on sales to the federal government.<sup>108</sup> Never mind complaints or even litigation, here a cabinet member of an economically *laissez faire* President threatened to override a firm’s pharmaceutical patent.

Secretary Thompson did not follow through on his threat, because he “cut a deal with the Bayer Corporation to buy a huge batch of the anti-anthrax drug Cipro at ninety-five cents a tablet, half what Bayer had been asking.”<sup>109</sup> The pro-competitive effects of patent protections and the importance of maximizing Bayer’s returns on research and development to encourage innovation paled in importance to the perceived need for the government to stockpile the anti-anthrax drug Cipro in the post-9/11 environment.<sup>110</sup>

The central point is that evaluating Bayer’s agreement to delay the entry of generic Cipro produced by Barr Labs requires an understanding of the federal government’s willingness to enforce antitrust policy as to generic drugs in the post-9/11 world. Again,

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106. *Id.* at 296. The author uses the term “consumer welfare” in the non-technical sense of the word.

107. *Id.* at 297.

108. Surowiecki, *supra* note 9, at 46.

109. *Id.*

110. Indeed, Canada actually did break Bayer’s patent on Cipro. See Amy Harmon & Robert Pear, *A Nation Challenged: The Treatment; Canada Overrides Patent for Cipro to Treat Anthrax*, N.Y. TIMES, Oct. 19, 2001, at A1 (discussing that “these are extraordinary and unusual times,” which call for extreme measures). See also Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1691 n.381 (2001) (discussing the federal government’s ability to utilize compulsory licensing to counter bioterrorism).

the brand drug-generic drug issue has been treated according to the core duality underpinning the debate: what is the proper balance between encouraging research and development (via patent extensions and market exclusivity) and encouraging generic competition to lower prescription drug prices for consumers? This article contends that any answer that ignores the government's willingness to enforce antitrust policy is fatally flawed. Specifically, an analysis of the Cipro litigation requires an understanding of the government's urgent desire to maintain an uninterrupted supply of Cipro, to allay bioterrorism concerns.

Where the Secretary of HHS is willing to break Bayer's patent on Cipro, how will federal courts treat antitrust complaints of horizontal restraints between Bayer and generic producers that seek to delay generic entry? There are competing possibilities. On the one hand, federal courts may be unwilling to do anything that could interfere in any way with a brand drug manufacturer's ability to produce a constant stream of bioactive Cipro. Or, following Secretary Thompson's lead, courts might be far less willing to grant deference to the brand-drug manufacturers claims of pro-competitive conduct.

This latter possibility is viable because it shows consistency with context. The FTC already filed four complaints against generic and brand-drug manufacturers who have entered into agreements to delay generic entry.<sup>111</sup> The FTC and House and Senate committees have all held hearings in the past eighteen months on the relationship between patents, antitrust, and prescription drug prices.<sup>112</sup> The House and the Senate have each introduced bills regarding generic drug competition and antitrust enforcement.<sup>113</sup> In its recent report, the FTC explicitly endorses the Senate's bill.<sup>114</sup> Secretary Thompson's threat means that all branches of government are involved in the brand drug-generic drug discourse: executive (Secretary Thompson and the FTC); legislative (both houses of Congress); and of course, judicial.

The examination of the total enforcement landscape is part and parcel of the historical approach to antitrust analysis. "Antitrust law itself is only a segment of the total legal

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111. See discussion *supra* Part II.B (discussing important critical provisions within the relevant legislation).

112. See *supra* note 8 and accompanying text (providing details of the committee's hearings).

113. Drug Competition Act of 2001, H.R. 1063, 107th Cong. (2001) [hereinafter "Competition Act"]; Greater Access to Affordable Pharmaceuticals Act of 2001, S. 812, 107th Cong. (2001) [hereinafter "Access Act"].

114. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>, at vi (last visited Mar. 6, 2003).



environment.”<sup>115</sup> Before turning to the few cases relating to the generic Cipro issue, it is first worthwhile to examine the proposed bills in Congress and the FTC Report. This approach is meant to address each branch of government in turn, consistent with the contextualist aspects of the historical approach.

Congressman Andrews introduced the House Bill regarding generic drug competition.<sup>116</sup> The Congressional findings specifically refer to the agreements at issue in this article.

Congress finds that . . . (2) there is a potential for drug companies owning patents on brand-name drugs to enter into private financial deals with generic drug companies in a manner that could tend to restrain trade and greatly reduce competition and increase prescription drug costs for American citizens; and (3) enhancing competition between generic drug manufacturers and brand name manufacturers can significantly reduce prescription drug costs to American families.<sup>117</sup>

The House bill simply requires brand drug and generic producers that enter into an agreement that “could have the effect of limiting the research, development, manufacture, marketing, or selling of a generic product” to notify the FTC and the Attorney General. Notice that the legislative branch of government is assigning enforcement powers<sup>118</sup> and responsibility for monitoring the issue to the executive branch, supporting the notion of a discourse between different branches of the federal government regarding generic drug competition.

The Senate bill, entitled the “Greater Access to Affordable Pharmaceuticals Act of 2001,” has more extensive plans for stimulating generic drug competition. The Senate bill states that

Congress finds that . . . (4) the Federal Trade Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in a manner that could restrain trade. . . .<sup>119</sup>

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115. Carstensen, *supra* note 101, at 1195.

116. Drug Competition Act of 2001, H.R. 1063, 107th Cong. (2001). In the Senate, Senator Patrick Leahy introduced an identical version of the Drug Competition Act of 2001, S. 754, 107th Cong. (2001). In a report released on July 30, 2002, the FTC officially recommended the notice provisions of this bill as a method of facilitating generic entry into a particular market. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>, at vii (last visited Mar. 6, 2003).

117. The Drug Competition Act of 2001, S. 754, 107th Cong. §§ 2, 3 (2001).

118. See Competition Act, *supra* note 113, § 7 (empowering the DOJ or the FTC to seek civil penalties up to \$20,000 per day per violation).

119. Access Act, *supra* note 113, § 2(a)(4).

The findings also refer to the CBO Report, specifically noting that “the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled in the last decade, from approximately 19 percent to 43 percent.”<sup>120</sup> The Access Act’s purpose is in part to “ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade.”<sup>121</sup>

To that end, the teeth of the bill go to the 180-day exclusivity period for the first ANDA filer, a generic producer. Amending the Hatch-Waxman Act, the bill provides that the generic producer with rights to the exclusivity period forfeits that right if it “fails to market the drug within 90 days after the date” the FDA approves the ANDA.<sup>122</sup> Obviously, if such language were the law, generic producers would be unable to enter into agreements to delay generic entry, as such conduct would have its logical legs cut out from under it. Such agreements would be useless after three months, as a new generic producer (i.e., not the first filer) would have rights to the 180-day exclusivity period. No such agreements would be valid for longer than three months.

As a redundant measure, the bill also forces a generic producer to forfeit its exclusivity rights if the producer “fails to get tentative approval of the application within 30 months after the date on which the application is filed.”<sup>123</sup> This provision is essentially the same 30-month extension period after a brand-drug manufacturer files a patent infringement action that appears in the Hatch-Waxman Act. It also discourages a brand-drug manufacturer from filing an infringement suit and negotiating to delay generic entry into the market, as such a delay is at most effective for two years. Such an agreement has only a limited life, and cannot delay generic entry into the market *in perpetua* as prior agreements did.<sup>124</sup> A Senate committee is currently reviewing this bill, after earlier review by the House Committee on Health, Education, Labor, and Pensions.

The pharmaceutical industry has decried the attempted amendment of the Hatch-Waxman Act. The Pharmaceutical Research & Manufacturers of America (PhRMA) argues that the Hatch-Waxman Act is working as Congress intended and no

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120. *Id.* § 2(a)(7).

121. *Id.* § 2(b)(2).

122. *Id.* § 3(a)(3)(c)(i)(I).

123. *Id.* § 3(a)(3)(c)(i)(IV).

124. See discussion *supra* Part II.C (noting the “genius” of the horizontal restraints at issue is its ability to permanently delay generic entry into the market via manipulation of the 30-day extension and 190-day exclusivity period).

compelling case has been made for changing the delicately-balanced law that allows for both the development of newer, better medicines and the faster introduction of generic medicines.<sup>125</sup> A PhRMA witness testified before a House subcommittee that the Hatch-Waxman Act is effectively meeting both of the objectives Congress sought to achieve.<sup>126</sup> PhRMA's perspective is that the antitrust concerns are best left to the FTC's enforcement efforts and that settlement of FTC complaints is effective.<sup>127</sup> "There is [thus] no need to amend the Hatch-Waxman compromise to deal with this issue."<sup>128</sup>

Similarly, a PhRMA official stated on March 25, 2002 that "attempts to re-open Hatch-Waxman [legislation] are at best short-sighted. They would seriously erode the incentive and protection for innovation that enables new drug development, and would be a devastating blow to America's patients."<sup>129</sup> "While generic drugs serve an important purpose in today's world, they cannot and will not ever offer the cutting-edge, life-saving innovation that modern medicine and our patients demand."<sup>130</sup>

Thus, consistent with the historical, contextualist approach to antitrust analysis, this article has briefly surveyed several of the major players in the dispute over generic drug competition: the executive branch (FTC, DHHS); the legislative branch (each house of Congress); and the private sector (pharmaceutical interest groups). Furthermore, the need for counter-terrorism pharmaceuticals after 9/11 is relevant to describing the legal culture in which the generic drug competition debate is enmeshed. Finally, the continuous rise in prescription drug prices has obvious bearing on the nature of pharmaceutical drug prices and generic competition. What remains is to anticipate the judiciary's likely response to the Cipro debate based on the existing conceptual framework.

#### *D. Whither Generic Drug Competition: The Recommended*

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125. *Recent Developments Which May Impact Consumer Access To, and Demand For, Pharmaceuticals: Hearing Before the House Subcomm. on Health*, 107th Cong. 51, 53 (2001) (statement of Gregory J. Glover, physician and attorney with the firm of Ropes & Gray, testifying on behalf of PhRMA).

126. *Id.* at 55 (stating that "the Hatch-Waxman compromise stimulates competition and provides limited research incentives" and that the Act is "balanced" in nature).

127. *Id.*

128. *Id.*

129. Statement By Richard I. Smith, PhRMA Vice President of Policy and Research on the Theft of Innovation, available at <http://www.phrma.org/publications/quickfacts/>

25.03.2002.348.cfm (last visited Mar. 4, 2003).

130. *Id.*

### Judicial Response

There are only three federal cases addressing Cipro and generic drug competition, including *Altman*.<sup>131</sup> On January 10, 2001, Judge Trager transferred thirteen different state antitrust suits regarding agreements to delay the entry of generic Cipro to the Eastern District of New York, consistent with the rules of the Judicial Panel on Multidistrict Litigation (JPML).<sup>132</sup> These cases come from seven different states: Arizona; California (five cases); Florida (three cases); Illinois; Kansas; New York; and Pennsylvania.<sup>133</sup> Neither *Altman* nor *Meyers v. Bayer AG*<sup>134</sup> have yet been consolidated by the JPML, though motions are currently pending in each case to do so.

Plaintiffs challenging an agreement between Bayer and Barr to delay the entry of generic Cipro ought to prevail. Such a recommendation of course depends on analysis of the total legal environment the Cipro issue arises in. This article has been an attempt to provide a rough picture of this environment. Beginning with the purpose of the Hatch-Waxman Act, this article explored the tension between the two objectives of that act: to facilitate research and development and encourage generic competition.<sup>135</sup> Economic data suggests that pharmaceutical prices remain higher than inflation, but that generic drugs rapidly gain market share after entry into the relevant market.<sup>136</sup> Concerned with rising prescription drug prices, Congress has already drafted bills attempting to enhance antitrust enforcement and diminish pharmaceutical manufacturers' ability to delay generic entry into the market by amending the Hatch-Waxman Act.<sup>137</sup> The FTC has been fairly aggressive in challenging such horizontal restraints.<sup>138</sup> Finally, the perceived post-9/11 need for Cipro prompted a cabinet member of a pro-deregulation president to threaten to unilaterally break Bayer's patent.<sup>139</sup>

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131. See *supra* notes 41-45 and accompanying text (discussing Bayer's CIPRO infringement lawsuit against a generic manufacturer).

132. *In re Ciprofloaxocin Hydrochloride Antitrust Litigation*, No. 1383, 2001 WL 253240, at \*1 (J.P.M.L. Jan. 10, 2001).

133. *Id.*

134. 143 F. Supp. 2d 1044, 1053 (E.D. Wis. 2001) (granting stay pending result of JPML proceedings).

135. See generally discussion *supra* Part II.

136. See discussion *supra* Part III (discussing the economic impact of generic drug entry into the market).

137. See *supra* notes 113-23 and accompanying text (discussing legislation in both houses of Congress, as well as the FTC).

138. See *supra* notes 33-44 and accompanying text (discussing the FTC's challenges to horizontal restraints).

139. See *supra* notes 110-11 and accompanying text (explaining the government's ability to utilize compulsory licensing to counter bioterrorism).

Against this backdrop, courts may be unwilling to sanction the conduct at issue in this article. Faced with (1) the economic data suggesting brand drug manufacturers still achieve a reasonable return on research and development, even as generics gain greater market share; (2) the fact that Congress has already expressed a desire, albeit a non-democratically confirmed desire inasmuch as the bill is not law, to disallow the conduct Bayer has committed; (3) the aggressive executive response to such horizontal restraints; and (4) the perceived need for an extensive supply of Cipro in the post-9/11 legal climate, it is difficult to imagine a court permitting pharmaceutical manufacturers to delay generic entry into the market. Such agreements run afoul of Section 1 of the Sherman Antitrust Act, which prohibits unreasonable restraints of trade.<sup>140</sup>

This article has attempted to define “unreasonable” not solely in terms of legal doctrine, but by examining the historical, economic, political and contextual factors that necessarily specify the contours of “unreasonable restraints of trade” as to generic drug competition. An agreement between a brand drug and generic drug producer to delay the latter’s entry into the market is an unreasonable restraint of trade in violation of the Sherman Act. These restraints actually allow a brand drug manufacturer to perpetually delay generic entry into the market by manipulating the statutory scheme created by the Hatch-Waxman Act. Whatever the pro-competitive effects of patents and market exclusivity protections for brand drug manufacturers might be, a restraint that effectively cuts off generic competition from a particular therapeutic market eviscerates the balance Congress sought to achieve in enacting the Hatch-Waxman Act.

Furthermore, as Professor Carrier observes in his article, facilitating innovation is a goal of antitrust law, as well as patent law.<sup>141</sup> Sanctioning horizontal restraints that “solve” the generic competition problem simply elevates patent protections over competitive considerations and does not necessarily foster innovation.<sup>142</sup> “To state that action within the scope of the patent should automatically be immune from antitrust scrutiny (so the incentives underlying the patent system are not diminished) ‘solves’ the patent-antitrust conflict only by according priority to

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140. 15 U.S.C. § 1 (1994 & Supp. 1997).

141. Carrier, *supra* note 12, at 801 (explaining that “[i]nnovation is the goal of the patent system and one of several important (and becoming ever more so) goals of the antitrust laws.”).

142. *See id.* at 816 (suggesting that courts apply a test in patent-antitrust disputes to determine “whether competition, rather than patents, is responsible for innovation in the industry.”).

the patent laws."<sup>143</sup>

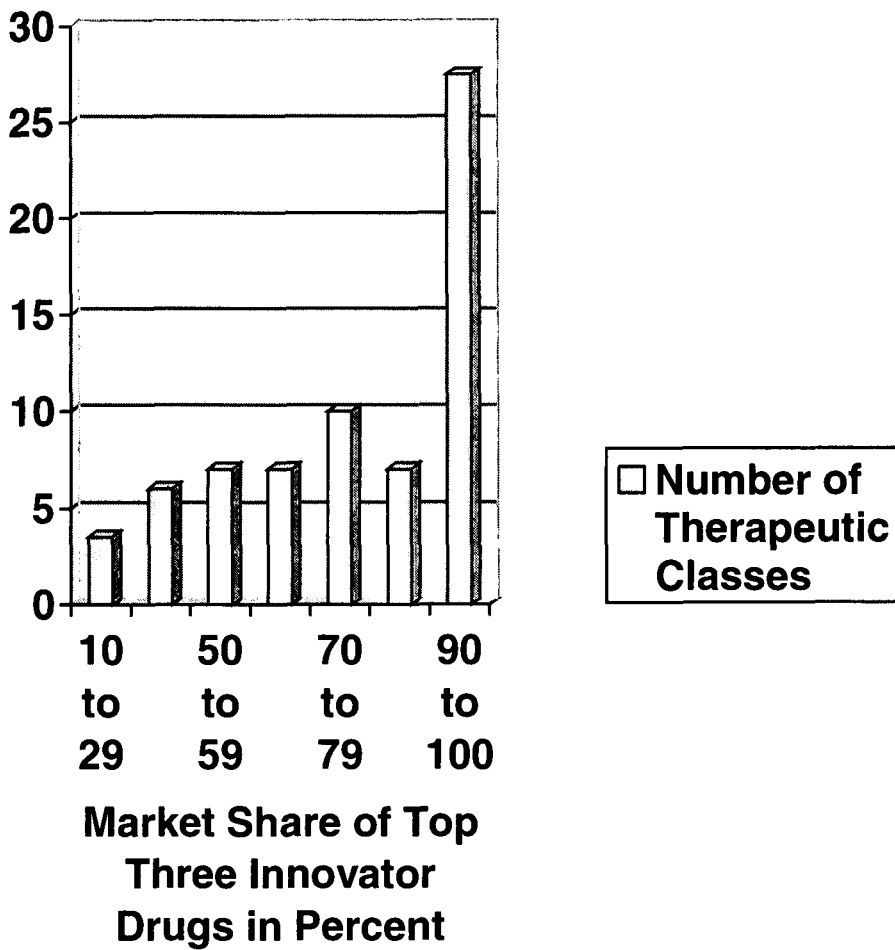
Finally, through the Hatch-Waxman Act, Congress sought to encourage generic competition, not remove it altogether. However, horizontal restraints, such as Bayer's agreement with Barr to delay generic Cipro entry into the market, does exactly that by removing generic competition by perpetually delaying it. Such conduct is inconsistent with the objectives of the Hatch-Waxman Act, is unwarranted by any economic or patent considerations, and is perhaps even dangerous (to the extent restriction of a supply of Cipro undermines national security and public health concerns). Accordingly, courts faced with the issue should follow the FTC and Congress' lead in disapproving of horizontal restraints that delay generic drug entry.<sup>144</sup>

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143. *Id.* at 764.

144. See *Countering Delays In Introduction of Generic Drugs*, 359 THE LANCET 181 (approving of the U.S. efforts to preclude agreements delaying generic drug entry). As a last note of caution, this article does not pretend here to reject the brand-drug manufacturers' concerns over increasing generic market share negatively impacting R&D returns. In fact, such claims have merit, though are not necessarily as far-reaching as brand-drug manufacturers maintain. The ever-increasing prescription drug prices are a fundamental problem facing the health care market and brand-drug manufacturers have the right to capitalize on their considerable R&D expenditures. Brand-drug manufacturers, moreover, have a legitimate economic interest in reducing the free-rider problem posed by generic imitators. The only point here is that horizontal restraints that delay generic entry into the market are not the legally viable path for addressing the brand-drug producers' concerns. What is the wisest path is beyond the scope of this project.

**Figure 1**



## Generics' Share of U.S. Prescription Drug Market, 1984-2000

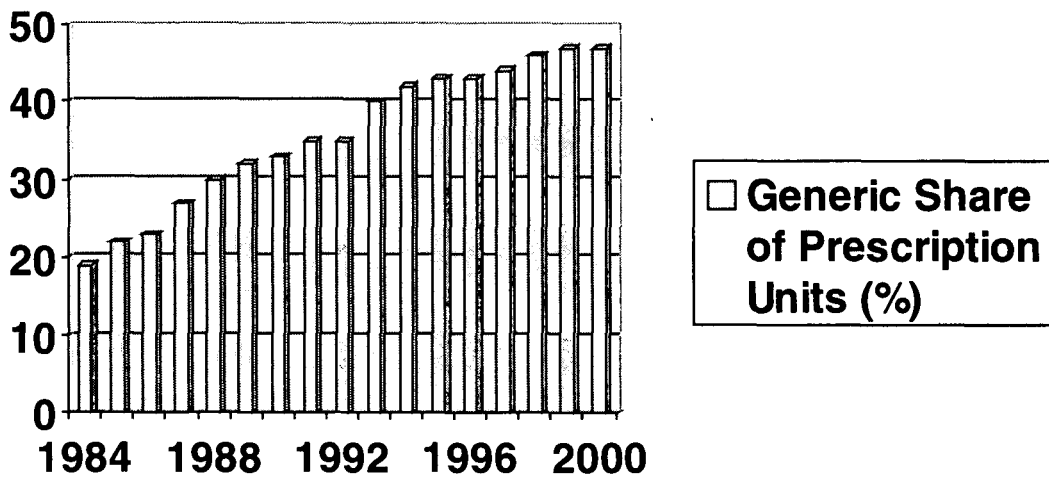


Figure 2

SOURCE: PhRMA Report, supra note 93, at 32.



