

COMMENT

THE DUBIOUS VALUE OF HATCH-WAXMAN EXCLUSIVITY*

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I. INTRODUCTION

The United States spends a considerable amount on prescription drugs—\$188.8 billion in private and public spending in 2004 alone,¹ with such expenditures potentially reaching \$291.5 billion by 2010.² Generic pharmaceuticals are a very attractive option for reducing the growth in drug spending when one considers that generic drugs filled fifty-six percent of all U.S. prescriptions in 2005, and yet accounted for only thirteen percent of total prescription drug expenditures.³ This is in remarkable contrast to nearly two decades ago, when 150 drugs without patent protection lacked generic competition.⁴

To increase the availability of generic alternatives, Congress enacted the Hatch–Waxman Act.⁵ Congress sought to increase availability in two principal ways. First, Congress intended the Act to facilitate market entry for generic drugs.⁶ Second, Congress wanted to encourage generic drug makers to challenge invalid patents protecting branded drugs and blocking generic market entry, as opposed to merely postponing entry until after the patents expire.⁷ To encourage patent challenges, the Hatch–

1. NAT'L HEALTH STATISTICS GROUP, CTNS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES BY SOURCE OF FUNDS AND TYPE OF EXPENDITURE: CALENDAR YEARS 2001–2006 tbl.4, available at <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>.

2. NAT'L HEALTH STATISTICS GROUP, CTNS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH CARE EXPENDITURE PROJECTIONS: 2005–2015 tbl.2, available at <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf>.

3. Tony Pugh, *Generics Will Benefit as 75 Drugs Lose Their Patent Protections*, KNIGHT RIDDER NEWSPAPERS, Apr. 27, 2006, http://www.mcclatchydc.com/staff/tony_pugh/story/13896.html.

4. Gerald J. Mossinghoff, *Overview of the Hatch–Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (“After 1962 . . . there were 150 drugs that were off-patent, but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to market, and . . . there were only fifteen ‘paper [new drug applications]’ for post-1962 generics.”); see also Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition: The Hatch–Waxman Act After One Decade* 23 (Duke Econ., Working Paper No. 95–11, 1995), available at <http://ssrn.com/abstract=40940> (noting that generic dispensing rose from 10% in the 1980s to nearly 40% in the 1990s).

5. Drug Price Competition and Patent Term Restoration (Hatch–Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 15 U.S.C., 21 U.S.C., and 35 U.S.C.).

6. See Grabowski & Vernon, *supra* note 4, at 23–24 (noting Congress sought to “spur drug price competition, and also to provide a positive stimulus for drug innovation” and that, as to price competition, “the Act has clearly been a tremendous success”).

7. See Thomas Chen, Note, *Authorized Generics: A Prescription for Hatch–Waxman Reform*, 93 VA. L. REV. 459, 464–66 (2007) (concluding that Hatch–Waxman paragraph IV encourages generic market entry); Jeremy Bulow, *The Gaming of Pharmaceutical Patents* 43–44 (Stanford Graduate Sch. of Bus., Research Paper No. 1804, 2003), available at <http://ssrn.com/abstract=412123> (suggesting that encouraging patent challenges increases

Waxman Act rewards the first generic drug maker to challenge a branded drug patent with a 180-day period as the sole generic competitor.⁸ To the extent the branded drug holds a monopoly, the statute creates a period of duopoly.

In their quest to extend the lifecycle of their various products, pioneer manufacturers⁹ have used a variety of strategies to discourage generic competition.¹⁰ Of late, pioneer manufacturers have sought to reduce the value of the 180-day market exclusivity period by introducing lower-priced, authorized generics or even discounting their own branded products.¹¹ A key question remains as to whether this conduct undermines the incentives created by the Hatch–Waxman Act and whether such conduct violates antitrust laws. To resolve this question, Part II first considers the purpose and effect of the exclusivity period on generic competition. Parts III and IV then examine the effects of conduct by pioneer manufacturers and whether such conduct is actually anticompetitive in fact and in law. Finally, after concluding that the 180-day exclusivity scheme has not worked as intended, Part V analyzes possible legislative alternatives to fix the exclusivity period, such as banning authorized generics or limiting the ability of the pioneer manufacturer to undercut the generic competitor. Considering the impracticability of fixing the Hatch–Waxman Act scheme and the exclusivity period’s questionable value in promoting competition, this Comment concludes that the exclusivity period provision could be eliminated without significantly impairing generic drug competition.

the efficiency of the patent system because it reduces the risk that invalid patents will be afforded a long period of exclusivity without producing innovation for society).

8. See *infra* Part II.A (discussing how 180-day exclusivity is obtained).

9. Pioneer manufacturer refers to a drug maker that first commercializes a drug as opposed to a generic firm, which in essence “copies” the product of a pioneer. Julia Rosenthal, *Hatch–Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 318 (2002).

10. An interesting example of the industry’s competitiveness is Abbott Laboratories’ alleged plan to increase sales of its more profitable combination HIV product. The pharmaceutical company planned to increase sales by raising the price of the less profitable single-drug product 400% or eliminating the pill form of the single-drug product, instead only selling a liquid version that “tasted like vomit” to encourage consumers to switch regimens. John Carreyrou, *Inside Abbott’s Tactics to Protect AIDS Drug*, WALL ST. J., Jan. 3, 2007, at A1 (noting that the “debate at Abbott . . . provides a rare inside look at a pharmaceutical company’s efforts to maximize profits and thwart competitors” and that “[t]he industry has come under fire in recent years for tactics such as . . . paying generic-drug makers to delay the introduction of cheap copycats”).

11. See *infra* Part III.A–B (discussing discounts on branded drugs and the authorized generic strategy).

II. THE LURE OF SUPRACOMPETITIVE PROFITS: MARKET EXCLUSIVITY AS A WAY TO ENCOURAGE ENTRY BY GENERIC MANUFACTURERS

A. *How the “First Applicant” Manufacturer Attains the Exclusivity Period*

One of Hatch–Waxman’s innovations is the Abbreviated New Drug Application (ANDA) approval process.¹² This new process reduces the filing requirements for a generic competitor—while increasing the protection for the pioneer manufacturer—by resolving patent infringement issues before the generic drug receives approval from the Food and Drug Administration (FDA).¹³

1. *Original Manufacturer Lists Information in the Orange Book.* When the pioneer manufacturer receives approval for its New Drug Application (NDA), the pioneer must provide the FDA with a list of any patents it claims cover the drug.¹⁴ The FDA then publishes the information in a publication commonly known as the “Orange Book.”¹⁵ The FDA does not evaluate the appropriateness of the listings submitted by the pioneer manufacturer.¹⁶

2. *Generic Manufacturer Must Certify the Status of Each Patent in the Orange Book Listing.* When the generic manufacturer files its ANDA, it must make a certification as to how each patent listed in the Orange Book applies to its generic product.¹⁷ The Act defines the possible certifications:

- I. that such patent information has not been filed,
- II. that such patent has expired,

12. 21 U.S.C. § 355(j) (2000 & Supp. 2006).

13. See Rosenthal, *supra* note 9, at 317–18 (explaining that the ANDA process is shorter because evidence of safety and efficacy is incorporated from the pioneer’s original New Drug Application and the generic must only show bioequivalence).

14. JOHN R. THOMAS, LIBRARY OF CONGRESS, AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION 4–5 (2006), available at http://digital.library.unt.edu/govdocs/crs/data/2006/upl-meta-crs-9508/RL33605_2006Aug08.pdf (summarizing procedures for resolving patent disputes).

15. *Id.* at 5.

16. Elizabeth H. Dickinson, *FDA’s Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 196 (1999) (“FDA relies on the submitter’s statement that the patent covers the drug product.”).

17. 21 U.S.C. § 355(j)(2)(A)(vii) (2000) (requiring that an abbreviated application contain a certification of the applicant’s opinion on each patent listed in the Orange Book).

III. of the date on which such patent will expire, or

IV. 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. . . .¹⁸

This last type of certification, known as “paragraph IV certification,” is important because submitting an ANDA with a paragraph IV certification constitutes patent infringement and can trigger an infringement suit by the patent owner.¹⁹

3. Paragraph IV Certification Triggers Notification. Furthermore, when a generic manufacturer makes a paragraph IV certification, it must provide notice to both the patent holder and the NDA holder.²⁰ The patent or NDA holder then has forty-five days to bring an infringement suit or the generic manufacturer can then bring an action seeking a declaratory judgment of noninfringement or invalidity.²¹ If the pioneer manufacturer does not file suit within forty-five days, the FDA can approve the ANDA immediately.²² If a suit is filed within the forty-five day period, however, the FDA’s approval can be delayed up to thirty months depending upon the outcome of the litigation.²³

4. Exclusivity Period for “First Applicants” Making a Paragraph IV Certification. To encourage generic manufacturers to challenge the validity of listed patents (and thus potentially clear the roadblock to generic competition formed by improperly listed patents), the Hatch–Waxman Act creates a potentially lucrative 180-day exclusivity period.²⁴ The Act shields the “first applicant”²⁵ of

18. 21 U.S.C. § 355(j)(2)(A)(vii) (2000).

19. See 35 U.S.C. § 271(e)(2) (2000) (“It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . .”); see also THOMAS, *supra* note 14, at 5–6 (noting that NDA holders must identify possible infringements of existing patents).

20. 21 U.S.C. § 355(j)(2)(B) (2000 & Supp. 2006) (prescribing the timing of the notice, the recipients of the notice, and the contents of the notice).

21. 35 U.S.C. § 271(e)(5) (Supp. 2004).

22. 21 U.S.C. § 355(j)(5)(B)(iii) (2000 & Supp. 2006).

23. *Id.*; see also Dickinson, *supra* note 16, at 198 (clarifying the FDA approval process).

24. 21 U.S.C. § 335(j)(5)(B)(iv) (2000 & Supp. 2006) (defining the 180-day exclusivity period); see also THOMAS, *supra* note 14, at 6 (“The Hatch–Waxman Act provides prospective manufacturers of independent generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical.”); Rosenthal, *supra* note 9, at 319 (highlighting that a provision meant to encourage competition has become a method to thwart it).

25. The Act defines a first applicant as one who files a “substantially complete” ANDA on the same day as the first such application for the drug was filed. 21 U.S.C.

an ANDA who makes a paragraph IV certification against competition from other ANDA applicants by delaying the FDA's approval of competing applications until 180 days after the first applicant begins to commercially market the drug.²⁶ The first applicant can lose its exclusive marketing period under limited circumstances,²⁷ which were added to prevent certain forms of abuse that have plagued this exclusivity provision.²⁸

B. The Commercial Value of Exclusivity

Once a successful first applicant enters the market as the only generic alternative to a branded drug, it can expect to command a relatively high price.²⁹ An FDA study of national retail sales data shows that when there is exactly one generic competitor, the generic drug is priced only about six percent less than the branded product at retail, on average.³⁰ Generic drugs, however, usually carry a higher markup at the retail level, which indicates that part of the first applicant's "reward" (or, after exclusivity ends, the potential savings to consumers) is transferred to middlemen in the distribution chain.³¹ Nonetheless, the exclusive generic

§ 355(j)(5)(B)(iv)(II)(bb), (cc) (Supp. 2006).

26. The 180-day exclusivity provision provides:

(iv) 180-day exclusivity period.—

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

21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. 2006).

27. See 21 U.S.C. § 355(j)(5)(D)(ii) (Supp. 2006) (providing circumstances in which a first applicant loses exclusivity).

28. Thomas P. Noud & Paul T. Meiklejohn, *The Developing Law of Pharmaceutical Patent Enforcement*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 437, 440 (2006) ("The Medicare Amendments were enacted in part to curb abuses by pioneer drug companies which sought to keep generic drugs off the market.").

29. RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION* 63 (2006) (explaining how the rewards can be great during the market exclusivity period for drugs whose sales while under patent protection are in the billions because "[i]n effect, during that period the two parties operate in a duopoly, such that each can charge a price somewhere between the competitive and monopoly levels").

30. CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., *GENERIC COMPETITION & DRUG PRICES* (2006), available at http://www.fda.gov/cder/ogd/generic_competition.htm (showing how average generic product prices fall when more competitors enter the market).

31. See James W. Hughes, Michael J. Moore & Edward A. Snyder, "Napsterizing" *Pharmaceuticals: Access, Innovation, and Consumer Welfare* 44 n.15 (Nat'l Bureau of Econ. Research, Working Paper 9229, 2002), available at <http://www.nber.org/papers/w9229> ("These prices [sic] differences are often muted at retail by the pattern of

manufacturer is able to charge more for its products than it could in a fully competitive market.³² One news account reported that the return on investment during the exclusivity period could be as high as 1,000%.³³

C. *Has the Incentive Worked?*

Very few lawsuits have been brought to challenge the validity or infringement of Orange Book-listed patents despite the invitation offered by Hatch–Waxman.³⁴ All that is needed to obtain the 180-day exclusivity period is a challenge to the validity of a drug patent or a claim that it is possible to make a noninfringing generic drug.³⁵ However, for a little more than a decade after the incentive's creation, the FDA enforced a more stringent standard for awarding exclusivity, which made exclusivity very rare.³⁶ This stringent standard illustrates that the incentive's value in encouraging generic entry is marginal, and its elimination would have a small impact on competition.

1. *FDA's Initial Stinginess in Awarding the Exclusivity Period.* Before the *Mova Pharmaceuticals v. Shalala*³⁷ decision in 1998, the FDA applied the provisions granting market exclusivity to the first applicant in a very restrictive manner. *Mova Pharmaceuticals* is significant because it struck down the FDA's restrictive provisions for awarding exclusivity, thus clearing the way for the FDA's current lenient approach.

Mova Pharmaceuticals and Mylan Laboratories each submitted ANDAs for a generic version of a diabetes drug.³⁸ Mova filed first, but the FDA stayed its application for thirty months because Pharmacia & Upjohn Company (Upjohn), the brand-name

higher retailer markups on generic drugs. Media reports indicate that some generic drugs had retail markups as high as 1000 percent above cost." (citing Elyse Tanouye, *Drugs: Step Markups on Generics Top Branded Drugs*, WALL ST. J., Dec. 31, 1998, at B1)).

32. See FOOD & DRUG ADMIN., *supra* note 30 (showing that generic drug prices fall as more competitors make the same product).

33. Pugh, *supra* note 3 ("Experts estimate that without an authorized generic, a generic firm with the six-month exclusivity period could expect a 1,000 percent return on investment.").

34. EPSTEIN, *supra* note 29, at 23 ("In any event, whatever the dramatic tales in individual cases, litigation is the exception and not the norm. In the vast majority of cases—approximately 95 percent of the time . . . generics are content to wait until patent expiration to begin commercial sales.").

35. Rosenthal, *supra* note 9, at 318–19.

36. See *supra* Part II.C.1 (discussing the FDA's initial stinginess in awarding the exclusivity period).

37. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998).

38. *Id.* at 1062.

company, sued for patent infringement within forty-five days after Mova provided notice of its ANDA.³⁹ Mylan, however, was not sued by Upjohn during the forty-five day period, and the FDA approved its application.⁴⁰ In response, Mova sued “to compel the FDA to delay the effective date of [the approval of Mylan’s application] until 180 days after the earlier of the dates that Mova won its suit or began to market its product.”⁴¹ The circuit court found that the FDA’s approach had essentially created a new requirement for invoking the 180-day exclusivity period: “[T]he FDA added its own requirement that the first applicant must have ‘successfully defended against a suit for patent infringement’ before the exclusivity period can begin to run.”⁴² The court also found that this new “successful-defense requirement [was] inconsistent with the statutory text and structure” of the Hatch–Waxman Act.⁴³ The court affirmed the lower court’s decision to strike down the regulation.⁴⁴ The *Mova Pharmaceuticals* holding opened the door to a new approach to awarding exclusivity.

2. *The Current FDA Practice in Evaluating Whether Exclusivity Is Warranted.* After *Mova Pharmaceuticals*, the FDA abandoned the successful-defense requirement and started making “exclusivity decisions on a case-by-case basis applying the literal words of the statute.”⁴⁵ Both the FDA’s misguided regulation and the court’s decision had a profound impact on the application and usefulness of the 180-day exclusivity period. Under the successful-defense regime, “the FDA had granted the 180-day exclusivity to [three] generic applicants for drug products covered by [three] NDAs.”⁴⁶ Under the FDA’s new approach, however, use of the exclusivity period has greatly increased, with “more than 60 ANDAs [receiving] 180 days of exclusivity.”⁴⁷

Despite the paucity of applicants that qualified for 180-day exclusivity under the old regime, 1,233 abbreviated applications

39. *Id.*; FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 59 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

40. *See Mova*, 140 F.3d at 1062.

41. *Id.*

42. *Id.* at 1065.

43. *Id.* at 1076.

44. *Id.*

45. FED. TRADE COMM’N, *supra* note 39, at 59.

46. *Id.* at 60; *see also* CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 3 n.4 (2003) (“In the years from 1984 to 1998, only three ANDA applicants qualified for 180-day exclusivity.”).

47. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 46, at 3 n.4.

were approved from 1984 to 1994.⁴⁸ This fact seemingly undercuts any attempt to credit the FDA's new approach with encouraging the emergence of vigorous generic competition because the agency approved a significant number of ANDAs even though it rarely awarded exclusivity.⁴⁹ Although the prospect of receiving an exclusive marketing period may have initially spurred additional generic competition, after several years, rational actors in the market must have noticed the elusive nature of exclusivity and discounted the potential value of exclusivity in their business decisions.

III. PIONEERS STRIKE BACK: REDUCING THE VALUE OF THE 180-DAY EXCLUSIVITY PERIOD

A. *Effect of Offering Discounts on the Branded Product as the First Generic Is Introduced*

Now that the FDA is awarding exclusivity to more ANDA applicants, pioneer manufacturers have met the increased competition with strategies to reduce the profitability of the exclusivity period. Merck's Zocor (simvastatin) is one of the blockbuster cholesterol-lowering drugs known as "statins."⁵⁰ Doctors prescribe these highly effective and safe drugs to help prevent heart disease,⁵¹ making them very popular in a country where high cholesterol levels are a pervasive problem.⁵² In 2005, sales of statins reached \$16 billion.⁵³

48. F.M. Scott Morton, *Entry Decisions in the Generic Pharmaceutical Industry*, 30 RAND J. ECON. 421, 426–27 (1999) (indicating that the dataset used in compiling this statistic was not a sample but rather "the complete set of ANDAs approved in the United States during this period").

49. See Rosenthal, *supra* note 9, at 319–20 (reciting statistics showing an improvement in consumer access to generic drugs from the enactment of the Hatch–Waxman Act to 1998, the same period during which the FDA used the "successful defense" requirement struck down in *Mova*).

50. Bill Alpert, *The State of Statins*, SMART MONEY, June 14, 2004, available at <http://www.smartmoney.com/barrons/index.cfm?story=20040614>. Other blockbuster statins include Pfizer's Lipitor and Bristol-Myers Squibb's Pravachol. *Id.*

51. See *id.* (noting that statins are effective at reducing the chance of heart attack and stroke with fewer side effects than aspirin).

52. See *Help for Your Cholesterol When the Statins Won't Do*, HARV. MEN'S HEALTH WATCH, Mar. 2005, at 1 (indicating that approximately 100 million Americans have an unhealthy cholesterol level).

53. Press Release, Food & Drug Admin., FDA Approves First Generic Simvastatin (June 23, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01394.html>.

In 2006, Teva Pharmaceuticals⁵⁴ and Ranbaxy Laboratories received approval of their ANDAs for simvastatin (for different dosage strengths).⁵⁵ Prior to the commercial introduction of the generic simvastatin products, Merck went on the offensive.⁵⁶ Merck contracted with Dr. Reddy's Laboratories to distribute an authorized generic version of Zocor, thus introducing additional price competition against the first applicants during their exclusivity period.⁵⁷ But in a less typical move for a pioneer manufacturer,⁵⁸ Merck also entered into agreements with health insurers to offer the brand-name drug at discounted, generic-level prices.⁵⁹

Merck's activities generated criticism by many, including Senator Charles Schumer of New York. Senator Schumer claimed that Merck's actions "could close the door on future generics" and characterized the tactics as "a desperate move to keep prices high and generics out of the market."⁶⁰ Schumer

54. IVAX Pharmaceuticals initially applied for ANDA approval of simvastatin. Teva Pharmaceuticals subsequently purchased IVAX Pharmaceuticals, thus acquiring the approved ANDA. *See* *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 121 (D.C. Cir. 2006).

55. *Id.* at 123; Press Release, Teva Pharmaceutical Indus. Ltd., Court of Appeals Affirms Teva's Generic Zocor® Exclusivity (Nov. 14, 2006), available at http://www.tevapharm.com/pr/2006/pr_642.asp; Press Release, Ranbaxy Labs. Ltd., Ranbaxy Granted Favorable Decision by the U.S. Court of Appeals Regarding Marketing Exclusivity for Simvastatin 80mg (Nov. 15, 2006), available at <http://www.ranbaxy.com/news/newsdisp.aspx?cp=799&flag=ARC>.

56. Instead of suing for patent infringement, Merck attempted to derail the introduction of two generic versions of Zocor by requesting that the FDA "delist" two patents on which the ANDAs depended. *Ranbaxy Labs.*, 469 F.3d at 121. Consequently, plaintiffs Teva and Ranbaxy "were required to delete the paragraph IV certifications from their ANDAs and thereby lost their eligibility for a period of marketing exclusivity." *Id.* The applicants successfully challenged the FDA decision in district court. *Id.* at 123–24. The D.C. Circuit affirmed:

We hold the FDA's requirement that a generic manufacturer's patent challenge give rise to litigation as a condition of retaining exclusivity when a patent is delisted is inconsistent with the Act, which provides that the first generic manufacturer to file an approved application is entitled to exclusivity when it either begins commercially to market its generic drug or is successful in patent litigation.

Id. at 121. The court noted that it was interpreting the statute as it existed before amendment by the Medicare Prescription Drug Modernization and Improvement Act of 2003, Pub. L. 108-178, 117 Stat. 2066 (2003). *Id.* at 122 n.*.

57. Joe Nocera, *Generic Drugs: The Window Has Loopholes*, N.Y. TIMES, July 1, 2006, at C1; *see also infra* Part III.B (explaining authorized generics and their impact on Hatch–Waxman).

58. *See* Heather Won Tesoriero & Barbara Martinez, *Cut-Rate Deals for Branded Zocor Worry Generics Makers*, WALL ST. J., July 14, 2006, at A9 (quoting a Ranbaxy spokesman who declared, "We've never seen this tactic before.").

59. Nocera, *supra* note 57 (discussing the agreements and noting, "Clearly, generic Zocor is going to be very cheap very quickly.").

60. Press Release, Charles E. Schumer, U.S. Senator, Schumer Reveals Merck Offering Payoffs to Discourage Health Plans from Using Generic Version of Zocor (June

stated that the deals entailed Merck paying a rebate in return for Zocor having a lower copay amount than any of the generic simvastatin products.⁶¹ Consumer advocates were also critical of the deals, arguing that they undermined Congress's intent in creating the 180-day exclusivity period because they allowed large pharmaceutical firms to lower the profits that the generic entrant can earn.⁶²

Evidence of these economic impacts is readily apparent. Merck's aggressive strategy resulted in Teva's shares dropping ten percent⁶³ and at least one stock analyst slashing his estimate for Teva's simvastatin revenue.⁶⁴ Blue Shield of California agreed to put generic Zocor on its lowest copayment tier "and told its 2.7 million commercial members that it wouldn't reimburse them for the generic version of the drug at all."⁶⁵ One report indicated that "members of UnitedHealth Group Inc. will pay around ten dollars for a month's supply of brand name Zocor and forty dollars for a generic after the drug [lost] patent protection."⁶⁶ The prices mentioned in news reports, however, only refer to copayment amounts; they do not specify what price UnitedHealth Group, or any other insurer, is actually paying for the product.

B. Authorized Generics

Another strategy that enables pioneer manufacturers to reduce the profitability of the exclusivity period is the introduction of authorized generics. Authorized generics are products distributed under license from the pioneer NDA holder, either by itself or by another pharmaceutical manufacturer.⁶⁷ Opponents to the practice define authorized generics as "brand

20, 2006), available at <http://schumer.senate.gov/SchumerWebsite/pressroom/record.cfm?id=259630&>.

61. See *id.* (criticizing Merck's methods).

62. Cf. Nocera, *supra* note 57 (discussing the motivation for reducing prices during the exclusivity period as cutting into "the rich profits the [generics] should be reaping during their exclusive 180-day window"); *Ultra-Cheap Drugs Worry Generic Makers*, AFX INT'L FOCUS, June 21, 2006 (discussing criticism from consumer advocates that the strategy helps patients in the short run but makes it more difficult for generics to challenge branded drugs).

63. See *Ultra-Cheap Drugs Worry Generic Makers*, *supra* note 62 ("With Merck's decision, U.S.-traded shares of the Israeli company plunged \$3.40, nearly 10 percent, to close at \$32.27 Wednesday on the Nasdaq. Shares of New Jersey-based Merck rose 35 cents to \$35.27 on the New York Stock Exchange.").

64. See *id.* (reporting that one analyst "lowered his revenue projections for Teva's generic Zocor for the second half of this year to \$65 million from \$385 million").

65. Tesoriero & Martinez, *supra* note 58.

66. *Ultra-Cheap Drugs Worry Generic Makers*, *supra* note 62.

67. THOMAS, *supra* note 14, at 1.

pharmaceutical products masquerading as generics.”⁶⁸ Other terms for these products include “branded” or “pseudo” generics.⁶⁹ Although they have attracted more notice recently, a similar practice was documented in a 1996 article: “Recently, brand-name pharmaceutical companies have begun to adopt a strategy of producing a generic version of their patented brand-name drug before the expiration of the patent . . . and to contract to supply the generic past the patent expiration date.”⁷⁰ However, this early practice may not have continued because it was not profitable enough at the time.⁷¹

When a pioneer manufacturer decides to release an authorized generic, it can release the generic version through another manufacturer⁷² or sell it directly (or through a subsidiary).⁷³ Several pioneer manufacturers such as Sanofi-Aventis,⁷⁴ Pfizer,⁷⁵ and Schering-Plough⁷⁶ own their own generic subsidiaries. Pfizer attracts particular attention for use of its

68. Generic Pharm. Ass’n, Authorized Generics, <http://www.gphaonline.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/HTMLDisplay.cfm&CONTENTID=1932> (last visited Apr. 11, 2008).

69. THOMAS, *supra* note 14, at 1.

70. Bryan A. Liang, *The Anticompetitive Nature of Brand-Name Firm Introduction of Generics Before Patent Expiration*, 41 ANTITRUST BULL. 599, 599 (1996).

71. Cf. THOMAS, *supra* note 14, at 8 (“[P]hysicians, pharmacists and patients more rapidly switch to generic drugs upon their introduction to the marketplace than a decade ago. Because the rate of generic adoption is much greater now, brand-name firms reportedly are more willing to ‘genericize’ their own brands in order to capture a share of that market.”); Nocera, *supra* note 57 (“[T]he 1980’s and especially the 1990’s were an extraordinary time in the drug industry, with one blockbuster drug after another brought to market. With profits rolling in, the giant pharmaceutical companies didn’t feel the need to pick up every nickel on the street.”).

72. See, e.g., Press Release, Baxter Healthcare Corp., Baxter Announces Launch of Authorized Generic Azithromycin for Injection (Mar. 23, 2006), available at http://www.baxter.com/about_baxter/news_room/news_releases/2006/03-23-06-azithromycin.html (“The launch marks the first time Baxter has been granted exclusive authorization by a pharmaceutical company to market a generic version of their brand product. Pfizer will manufacture generic azithromycin for injection and Baxter will sell and market the product in the United States.”).

73. See, e.g., Press Release, Schering-Plough Corp., Schering-Plough Announces Warrick Pharmaceuticals Launches Generic Ribavirin Product in the United States (Apr. 9, 2004), available at http://www.schering-plough.com/schering_plough/news/release.jsp?releaseID=513291 (announcing the release of its own generic ribavirin product using its wholly owned subsidiary Warrick Pharmaceuticals).

74. Alicia Ault, *Generic Drugs: A Big Business Getting Bigger*, SCIENTIST, June 20, 2005, at 36, available at <http://www.the-scientist.com/article/display/15551/> (“In the meantime, some brand-name pharmaceutical companies have not been shy about moving into the generics territory. Sanofi-Aventis, which is [sic] third biggest drug company, recently established a generics division, Winthrop Medicines.”).

75. See *infra* text accompanying notes 77–79 (discussing Pfizer’s use of Greenstone Limited as its authorized generics division).

76. See Schering-Plough, *supra* note 73 (announcing the release of a generic drug through a wholly owned subsidiary).

subsidiary Greenstone Limited.⁷⁷ Discussing Greenstone's strategy in *Chain Drug Review*, Bill Kennally, Greenstone's president, stated that "[t]he model today is consistent with the original model [that motivated its formation in 1993] in that Greenstone launches generic versions of branded products once other generic competition enters the market."⁷⁸ The article mentions that "[Greenstone] does not have an [ANDA] strategy," which highlights the difference in the firm's operations compared to traditional generic manufacturers.⁷⁹ With the increasing use of authorized generics, generic manufacturers have sought to end the practice administratively through the FDA and then through the courts. The results in the *Teva* and *Mylan* cases, discussed below, show that only Congress can change the way companies produce and market authorized generics.

1. *Teva's Legal Challenge of Authorized Generics.* Teva Pharmaceuticals is one company that has sought to prevent a pioneer manufacturer from offering an authorized generic drug during its exclusivity period. The dispute was set in motion when Purepac Pharmaceutical Company filed the first ANDA containing a paragraph IV certification for gabapentin,⁸⁰ the generic therapeutic equivalent for Pfizer's Neurontin.⁸¹ Teva and Purepac entered into an agreement to share the exclusivity period awarded to Purepac.⁸² During the exclusivity period, Pfizer released an authorized generic version of its own drug, through its Greenstone Limited subsidiary, and directly competed against Teva and Purepac.⁸³ Teva filed a petition requesting the FDA to prohibit the use of authorized generics to compete against ANDAs within the 180-day exclusivity period.⁸⁴ Teva also requested, in the alternative, that Pfizer be required to file a supplemental NDA before distributing an authorized generic

77. See Ault, *supra* note 74, at 38 (tracing Pfizer's acquisition of Greenstone back to Pfizer's merger with Pharmacia, which had set up the division to produce authorized generics).

78. *Greenstone Ltd.*, CHAIN DRUG REV., Sept. 25, 2006, at 70 (profiling Greenstone's business model and its opposition to congressional efforts to ban authorized generic drugs during the 180-day exclusivity period).

79. *Id.*

80. Doctors prescribe gabapentin to treat epileptic seizures and postherpetic neuralgia, which is "horrific pain that sometimes follows shingles." Jane E. Brody, *A Chance Find, and Voilà! Goodbye, Hot Flashes. Hello, Sleep.*, N.Y. TIMES, Mar. 28, 2006, at F6.

81. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005).

82. *Id.*

83. *Id.*; see also Scott Hensley, *Pfizer to Make Generic Version of Its Zoloft*, WALL ST. J., June 29, 2006, at B1 (discussing Pfizer's relationship to Greenstone Limited).

84. *Teva*, 410 F.3d at 52.

version.⁸⁵ The FDA rejected the petition, and Teva brought suit in district court.⁸⁶ The district court granted summary judgment in favor of the FDA and Teva appealed.⁸⁷

On appeal to the D.C. Circuit, Teva argued that in enacting the Hatch–Waxman Act, Congress intended to give the first applicant of an ANDA total exclusivity in the generic market, and that the approach the FDA took in allowing authorized generics frustrated Congress’s purpose by allowing additional generic competition.⁸⁸ The court reviewed the FDA’s interpretation of the statute using the *Chevron*⁸⁹ framework.⁹⁰ The court determined that Congress’s intent was clear and the statute was unambiguous.⁹¹ First, the court noted that the provision creating exclusivity for the first applicant did not mention NDAs or its holders at all.⁹² Next, the court reiterated the FDA’s finding that there were no provisions in the Hatch–Waxman Act that allowed for refusal or withdrawal of NDA approval based upon “marketing arrangements.”⁹³ Finally, Teva conceded that prior to the enactment of the Act, nothing precluded NDA holders from releasing an authorized generic.⁹⁴ After addressing Teva’s premises, the court stated: “There is simply no way to read that limitation upon what the FDA may do in such a way as to prevent the [pioneer manufacturer] . . . from marketing a brand-generic product.”⁹⁵ Nor could the FDA require Pfizer to file a supplemental NDA, Teva’s proposed alternative remedy.⁹⁶ According to the court, the Act allows a supplemental filing only on safety or efficacy grounds.⁹⁷ The court held that “the Act clearly does not prohibit the holder of an approved NDA from

85. *Id.* at 52–53.

86. *Id.* at 53.

87. *Id.*

88. *Id.*

89. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

90. *Teva*, 410 F.3d at 53 (citing *Chevron* and explaining that courts must review agency interpretation of statutes with a two-step test: first, the court shall determine whether Congress has addressed the issue in question—if so, and if the intent of Congress is unambiguous, the court as well as the agency must give effect to Congress’s expressed intent; second, if Congress has not addressed the issue, the court must determine if the agency has permissibly interpreted the statute).

91. *Id.* at 53–54 (“The means the Congress ‘deemed appropriate, and prescribed’ to give generic drug makers an incentive to challenge brand-drug patents is unambiguous . . .”).

92. *Id.* at 53.

93. *Id.*

94. *Id.*

95. *Id.* at 54.

96. *Id.* at 54–55.

97. *Id.*

marketing, during the 180-day exclusivity period, its own 'brand-generic' version of its drug."⁹⁸

2. *Mylan's Failed Challenge.* Mylan Pharmaceuticals also made an unsuccessful attempt to use the FDA petition process to prevent an NDA holder from selling an authorized generic drug during the exclusivity period. Mylan Pharmaceuticals received FDA approval of its ANDA for Macrobid.⁹⁹ After Mylan received approval, Procter & Gamble Pharmaceuticals licensed an authorized generic drug harming Mylan's sales.¹⁰⁰ Mylan, like Teva,¹⁰¹ unsuccessfully petitioned the FDA for a ruling that the authorized generic drug could not be sold during the 180-day exclusivity period.¹⁰² Thereafter, Mylan sued in district court, which stayed the matter pending Teva's appeal in the D.C. Circuit.¹⁰³ After the case resumed, the FDA moved to dismiss for failure to state a claim upon which relief could be granted.¹⁰⁴ The court granted dismissal.¹⁰⁵ On appeal to the Fourth Circuit, Mylan made the same basic arguments as did Teva,¹⁰⁶ with the court reaching the same results. The court was unwilling to substitute the alleged intent of Congress for the unambiguous statutory command.¹⁰⁷

With two circuit courts adopting the view that the Hatch-Waxman Act is unambiguous, it seems unlikely that generic manufacturers will find aid in any corner other than Congress. As both courts suggested, because of the statute's unambiguous text, the FDA is unable to affect any change in the legislative scheme.¹⁰⁸

98. *Id.* at 55.

99. *Mylan Pharms., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 271 (4th Cir. 2006).

100. *Id.* ("Just as Mylan began selling its generic drug, a third party under license from Procter & Gamble started selling a competing generic version. Sales of the generic authorized by Procter & Gamble crimped revenues from Mylan's version.")

101. *Id.* at 273 ("Teva Pharmaceuticals USA, Inc., another generic drug maker, submitted a petition in June 2004 seeking a similar ruling.")

102. *Id.* at 271.

103. *Id.* at 274.

104. *Id.*

105. *Id.*

106. *Compare id.* at 275–76 (discussing Mylan's congressional intent argument), *with* *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53 (D.C. Cir. 2005) (evaluating Teva's functional interpretation argument).

107. *Mylan*, 454 F.3d at 275–76 (listing three reasons why Mylan's argument must fail).

108. *Id.* at 276 ("Prior agency interpretation (whether or not it supports Mylan's reading) is irrelevant because the statute unambiguously forecloses that reading."); *Teva*, 410 F.3d at 55 (stating that the court declined to reach the issue of whether the FDA's

IV. ANALYSIS OF ANTICOMPETITIVE EFFECTS

Critics have suggested the conduct described in this Comment, such as discounting the branded drug or introducing an authorized generic version, is anticompetitive.¹⁰⁹ Senator Schumer, deriding the practice of using authorized generics, declared: “It is a form of predatory pricing. [Pioneer manufacturers] are trying to put a dagger through the heart of the generic industry.”¹¹⁰ No doubt, many of the strategies employed in the drug industry are aggressive, but do they meet the economic and legal tests of predation? Examining drug industry practices, pricing does not appear predatory or even anticompetitive.

A. *The Basics of a Predatory Pricing Claim*

To determine whether predatory pricing arises from a pioneer manufacturer’s conduct, it is helpful to first look at a basic definition of predatory pricing. After providing a definition, this Part discusses the skepticism many economists have of predatory pricing. Finally, this Part reviews the elements of a predatory pricing claim.

1. *A Basic Definition.*

Predatory pricing is defined in economic terms as a price reduction that is profitable only because of the added market power the predator gains from eliminating, disciplining, or otherwise inhibiting the competitive conduct of a rival or potential rival. Stated more precisely, a predatory price is a price that is profit-maximizing only because of its exclusionary or other anticompetitive effects.¹¹¹

From this definition, the anticompetitive nature of predation is clear. Yet, when one tries to apply this definition to the conduct of market participants, a principal question arises: How can one

ruling was inconsistent with its prior interpretation upon finding the statute unambiguous).

109. See Daniel Yi, *Savings Ahead in Generic Medicines*, L.A. TIMES, July 15, 2006, at A1 (citing concerns of consumer advocates and lawmakers that price slashes are anticompetitive and ultimately “discourage generics from entering the market in the long run”); Pugh, *supra* note 3 (discussing claims by opponents that authorized generics are anticompetitive).

110. Nocera, *supra* note 57.

111. Patrick Bolton, Joseph F. Brodley & Michael H. Riordan, *Predatory Pricing: Strategic Theory and Legal Policy*, 88 GEO. L.J. 2239, 2242–43 (2000) (citation omitted).

determine when a price reduction goes beyond ordinary and desired competition in the market place?¹¹²

2. *Traditional Skepticism.* Traditionally, the existence of predation in the real world has been viewed with suspicion among economists and courts.¹¹³ Many argue that predation is an irrational strategy because to be successful a monopolist must lower his price below cost and incur a “substantial loss for gains that not only are deferred but may be temporary, since once the existing competitors are driven out of the market and a monopoly price is established, new competitors will be attracted to the market by that price; the tactic may have to be repeated.”¹¹⁴ This perceived irrationality makes economists view the practice as unlikely in a world of largely rational actors.

3. *U.S. Supreme Court Requirements.* In *Brooke Group v. Brown & Williamson Tobacco Corp.*,¹¹⁵ the Supreme Court established that for a plaintiff to prevail on a predatory-pricing claim under antitrust law, he must show that (1) “the prices complained of are below an appropriate measure of its rival’s costs”¹¹⁶ and (2) “that the [rival] had a reasonable prospect, or, under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices.”¹¹⁷ The Court noted that it had “rejected elsewhere the notion that above-cost prices that are below general market levels or the costs of a firm’s competitors inflict injury to competition cognizable under the antitrust laws.”¹¹⁸ The Court, however, failed to resolve, or left open for further development, the question of what the appropriate standard is to evaluate an alleged predator’s costs.¹¹⁹

112. See *infra* Part IV.B–C (discussing the traditional and modern approaches to determining predation).

113. See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 308 (6th ed. 2003) (noting that “confirmed instances of predatory price discrimination were rare even before the practice was illegal”); cf. Jonathan B. Baker, *Predatory Pricing After Brooke Group: An Economic Perspective*, *ANTITRUST L.J.*, Spring 1994, at 585–86 (discussing how two FTC commissioners argued whether predation is more like a white tiger or a unicorn, suggesting that predation is either very rare or nonexistent).

114. POSNER, *supra* note 113, at 308.

115. *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993).

116. *Id.* at 222.

117. *Id.* at 224; see also *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 528 (5th Cir. 1999) (declaring that “the standard for inferring an impermissible predatory pricing scheme is high” and restating the *Brooke Group* elements for a predatory pricing claim).

118. *Brooke Group*, 509 U.S. at 223 (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 340 (1990)).

119. See Baker, *supra* note 113, at 592 (“[T]he Court expressly ‘decline[d] to resolve the conflict among the lower courts over the appropriate measure of cost’” (quoting

B. Traditional Predation and Average Variable Costs in a Single Market

Many circuit courts have adopted a variant of the Areeda–Turner average variable cost test.¹²⁰ The test begins with the premise that a firm’s marginal cost is the lowest nonpredatory price that a firm can set in the short run.¹²¹ However, because marginal cost is difficult to measure, the average variable cost is used instead.¹²² The test states that prices “below reasonably anticipated average variable cost should be conclusively presumed unlawful.”¹²³

1. *Applied to Brand Drug Discounting.* It appears particularly difficult to target brand-discounting behavior¹²⁴ using a predation theory under current law. First, it is unclear whether pioneer manufacturers are pricing their products below marginal cost or average total cost. In the controversial Merck/UnitedHealth Group arrangement,¹²⁵ the publicly available information makes it difficult to determine whether below-cost pricing is occurring. For example, one account of the Merck/UnitedHealth Group deal stated that it “allows patients to pay 75% less for the brand name product than the generic version.”¹²⁶ Other stories alluded to similar figures regarding

Brooke Group, 509 U.S. at 222 n.1); see also Bolton, *supra* note 111, at 2260 (“[T]here appears to be a brightening possibility that the courts will begin to analyze predatory pricing in the light of modern economics.”).

120. See William J. Baumol, *Predation and the Logic of the Average Variable Cost Test*, 39 J. LAW & ECON. 49, 49 (1996) (noting that the Areeda–Turner average variable cost test “has played a key role in adjudication” in many courts since 1975); see also PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶ 724, at 284–93 (2d ed. 2002) (generally discussing jurisprudence regarding the Areeda–Turner test, including those jurisdictions that refused to adopt the test). See generally Phillip Areeda & Donald F. Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697, 732–33 (1975) (advocating an average variable cost test and remarking on what pricing techniques should be deemed legal).

121. See AREEDA & HOVENKAMP, *supra* note 120, ¶ 724, at 287 (justifying marginal cost on the grounds that it is the price obtained from perfect competition).

122. See POSNER, *supra* note 113, at 311–12 (noting that “marginal cost is not a figure carried on a firm’s books of account or readily derivable from the figures that are,” but the “average variable cost is a pretty good proxy for marginal cost in the long run”); see also AREEDA & HOVENKAMP, *supra* note 120, ¶ 724, at 287 (noting some courts use average total cost because marginal cost is not an appropriate long-term price).

123. AREEDA & HOVENKAMP, *supra* note 120, ¶ 724, at 288.

124. See *supra* Part III.A (discussing discounting of a branded drug ahead of the generic’s product launch).

125. See *supra* note 59 and accompanying text.

126. *Cutting Edge Information; Pharmaceutical Industry Braces Itself for Losses as Patents Expire, Develops Counter Strategies*, MED. PAT. WK., Aug. 27, 2006, at 9.

patient copayments.¹²⁷ However, these reports and the conclusions drawn by commentators are misleading. Copayments, for instance, do not necessarily have a direct relationship to the price paid for the drug.¹²⁸ Furthermore, insurers and manufacturers may cloak their sales agreements in secrecy, making it difficult for anyone other than governmental agencies to learn of the pricing provisions. Only an inference, albeit a strong one, can be drawn suggesting that Merck is offering the drug at a much lower price than generic simvastatin. This falls short, however, of conclusively establishing that Merck is pricing its product below its average variable cost.

2. *Applied to Authorized Generics.* Authorized generics pose the same problems with proving or carrying out below-cost pricing. If the pioneer manufacturer contracts with an outside firm to distribute the authorized generic, the outside firm will likely seek compensation. This further increases the predator's costs and either tempers the discounts or increases the losses on each sale. If a pioneer distributes its product through a subsidiary, detection of predatory pricing may be difficult, especially if the firm does not report the profit and losses of its brand and generic versions separately.¹²⁹

3. *Difficulty of Establishing Recoupment.* Finally, the *Brooke Group's* recoupment requirement would be difficult to establish. A commentator notes that approximately four generic manufacturers file ANDAs per patent.¹³⁰ The existence of an abbreviated application is usually kept secret until after FDA approval, but applications containing paragraph IV certifications become known to the pioneer manufacturer through the notification provision.¹³¹ Thus, several generic manufacturers may begin the FDA approval process without knowing how many

127. See *supra* note 66 and accompanying text (stating that patients would pay \$40 for generic version as opposed to \$10 for one month's supply of Zocor).

128. See Barbara Martinez, *Drug Co-Pays Hit \$100*, WALL ST. J., June 28, 2005, at D1 (describing copays as "a set portion of the pharmacy bill that patients pay out of their own pockets—to give patients a financial stake in what drugs they and their doctors choose").

129. See, e.g., PFIZER INC., 2005 FIN. REPORT 35, available at <http://www.pfizer.com/files/annualreport/2005/financial/financial2005.pdf> (reporting financial operations of Pfizer and its subsidiaries, including its wholly owned subsidiary Greenstone Limited, on an aggregated basis).

130. Bulow, *supra* note 7, at 47 ("With an average of approximately four filers per patent the 180 day exclusivity has certainly helped to attract many generic firms, but the alternative inference is that exclusivity is no longer warranted.").

131. See *supra* text accompanying notes 20–23 (examining the notification requirement).

firms plan to enter the market. Even if later filers do not enter the market after seeing the pricing practices during the exclusivity period, those firms remain poised on the periphery of the market, ready to enter should the predatory efforts succeed. However, if multiple firms do enter the market at close to the same time, such a scenario makes it even harder for the predator to accomplish its goal of driving out competitors. With additional firms, losses caused by the predator are more widely distributed, increasing the likelihood that generic manufacturers remain financially stable.

Assuming that the brand drug discounting or other strategies employed by the pioneer manufacturers are anticompetitive, traditional predatory pricing litigation does not appear capable of reaching and punishing such conduct.

C. Modern Economic Theories That May Suggest Anticompetitive Effects

While traditional predatory pricing theory recognized only a limited type of anticompetitive conduct, modern commentators and economists have recently recognized new theories under which a rational actor may engage in such action.¹³² Though these theories have not been fully tested in the courts and are perhaps unlikely to enter the realm of antitrust law, they can be helpful nonetheless in determining whether the conduct is anticompetitive and how to fashion a remedy.

1. Above-Cost Prices as Predatory. One commentator observed that “[a] firm can deter aggressive competition with a low price, even if the low price exceeds the price-cutter’s average cost, so long as the price is sufficiently low relative to its rivals’ costs.”¹³³ However, courts require a cost standard in order to give businesses a workable rule to follow.¹³⁴ In the generic market, the pioneer manufacturer likely enjoys lower manufacturing costs due to valuable experience gained from producing the drug for the duration of its patent.¹³⁵ Generic drugs are further

132. See, e.g., *infra* Part IV.C.2 (discussing multimarket recoupment, one form of new anticompetitive predatory behavior).

133. Baker, *supra* note 113, at 591.

134. See Bolton et al., *supra* note 111, at 2271 (“A cost standard can be faulted as difficult and expensive to prove, and also under-inclusive, because prices above cost can be both predatory and injurious to competition. Despite these problems, a cost benchmark is generally necessary for effective business planning for an activity as ubiquitous as pricing.”).

135. Cf. Bulow, *supra* note 7, at 43 (“It is exceedingly unlikely that a generics firm will have lower production costs than the branded firm that has been selling a medicine for years.”).

handicapped because they are not perfect substitutes for the branded drug.¹³⁶ Even though the generics are bioequivalent and just as effective, physicians generally value generic drugs less than the branded counterpart.¹³⁷

For insurers, it may be economical to pay more for a branded drug at near generic prices if it can cut spending on other branded but still patent-protected drugs. For example, Zocor is the first of the superstatins to lose patent protection.¹³⁸ A significant number of patients could safely switch to Zocor and away from other drugs, such as Pfizer's Lipitor, which are under patent protection and hence more expensive.¹³⁹ Some insurers have adopted a strategy of encouraging patients on a drug with longer patent protection to switch to a different drug in the same category that has a generic available or will have a generic soon.¹⁴⁰ Usually, insurers steer patients toward its preferred drug by instituting restrictions on the use of nonpreferred drugs through formulary control¹⁴¹ or by placing the drug with longer protection in a nonpreferred tier of drugs that carry higher copays.¹⁴² However, the insurer may have greater success in its efforts to convert patients over from other drugs if it is able to offer another brand-name drug as the alternative. In an era of direct-to-consumer marketing,¹⁴³ it may be much easier to

136. See *id.* ("No one thinks of the generic product as superior to the branded product. At the very best it is identical."); Press Release, Medco Health Solutions, Inc., Survey Reveals Seven Out of 10 Doctors Concerned About Safety of Prescription Meds.; Risk/Benefit Thinking Supports Generics (May 18, 2006), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=131268&p=irolnewsArticle&ID=858360&highlight=> (reporting on a survey which "found that physicians trail consumers and pharmacists regarding their knowledge of and confidence in the safety and effectiveness of generic drugs"). Nearly 20% of the doctors surveyed did not consider generics as safe as brand drugs and 25% did not find generics to be chemically identical. *Id.*

137. Medco Health Solutions, Inc., *supra* note 136.

138. See Alpert, *supra* note 50 (noting that demand for brand name statins should drop once simvastatin is available).

139. See Bruce Japsen, *Generic Zocor Won't Be a Market Healer*, CHI. TRIB., Dec. 29, 2005, at C1 (quoting pharmacist who stated that statins are "pretty much interchangeable").

140. See Tesoriero & Martinez, *supra* note 58 ("Aetna had been aggressively moving its patients to Zocor from other cholesterol fighters in anticipation of the generics launch. As a result, Aetna had about twice as many of its cholesterol patient[s] on Zocor as the national average, and has already moved roughly 92% of its Zocor takers to simvastatin.").

141. See Martinez, *supra* note 128 ("Plans also are adopting 'step therapy,' that requires patients to try less-expensive products for a specified period of time before 'stepping up' to something more expensive.").

142. See Japsen, *supra* note 139 (reporting that Express Scripts plans to "put Lipitor in the more expensive 'non-preferred tier,' which can [add] on another \$20 on top of the health plan enrollee's brand-name co-payment").

143. See HENRY J. KAISER FAMILY FOUND., IMPACT OF DIRECT-TO-CONSUMER

convince patients to switch to another brand-name drug, especially when the other blockbuster drug enjoys its and the manufacturer's name recognition.¹⁴⁴ Even though consumers generally believe and accept generics as a safe and effective alternative to brand-name drugs, some physicians and patients do not believe branded and generic drugs are equivalent and, presumably, would be resistant to changing.¹⁴⁵ The moral-hazard problem facing physicians is twofold: first, patients, not doctors, are responsible for costs; and second, when insurance is present, patients are under even less pressure to reduce costs.¹⁴⁶ Generic substitution laws do not help the problem because they only allow pharmacists to dispense a generic therapeutic equivalent, not a different drug in the same category.¹⁴⁷ Therefore, even if the manufacturer only lowers its price to the same level as the generic competitor, the insurer may agree to make the brand preferred if it believes efforts to convert patients over to the lower-cost drug would be successful.

2. *Multimarket Recoupment.* In seeking to create antitrust liability based on low but above-cost prices, recoupment—the second element of the predatory pricing definition—becomes even more important.¹⁴⁸ Without requiring recoupment, procompetitive discounting could become ensnared in antitrust liability and thus chill competition.¹⁴⁹ Just as modern theory suggests a loosening of

ADVERTISING ON PRESCRIPTION DRUG SPENDING 4 (2003), available at <http://www.kff.org/rxdrugs/upload/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf> (summarizing results from study that found industry spending on Direct-to-Consumer advertising has experienced growth of 28% annually from 1996 to 2001).

144. Cf. Press Release, Univ. of Mich. Sch. of Pub. Health, SPH Researcher Duane Kirking Examines Generic vs. Brand Name Meds. (Oct. 10, 2001), available at http://www.sph.umich.edu/news_events/15press.html (“While drug advertising aimed directly at consumers has developed name recognition among patients, often they can be won over to generics fairly easily if there is a financial incentive.”).

145. See Medco Health Solutions, *supra* note 136 (suggesting physicians are less trusting of generic drugs than consumers).

146. A moral hazard is “[t]he tendency of an insured to relax his efforts to prevent the occurrence of the risk that he has insured against because he has shifted the risk to an insurance company . . .” POSNER, *supra* note 113, at 109; see also Judith K. Hellerstein, *The Importance of the Physician in the Generic Versus Trade-Name Prescription Decision*, 29 RAND J. ECON. 108, 110 (1998) (noting that when states impose additional costs on prescription writing “even very small costs have a large effect on physician decisions,” and suggesting that such results present “serious agency problems in the current delivery system for prescription drugs”).

147. See Hellerstein, *supra* note 146, at 109 (“Most states now have what are known as ‘permissive substitution laws’ that allow a pharmacist to substitute a therapeutically equivalent drug for the one written on the prescription.”).

148. See *supra* note 111 and accompanying text (defining predatory pricing).

149. See Baker, *supra* note 113, at 587 n.11 (discussing the Chicago School’s concerns

the below-cost standard, it also suggests another way a predator can recoup its investment in a predatory strategy: collecting its profits in another market. Using this strategy, a firm creates a predatory reputation by reducing prices in one of the markets in which the firm faces competition.¹⁵⁰ The firm cultivates this reputation in the hope that its competitors in other markets will not compete for fear that they could be the next target.¹⁵¹ The pharmaceutical industry could implement this strategy relatively easily. The major pioneer manufacturers have numerous products, which each likely constitute their own product market. It is very common to refer to the product development activities of both generic and pioneer manufacturers as a “pipeline.”¹⁵² For pioneer manufacturers, the pipeline is the movement of a compound from initial discovery to clinical trials and, hopefully, to FDA approval and market entry. For a generic manufacturer, the pipeline consists of patented drugs it wishes to copy after their patent terms expire in the future. In this type of industry, multimarket recoupment is possible because new postpatent markets always loom in the distance for the pioneer firm. For the pioneer, it may be rational to create a predatory reputation in a current market with generic competitors in the hope that generic manufacturers will either delay entry or behave less aggressively when the pioneer’s next product loses its patent protection. A delay or lessening in competition prolongs the time for the supracompetitive price, creating value for the predator.¹⁵³

Both types of conduct examined in this Comment can be used to create a predatory reputation. Brand-discounting and

regarding the prosecution of predation claims).

150. *See id.* at 590 (illustrating an example of predation whereby a chain store cuts prices in a few of its markets and thus “develop[s] a reputation as a predator by reducing price in a small number of markets”).

151. *Id.* 590–91 (“Most of the victimized rivals never experienced a price war but were merely intimidated by the threat of a price war into engaging in less aggressive behavior than they would otherwise have found most profitable.”). Disciplining rivals is anticompetitive and exclusionary because it restricts growth of competition. *See Bolton et al., supra* note 111, at 2268–69. To prove a disciplinary effect, the following elements must be shown:

- (1) the victim is a rival firm whose competition threatens or potentially threatens the profits of the predator; (2) following the period of below-cost pricing, the victim raised its prices, became less aggressive, or otherwise restrained its competitive conduct—or that the below-cost pricing was capable of producing this result; and (3) the below-cost pricing was a substantial factor in causing these exclusionary effects.

Bolton et al., *supra* note 111, at 2269.

152. *See, e.g., Merck, Merck Pipeline*, <http://www.merck.com/finance/pipeline.swf> (last visited Apr. 26, 2008) (summarizing Merck’s research pipeline).

153. *See FOOD & DRUG ADMIN., supra* note 30 (discussing findings of the FDA that show drug prices decline as additional generic versions of the drug become available).

authorized generics have the same effect on independent generic entrants: they have the capacity to drastically reduce profitability of new entries by accelerating the price decline from the precompetition monopoly market to a fully competitive one. However, pioneer manufacturers could have difficulty carrying out such a strategy considering the number of competitors waiting to enter the market with generic versions.

D. Conclusion

Although predation theory continues to develop, it is unlikely that generic manufacturers will be able to bring a successful predation claim based upon either brand-discounting or authorized generics. If policymakers disagree with the assessment that these strategies are not anticompetitive, then a legislative solution is necessary.

V. POSSIBLE RESPONSES

A. Prohibiting Authorized Generics During the 180-Day Exclusivity Period

1. *A Recent Attempt.* During the 109th Congress, Senators Rockefeller, Schumer, and Leahy introduced S. 3695, a bill to prohibit authorized generics from being introduced during the 180-day exclusivity period.¹⁵⁴ Senator Rockefeller stated that the bill was important to maintaining a competitive pharmaceutical industry:

This 6-month incentive is crucial to maintaining the balance between encouraging brand drug companies to make new drugs and encouraging generic drug companies to make existing drugs more affordable. Challenging a brand name drug's patent takes time, money, and involves absorbing a great deal of risk. Generic drug companies rely on the added revenue provided by the 180-day exclusivity period to recoup their costs, fund new patent challenges where appropriate, and ultimately pass savings onto consumers.¹⁵⁵

The law would function by prohibiting the NDA holder from manufacturing or authorizing any other person to manufacture

154. S. 3695, 109th Cong. (2006); 152 CONG. REC. S7927 (daily ed. July 19, 2006) (statement of Sen. Rockefeller) ("Our legislation would prohibit brand name manufacturers from introducing so-called 'authorized generics' during the 180-day period that Congress intended true generics to have exclusive market rights.").

155. *Id.*

an “authorized generic drug.”¹⁵⁶ The key provision of the bill is its definition of “authorized generic drug”:

[A]ny version of a listed drug . . . that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice [that an ANDA filer is making a paragraph IV certification] with respect to that listed drug; and

(B) does not include any drug to be marketed, sold, or distributed—

- (i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv) [paragraph IV certification]; or
- (ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).¹⁵⁷

2. *Loopholes in a Bill to Close a Loophole.* By virtue of this definition, the bill appears to only prevent an authorized generic from being introduced *after* the pioneer manufacturer has received notice of the paragraph IV patent challenge. This may prevent the pioneer from licensing its NDA to a third-party manufacturer unless it is willing to give up revenue before it has certain knowledge that it will face competition. This may be a viable option if the pioneer firms are able to predict the timing of an ANDA competitor.¹⁵⁸ However, in an even more likely scenario, the pioneer would simply sell the authorized generic through its own generic subsidiary. By doing so, the firm can use its corporate control over the subsidiary to keep the price very close to the monopoly price until true competition emerges. This would have little to no financial impact on the pioneer because the profits would flow back to it by virtue of ownership.

Even if the proposed bill successfully stops authorized generics, it does nothing about the discounting of branded drugs, as Merck did with Zocor.¹⁵⁹ This strategy has as much potential to erode the value of the 180-day exclusivity period as does the threat from authorized generics.¹⁶⁰ While the bill would eliminate one form of gaming the 180-day exclusivity period, it would likely

156. S. 3695, 109th Cong. § 1 (2006).

157. *Id.*

158. *But see supra* text accompanying notes 20–23, 131 (mentioning that patent and NDA holders must only be notified at time of filing with the FDA).

159. *See supra* Part III.A (discussing Merck’s ability to offer discounts through its relationship with health insurers).

160. *See supra* notes 60–66 and accompanying text (noting criticisms leveled at Merck’s discounting practice).

not be as effective at restoring Congress's scheme of richly compensating patent challengers as Senator Rockefeller's comments suggest.¹⁶¹ Instead, this bill will likely contribute to what one FTC commissioner termed the "whack-a-mole" problem it faces in the industry.¹⁶²

B. Would Regulating Prices During the 180-Day Exclusivity Period Work?

Senator Rockefeller's statement that Congress intended to reward the paragraph IV challenger suggests that perhaps Congress was expecting the sort of pricing behavior previously employed by brand-name drug manufacturers. A study examining competition up to 1993 found that when a generic drug entered the market, the pioneer raised its prices and held on to only the least price-sensitive market segment.¹⁶³ A more recent study found the same effect present today, albeit that brand prices increase even faster when there is an authorized generic available.¹⁶⁴ So it is entirely possible that Congress's scheme did yield substantial rewards for the few first applicants who entered the market before the authorized generics and discounting practices took off in popularity.¹⁶⁵

However, because pioneer manufacturers regularly attempt to reduce the value of the exclusivity incentive, in practice it will be increasingly hard for Congress to maintain its vision.¹⁶⁶ The

161. See 152 CONG. REC. S7927 (2006) (discussing the purpose and aim of the Hatch–Waxman Act).

162. See Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in Healthcare Conference (May 12, 2005), available at <http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf> ("[W]e seem to have a bit of a 'whack-a-mole' problem with the pharmaceutical industry—as soon as we address one competitive problem, yet another related issue pops up that we need to whack back down.").

163. See Hughes et al., *supra* note 31, at 6 ("[B]rand name producers did not typically cut their prices in response to generic entry and indeed that incumbents raise their real prices post entry. . . . Thus, incumbents decide to cede the bulk of the market to generics and retain the relatively small brand loyal segment.").

164. See HOLLIS & LIANG, *supra* note 67, at 18 ("An increasing trend for brand prices after generic entry is expected, and is a well-known effect. . . . However, the fact that brand prices increase *more* in markets with [authorized generics] may explain a large part the PhRMA study finding that generic price discounts are larger in markets with [authorized generics].").

165. The number of first applicants that entered and enjoyed such large rewards would seem to be small considering the low number of exclusive marketing periods granted by the FDA during the early years of the act. See *supra* text accompanying notes 46–48 (reviewing the number of first applicants).

166. See Nocera, *supra* note 57 (quoting George Barrett, President of Teva North America, as saying, "When you see the number of major drugs that are coming off patent, it would be unreasonable to expect a brand company to just stand still.").

incentive more than compensates for winning a lawsuit. Unlike awarding attorney's fees to the successful party, the first applicant enjoys the benefit of the exclusivity period regardless of the outcome in the case. A loss in the infringement suit only delays receiving the incentive until after the patent no longer blocks generic manufacturers.¹⁶⁷ It is also different from other incentives, such as tax credits, because the value of the exclusivity incentive is paid directly by consumers and is determined by market forces. Because pioneers reduce prices in order to undermine the exclusivity period, perhaps the only way to salvage what Congress intended is to institute limited price regulation of the brand drug during the exclusivity period.

1. *First Hurdle: Picking the Price.* For the exclusivity incentive to work as intended, it relies on keeping the price in the market close to the monopoly price level. A difficult issue is determining the appropriate price. One possibility is to average the brand firms' selling prices over a period of time before any generic announces its intended entry (when the pioneer receives its notice of a paragraph IV challenge to its patents). Another possibility is to use the best price calculation administered by the Centers for Medicare and Medicaid Services, which was modified in 2005 to require manufacturers to account for authorized generic pricing in the "best price calculation."¹⁶⁸ This data, reported by the manufacturers on a monthly basis, sets reimbursement levels to states for the Medicaid program. Because the data is collected by a governmental agency, it may be the best source of pricing information. Presumably, the data is well-scrutinized because it is used to determine the disbursements of federal funds.¹⁶⁹

167. See 21 U.S.C. § 355(j)(5)(B) (2000 & Supp. 2006) (providing that the effective date of approval for the first-filer's ANDA will be a date no earlier than the expiration of the patent that was infringed).

168. Generic Pharm. Ass'n, *supra* note 68 ("The new law contains a provision that will require brand pharmaceutical companies to include authorized generics in the 'best price' calculation that is provided to the Centers for Medicare and Medicaid Services. Due to an ambiguity in the current law, some brand companies were not required to include authorized generics in their best price calculation . . .").

169. See 42 U.S.C. § 1396r-8(a)-(c) (2000 & Supp. 2004) (detailing the method by which manufacturers report drug pricing and potential penalties for failure to do so properly); see also Lesley Ann Skillen & Megan M. Scheurer, *Whistles Blowin' in the Wind: Past, Present and Likely Future Landscape of Pharmaceutical Fraud Cases*, ABA NAT'L INST. ON HEALTH CARE FRAUD 2004, available at http://www.getnicklaw.com/media/article_30.html (discussing case where Bayer did not report a discount it offered on a drug, resulting in a civil settlement of \$251 million and a \$5.6 million fine for violations of the Food, Drug and Cosmetics Act).

However, selecting a time period to use is an important consideration. If the pioneer manufacturer knows ahead of time that a particular time period will serve as a benchmark, it may have an incentive to change its pricing (and thus defeat the purpose of the price regulation). By examining the pioneer's pricing over a longer period of time, the government may discourage attempts at manipulation. If the government used a longer period that included the patent term, a pioneer manufacturer engaged in gaming the average would have to give up an even larger amount of its monopoly profits.¹⁷⁰ One potential pricing period to analyze is the six months prior to the firm receiving notice of the paragraph IV challenge.¹⁷¹ Once the price is selected, the brand firm would have to maintain its average price or the best price above that level during the market exclusivity period, forming a price floor.

2. *Problems with a Price Floor.* Even if a satisfactory price target could be established, a number of problems still could arise. A price floor would affect the long-term purchasing agreements between pioneer manufacturers, insurance companies, and pharmacy benefit managers. Frequently, the price paid by an insurer or benefit manager depends upon their usage of other products made by the brand manufacturer. These agreements are socially desirable because they are reached freely between market participants. Any restrictions on the ability of parties to contract could lead to less economic efficiency.¹⁷² Because of the different prices that manufacturers legitimately charge different parties, it could be difficult for a firm to maintain the average at no fault of its own.¹⁷³

Another problem is enforcement. If the brand's pricing were to fall below the threshold, or were close to doing so, what should the outcome be? Forcing a price increase would be unfair to customers who believed their costs were set by their respective

170. Increasing the cost of gaming in this manner makes it more difficult for a firm to engage in predatory behavior because it increases its losses and runs the risk of not being able to recoup its profits. *See supra* text accompanying note 114 (discussing why economists view the rationale of predation strategies with skepticism).

171. *See supra* Part II.A.3 (describing when an ANDA applicant must send a notification of its application to the manufacturer).

172. *See* POSNER, *supra* note 113, at 12 (discussing how a contract entered into voluntarily by two parties presumably satisfies the Pareto-superior test of efficiency).

173. For example, if another drug enters the market and is attractive to some users of the regulated drug, those consumers that lack purchasing contracts, receive fewer discounts, or pay full price are more likely to switch. While this would lead to a drop in average sales price for the regulated drug, it would not likely affect the product's lowest price.

contracts. Fines or penalties could have unpredictable effects on pioneer conduct and could possibly harm consumers. While targeting prices seems like the only way to eliminate abuse of the 180-day exclusivity period, price regulation is perhaps too blunt of an instrument to prevent such harm.

C. Eliminate the 180-Day Exclusivity Period

Some have suggested eliminating the exclusivity period altogether.¹⁷⁴ There are several valid reasons for eliminating the provision: it has not been used often; it needlessly delays generic competition; and it is easily gamed. This suggests that the exclusivity period is not essential to accomplishing the goals of the Hatch–Waxman Act. Further, there is no reasonable prospect for settling the problems it raises once and for all.

1. *Not Necessary to Enhance Generic Competition.* The FDA's earlier interpretation of the Act resulted in rare awards of an exclusivity period.¹⁷⁵ Yet, the statute was still enormously successful in promoting generic competition. In the pre-1998 period, it is likely that the other aspects of the Act, which reduced the costs of receiving generic approval, were a more significant factor in encouraging increased generic competition.¹⁷⁶ In fact, from 1984 to 2000, ninety four percent of ANDAs "filed with the FDA . . . raised no patent issues."¹⁷⁷ This strongly suggests that other aspects of the abbreviated application process made it more desirable than the standard NDA process.¹⁷⁸

174. See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 425 (1999) ("It is now reasonably clear that the 180-day rule has been abused and produces no real public benefit that would not occur in its absence."); see also Bulow, *supra* note 7, at 42 ("A number of thoughtful analysts have proposed either elimination or revision of the 180 day rule.")

175. See *supra* Part II.C.1 (discussing the impact of *Mova Pharmaceuticals* on FDA grants of exclusivity).

176. See FED. TRADE COMM'N, *supra* note 39, at 10 (reporting that from 1984–2000, only 483 ANDAs contained paragraph IV certifications out of a total of 8,019 ANDAs filed during the period).

177. FED. TRADE COMM'N, *supra* note 39, at 10.

178. E.g., F.M. Scherer, *Pricing, Profits and Technological Progress in the Pharmaceutical Industry*, J. OF ECON. PERSP., Summer 1993, at 97, 100 ("[T]he procedures for approving generic substitutes for drugs without patent protection were radically simplified. The new would-be competitor must show only that its active ingredient is chemically identical to an approved drug and that blood levels in humans, usually demonstrated through 24 live subject tests, are within the statistical bounds (plus-or-minus 20 percent) imposed for the original drug."). Clinical trials for NDAs are more extensive, taking an average of 8.6 years to complete and requiring far larger numbers of test subjects (1,000–5,000 subjects used in Phase III trials alone). PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY PROFILE 5 (2006), available at <http://www.phrma.org/files/2006%20Industry%20Profile.pdf>

2. *Exclusivity Further Delays Generic Competition.*

Considering the questionable value of the exclusivity incentive, allowing it to remain prevents additional competitors from entering the market and lowering prices.¹⁷⁹ Under current law, the first applicant can block subsequent filers from receiving approval for up to thirty months while its application is in review.¹⁸⁰ In the worst-case scenario, additional manufacturers could be delayed by up to thirty months after the first applicant filed its ANDA, plus seventy-four days from the day the first applicant begins marketing, and finally another 180 days until after the exclusivity period. Therefore, instead of rewarding the first manufacturer ready to deliver its product, it rewards the firm that is the most adept at delivering a completed ANDA to the FDA.¹⁸¹

3. *No Good Way to Fix It.* There appears not to be a way to correct the numerous flaws in the statutory scheme. Proposals to stop authorized generics will do very little considering the alternative strategies available to reduce drug prices during the exclusivity period. The amount of time and effort spent on policing a very small part of the market is likely inefficient, and Congress should concentrate on making rules that are straight-forward rather than a loose framework that is costly to continually reinvestigate and patch.

VI. CONCLUSION

The Hatch–Waxman Act, by all accounts, has been tremendously successful in encouraging a strong generic marketplace, which makes high quality pharmaceuticals available at a very low cost when compared with the efficiency gains of lengthened lifetimes. While some point to the gaming taking place in the market and the concerns of anticompetitive conduct, perhaps the proper conclusion is that the market is working: neither side is strong enough to completely overpower

179. When there is only one generic manufacturer, a generic drug's average price is 94% of the brand price. See FOOD & DRUG ADMIN., *supra* note 30 (providing pricing information as affected by entrance of subsequent generics). The introduction of a second and third generic manufacturer leads to prices that are 52% and 44% of the brand prices, respectively. *Id.*

180. 21 U.S.C. § 355(j)(5)(B)(iii) (2000 & Supp. 2006). A “failure to market forfeiture” occurs if the first-filer does not begin marketing the drug until after seventy-five days of receiving approval or if its application is not approved within thirty months of filing. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa) (Supp. 2006).

181. See Bulow, *supra* note 7, at 44 (“One problem with the current system is that it rewards entrants not based on actual contribution but based on filing date Consistent with the concept that firms should be rewarded for what they contribute, any exclusivity period should be given to the first firm to make entry feasible.”).

the other. Considering the alternatives, Congress should strongly consider eliminating the 180-day exclusivity period to reduce the game playing present under the current system and return more of the savings offered by generic drugs back to consumers.

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