

GAMING THE HATCH-WAXMAN SYSTEM: HOW PIONEER DRUG MAKERS EXPLOIT THE LAW TO MAINTAIN MONOPOLY POWER IN THE PRESCRIPTION DRUG MARKET

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I. INTRODUCTION

In 1984, Congress enacted the landmark Drug Price Competition and Patent Term Restoration Act, or the “Hatch-Waxman Act.”¹ The twin goals of the Act were to encourage more pharmaceutical research and development of breakthrough or “blockbuster” drugs and to make available less expensive generic equivalents.² The Act provided market exclusivity periods for the sale of brand name drugs, granted patent extensions to pioneer drugs, and established new procedures for the Food and Drug Administration (“FDA”) to approve generic drugs.³ By balancing the interests of brand name and generic drug makers in this three-pronged approach, the Hatch-Waxman Act was a common sense formula for producing the best and most affordable medicines for health care consumers in America.

Eighteen years later, this system has fallen out of balance due to the aggressive manipulation of the Hatch-Waxman Act’s provisions in a health care environment in which prescription drug use has grown exponentially in recent years. By finding innovative ways to invoke the Act’s market exclusivity and patent extension provisions and to create anti-competitive agreements with potential generic competitors, many pioneer drug makers have ensured their continued domination of the prescription drug market. Moreover, by devoting much of their revenues to direct-to-consumer

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in sections of 15 U.S.C., 21 U.S.C., 28 U.S.C., and 35 U.S.C.). The congressional sponsors are Senator Orrin Hatch and Representative Henry Waxman.

2. *Id.*

3. *Id.*

advertising (“DTC”) campaigns, these same companies have contributed to the high consumer demand for, and often doctor-prescribed, name brand drugs instead of generic equivalents. Together, these legal and marketing efforts have delayed the availability of less expensive, generic drugs, thereby thwarting one of the two Hatch-Waxman Act goals. Moreover, these industry activities have spurred intense congressional debates on the inaccessibility of prescription drugs, advocacy groups lobbying for access to cheaper drugs, and consumers becoming more burdened with expensive drug bills.

This article examines the evolution of the prescription drug approval process that culminated in the enactment of the Hatch-Waxman Act in 1984.⁴ It explains the three-part system established by the Act and how each operates in today’s health care market. It probes the way in which pioneer pharmaceutical companies increase their blockbuster drug profits through aggressive, legal, and sometimes illegal, maneuvers. It also examines the effect of pervasive direct-to-consumer advertising on health care expenditures and prescription use. Arguing that the pioneer drug makers are responsible for inflated prices that make prescription drugs inaccessible for many Americans, the article closes with some policy recommendations. It concludes that effective reform of the Hatch-Waxman Act involves setting higher standards for patent infringement suits, eliminating the automatic thirty-month stay on generic competition, discouraging excessive DTC advertising, and providing more information to patients and doctors on new brand name drugs.

II. THE PRESCRIPTION DRUG APPROVAL PROCESS BEFORE THE HATCH-WAXMAN ACT

Throughout the twentieth century, Congress imposed increasing oversight over the development and availability of pharmaceutical products. Initially, congressional concerns focused on drug safety, and soon after, on efficacy. By 1984, Congress wanted not only to ensure safety and efficacy, but also wanted to stimulate innovation in new blockbuster drugs and to encourage financial accessibility of these medications.⁵

4. *Id.*

5. *Id.*

A. Reforming the Statute to Shift From Safety Only to Safety Plus Efficacy and Affordability

In 1906, Congress passed the Pure Food and Drugs Act to prohibit manufacturers from introducing misbranded and adulterated foods and drugs into interstate commerce.⁶ In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act to add quality standards for food and drugs and to require proof of safety to obtain FDA approval.⁷ The Act gave the FDA authority over the labeling of both prescription and over-the-counter pharmaceutical drugs, but it did not grant the agency control over drug advertising, which remained with the Federal Trade Commission ("FTC").⁸

In 1962, Congress passed the Kefauver-Harris Amendments to the original 1938 Act, which made safety standards more stringent, opened the door to generic competition, and transferred authority for prescription drug advertisements from the FTC to the FDA.⁹ Prior to 1962, a new drug was automatically approved if the FDA did not reject it within 180 days for failure to be safe for its suggested use.¹⁰ After 1962, the stricter safety testing requirements for new drugs included substantial evidence of efficacy and more expansive human clinical trials to ensure that the pharmaceutical products cured or treated the ailment for which they were prescribed.¹¹ Following this heightened standard, the approval process took as long as

6. Pure Food and Drugs Act, Pub. L. No. 59-384, Chap. 3915, 34 Stat. 768 (1906).

7. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-395 (2000)). See Paul M. Wax, *Elixirs, Dilutents, and the Passage of the 1938 Federal Food, Drug & Cosmetic Act*, 122 ANN. INTERN. MED. 456 (1995) (describing how Congress passed this legislation in response to the Elixir Sulfanilamide tragedy). See also Paul M. Wax, *Elixir Sulfanilamide-Massengill Revisited*, 36 VET. HUMAN TOXICOLOGY 561 (1994).

8. Federal Food, Drug, and Cosmetic Act, *supra* note 7. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-395).

9. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified, as amended, at 21 U.S.C. §§ 301-381). The statute is named after its congressional sponsors. See generally Louis Lasagna, *Congress, the FDA, and New Drug Development: Before and After 1962*, 32 PERSPECTIVES IN BIOLOGY & MED. 322, 330-31 (1989) (explaining the 1962 amendments and how Congress passed this legislation in response to the Thalidomide disaster in Europe and the United States).

10. Federal Food, Drug, and Cosmetic Act, *supra* note 7. See also Lisa C. Will, Note, *Accelerated FDA Approval of Investigational New Drugs: Hope for Seriously Ill Patients*, 94 DICK. L. REV. 1037, 1039 (1990) (explaining that the passage of the Kefauver-Harris amendments marked the beginning of a new era of enhanced, centralized FDA regulation of the new drug approval process, which led to slower drug approval).

11. Drug Amendments of 1962, *supra* note 9. Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified, as amended, at 21 U.S.C. §§ 301-355(d)(e)). See also William M. Brown, A "Highly Artificial Act of Infringement," *Indeed, But it Can Still Cost You Attorneys' Fees... Comment on Yamanouchi v. Danbury*, 33 UWLAR 117, 123 n.44 (2001) (explaining the three-phase clinical trials involve Phase I to test the drug's safety on only healthy volunteers that include 20-100 people, Phase II to test its efficacy on 100-500 patients suffering from the disease or condition in question, and Phase III to ensure the drug actually works through placebo, random and double-blind tests on 1000-3000 patients). See also Alvin J. Lorman, *FDA/Patent Law Intersection: What's New with Hatch-Waxman*, 666 PLI/PAT 337, 353 (2001) (describing the testing and approval phases of the FDA regulatory review period).

thirteen years.¹² Brand name drug manufacturers argued this delay reduced the effective life of their patents and drastically diminished their recuperation of production costs, making it necessary to invest more in the research and development of new life-enhancing pharmaceutical products.¹³

These amendments also made generic competition more feasible through the creation of "paper" New Drug Approval ("NDA") applications. Generic drugs approved before 1962 could obtain FDA approval based upon literature on the chemical in question that demonstrated its safety so long as the generic product was bioequivalent to the patented drug.¹⁴ However, since the Kefauver-Harris Amendments only applied to generic drugs pre-1962, any generic product after that date still had to complete a full NDA before acquiring FDA approval.¹⁵ The immense cost of conducting studies and the limited profits available to generic drug companies resulted in the majority of companies not even attempting to complete NDA applications.¹⁶ By 1984, only fifteen paper NDAs for post-1962 generic drug, out of 150 prescription drugs for which patents had expired, existed in the market.¹⁷

More concerned with enhancing recuperation opportunities for pioneer pharmaceutical companies than in making generics more accessible to the public, in 1978 President Carter initiated a comprehensive review of industrial innovation and patent term restoration.¹⁸ Three years later, the Senate unanimously passed the Patent Term Restoration Act to achieve the president's goals of extending the terms of patents to a seven-year

12. Commission on the Federal Drug Approval Process, *Final Report Prepared by the Subcommittee on Natural Resources, Agricultural Research and Environment and the Subcommittee on Investigation and Oversight of Science and Technology*, 97th Cong., 2d Sess. 2 (1982) (explaining that from the synthesis of the New Chemical Entity ("NCE") to the approval of the new drug, the FDA approval process now took approximately nine to thirteen years). See also *FDA's Drug Review and Approval Times*, Center for Drug Evaluation and Research, 1 <http://www.fda.gov/cder/reports/reviewtimes/default.htm> (July 30, 2001) (explaining that new drug approval times have been cut in half from a median of twenty-two months in 1992 to a median of less than twelve months in 1999).

13. Will, *supra* note 10, at 1038. Although designed to provide greater protection to the American public by requiring proof of both safety and efficacy, the 1962 amendments have created an unacceptably large increase in approval time, a decrease in incentive for drug innovation, and a barrier to the acquisition of necessary drugs for seriously ill patients.

14. Drug Amendments of 1962, *supra* note 9. Brown, *supra* note 11, at 125 (describing how pioneer drugs submit an NDA, which is an application to the FDA for permission to market the drug that contains extensive information on all the animal and human studies conducted, how and where the new drug will be manufactured, how the drug's performance will be maintained, stability tests, and the drug maker's ability to make, package, label, and market the drug).

15. Drug Amendments of 1962, *supra* note 9. See *United States v. Generix Drug Corp.*, 460 U.S. 453, 461 (1983) (concluding that a generic version of a drug that was already approved by FDA after 1962 was still a "new drug" under the Federal Food, Drug, and Cosmetic Act).

16. Brown, *supra* note 11, at 127.

17. H.R. REP. NO. 98-857, pt. 1 (1984). See also Gerald J. Mossinghoff, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act*, 54 FOOD AND DRUG L.J. 187, 187 (1999).

18. Mossinghoff, *supra* note 17, at 188. See Brown, *supra* note 11, at 124.

limitation.¹⁹ It failed to become law, however, because the same bill was placed on the House Suspension Calendar where it garnered a simple majority of the votes.²⁰ Consequently, after the shift to safety and efficacy standards in FDA approval, no substantive changes were made to the drug approval process between 1962 and 1984.

III. HATCH-WAXMAN

Aiming to add affordability to the drug approval equation, Congress passed the Hatch-Waxman Act, which was signed into law on September 24, 1984.²¹ The purpose of the Hatch-Waxman Act was two-fold. It was intended to encourage the accessibility of less expensive generic drugs and to minimize uncompensated regulatory delay for pharmaceutical companies engaged in costly, risk-infused investments in research and development.²² Hatch-Waxman created a simplified generic drug approval process, called abbreviated new drug applications (“ANDAs”), market exclusivity periods for both pioneer and generic drugs, and patent term extensions.²³ The law marked the first time the FDA had to consider the existence of patents as part of its approval process for certain new drugs.²⁴ In theory, these provisions were designed to balance, simplify, and expedite the regulatory process for both brand name and generic drug makers. In practice, however, they have opened the door to costly lawsuits that delay bringing inexpensive generics to the market, the abuse of market exclusivity and patent extension loopholes, anticompetitive deal-making between generic and name brand

19. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in sections of 15 U.S.C., 21 U.S.C., 28 U.S.C., and 35 U.S.C.). Implementing regulations, 21 C.F.R. pt. 314 (1998).

20. Mossinghoff, *supra* note 17, at 188. The Suspension Calendar requires two-thirds majority for passage.

21. Drug Price Competition and Patent Term Restoration Act, *supra* note 19. See also Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) [hereinafter CBO, *Increased Competition*] available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (describing how Hatch-Waxman helped increase the supply of generic drugs, which resulted in more innovator drugs facing generic competition after their patents expired, which in turn, caused pioneer drug firms to lose over forty percent of their market to generic drugs). See also *Am. Bioscience v. Bristol-Myers Squibb*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000); Federal Trade Commission Brief as *amicus curiae*, at 5, available at <http://www.ftc.gov/os/2000/09/amicusbrief.pdf> (2000) (stating that generic drug companies typically charge seventy to eighty percent of the brand name drug manufacturer's prices and as additional versions of the same drug enter the market, the price sometimes falls to a level of fifty percent of the brand name drug price).

22. H.R. REP. NO. 98-857(I), 98th Cong., 2d Sess., pt. 1, at 14-15 (1984), *reprinted* in 1984 U.S.C.A.N. at 2647-48. (The purpose was “to make available more low cost generic drugs by establishing a generic drug approval process for pioneer drugs first approved after 1962 . . . [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market approval.”). See also Mossinghoff, *supra* note 17, at 187.

23. Drug Price Competition and Patent Term Restoration Act, *supra* note 19.

24. Elizabeth H. Dickinson, *Symposium Issue—Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act*, 54 FOOD AND DRUG L.J. 195 (1999).

drug firms, and hefty revenues that are not devoted to research and development.

A. Abbreviated New Drug Applications

To resolve the discrepancy between pre-1962 and post-1962 generic drugs, Hatch-Waxman created the ANDAs for generic products equivalent to pioneer drugs first approved after 1962.²⁵ For new drugs, it maintained the rigorous NDA process, but now required the FDA to publish any claimed patents for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is called the "Orange Book."²⁶ Any generic drug company could use the original drug maker's NDA to prove safety and efficacy in its ANDA so long as the generic was "bioequivalent" to the patent listed in the Orange Book, and it completed one of four ANDA certifications.²⁷ The four possible certifications are set by: Paragraph I if no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA;²⁸ Paragraph II if the patent has expired;²⁹ Paragraph III if the patent will expire on a stated date;³⁰ or Paragraph IV if the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval.³¹ Paragraphs I to III do not create a cause of action because the FDA can easily determine whether a patent has been submitted or when a patent expires. However, patent infringement is a legal question that cannot be answered by the FDA.

If a Paragraph IV ANDA is filed and the patent holder files an infringement suit within forty-five days of the required notice from the generic applicant, Hatch-Waxman prohibits FDA approval of the ANDA until the end of a thirty-month stay or on the date a court decides the patent is invalid or not infringed.³² The mere filing of an infringement therefore

25. *Id.* Hatch-Waxman requires the FDA to approve or disapprove an ANDA within 180 days of receipt and reject any ANDA for a minimum of five years after granting approval to the pioneer drug, or for a period of three years if it is an over-the-counter drug. See 21 U.S.C. § 355.

26. 21 U.S.C. § 355(j). It is named after the color of the publication's orange cover. The patents claim a product, a method of using a product, or a method of manufacturing a product.

27. *Id.* Bioequivalence requires an FDA finding that "the rate and extent of absorption of the [new] drug do not show a significant difference from the rate and extent of absorption of the listed drug." 21 U.S.C. § 355(j)(8)(B)(i).

28. 21 U.S.C. § 355(j)(2)(A)(vii)(I).

29. 21 U.S.C. § 355(j)(2)(A)(vii)(II).

30. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

31. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

32. 21 U.S.C.A. § 355(j)(4)(B)(iii)(I)(II)(III)(c)(3)(C) (West 1999). If a generic drug company wins in lower court and the patentee appeals, the generic will often not want to risk liability for damages by bringing a generic drug product to the market before the patent litigation is resolved, even if the thirty months have passed. Dickinson, *supra* note 24, at 198.

can provide additional years of a generic-free market, regardless of the merits of the lawsuit.³³ This provision of Hatch-Waxman can also encourage generics to wait until the listed patent expires before entering the market to avoid the automatic thirty-month stay and time consuming lawsuits.³⁴

B. Market Exclusivity

The second prong to the Hatch-Waxman drug approval system is market exclusivity. The Act established 180-day generic drug exclusivity for the first ANDA applicant, five-year new chemical entity ("NCE") exclusivity, and three-year new clinical study exclusivity.³⁵ Congress also created two additional exclusivity provisions: seven-year orphan drug exclusivity³⁶ and six-month pediatric exclusivity.³⁷ If a pioneer drug company can secure a combination of these exclusivity periods, it can obtain a significant amount of additional time to exclusively market and sell their products at higher prices and without generic competition. Generics can also generate large profits through market exclusivity. If a generic drug company secures the 180-day market exclusivity where its only competition is the name brand drug, which can cost twice as much as the generic, it can obtain considerable profits as health insurance companies adjust their coverage plans to include its generic alternative and consumers become familiar with the product. This provision aiding the first ANDA applicant in the

33. 21 U.S.C.A. § 355(j)(4)(B)(iii)(c)(3)(C) (West 1999). See also CBO, *Increased Competition*, *supra* note 21.

34. Dickinson, *supra* note 24, at 198. This strategy further delays making cheaper drugs available in cases where the patent is invalid or not infringed on, but can also leave the brand name drug company holding the patent unprepared for generic competition because the ANDA is secret until the approval date.

35. Drug Price Competition and Patent Term Restoration Act, *supra* note 19. The five-year NCE exclusivity is granted to the most innovative drugs because they contain no active moiety previously approved by FDA, and thus are completely new building blocks of the drug products. The three-year clinical investigation exclusivity is granted for changes to the drug product, which require reports of new clinical investigations. Some examples of the latter exclusivity include changes in dosage form, for new indications and for switches from prescription to over the counter drug products. If there are other indications not covered by this exclusivity then generics can be approved for those indications during this three-year period. See also Dickinson, *supra* note 24, at 200-01.

36. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified in scattered sections of 21 U.S.C.). The Act grants a seven-year period of market exclusivity for new drugs that are developed for treatment of rare diseases with fewer than 200,000 afflicted patients in the United States, and bars approval of the same drug for the same disease or condition, even from a second full NDA. See Dickinson, *supra* note 24, at 202.

37. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified as amended in scattered sections of 21 U.S.C.). The Act grants a six-month period of market exclusivity for new drugs that are tested for use by children at the request of the FDA. Because the purpose is merely to inform the public, it does not require new labeling or evidence of safety and effectiveness in the children's studies. See Dickinson, *supra* note 24, at 203. In December 2001, Congress passed the Best Pharmaceuticals for Children Act, S. 1789, which reauthorized FDAMA, and on January 4, 2002, President George W. Bush signed it into law. Pub. Law. No. 107-109, 115 Stat. 1408 (2002).

prescription drug market also provides an incentive to challenge invalid patents and develop alternative forms of patented drugs.³⁸

C. Patent Term Extensions

The final part of the Hatch-Waxman system is the patent extension process. The Hatch-Waxman Act permits patent term extensions or restorations to compensate the pioneer drug makers for the lengthy regulatory review process, provided the term has not expired and has not already been extended.³⁹ The extension term for a pioneer drug is equal to one-half of the time of the investigational new drug ("IND") period, running from the time in which a pioneer can begin human clinical trials plus the time during the NDA review period.⁴⁰ However, if the patent was issued after the date of enactment or if the patent was issued before the date of enactment, and no clinical testing had been conducted, the extension cannot exceed five years.⁴¹ If the patent was issued for a drug before the date of enactment and clinical testing had begun, it was considered a pipeline drug that could not obtain an extension exceeding two years.⁴² The reason for this distinction was "to encourage the research and development of future products. All products which had not yet undergone testing or review by the Food and Drug Administration were judged to be appropriately eligible for the full five years of patent extension."⁴³

The patent term was further lengthened in 1994 following the ratification of the Agreement on Trade-Related Aspects of Intellectual Property Rights⁴⁴ and the passage of implementing legislation.⁴⁵ The new law

38. See *Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998) (holding that the FDA's regulations were inconsistent with the statute and invalid, thereby confirming that when a generic follows all applicable FDA regulations and is entitled to a final approval effective on that date, it will not be denied).

39. Drug Price Competition and Patent Term Restoration Act, *supra* note 19. See also Mossinghoff, *supra* note 17, at 2 (stating that the review period for new drugs used to delay entry into the market for years, but today takes approximately 12-14 months).

40. *Id.* See also *Oversight--The Food and Drug Admin.'s Process for Approving New Drugs: Hearing before the Subcomm. on Sci., Research and Tech. of the House Comm. on Sci. and Tech.*, 96th Cong., 1st Sess. 76 (1979) (testimony of William Wardell) (explaining that an IND must include information adequate to demonstrate that it is safe to test the drug on human subjects and to indicate drug composition, manufacturing and control data, results of animal testing, training and experience of the investigators, and a plan for clinical investigation).

41. Drug Price Competition and Patent Term Restoration Act, *supra* note 19.

42. *Id.*

43. 106 Cong. Rec. H4219 (daily ed. June 14, 1999) (statement of Rep. Henry Waxman).

44. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Annex 1C to WTO Agreement, 33 I.L.M. 1125, 1197 (1994) available at http://www.wto.org/english/docs_e/legal_e/27-trips.wpf [hereinafter WTO-TRIPs Agreement].

45. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994). (codified at 35 U.S.C. § 154).

gave a drug with a patent in effect or pending on June 8, 1995 a twenty-year patent term from the patent application date or a seventeen-year patent term from the date the patent was granted, whichever was longer.⁴⁶ The difference between these two time periods was named the "Delta Period," defined as a safe harbor when no generic drug company could compete in the market.⁴⁷ In addition, in 1996 a patent term of twenty years from its filing date pursuant to the Uruguay Round Agreements Act⁴⁸ was permitted to extend even further through a Hatch-Waxman patent restoration.⁴⁹ Consistent with the Hatch-Waxman goal of innovation, the reasoning for this decision was that pioneer drugs face unnecessary delays in the FDA approval process.⁵⁰

IV. MANIPULATING THE HATCH-WAXMAN SYSTEM

Over the past eighteen years, this drug approval system has been manipulated to delay bringing generics to the market and garner more profits for brand name drug manufacturers. The shrewd tactics of these drug companies, which in some cases may be illegal, have delayed the sale of generic drugs through improper patent listing with the FDA, unmeritorious infringement lawsuits against Paragraph IV ANDA applicants, and anticompetitive agreements between pioneer and generic drug makers.⁵¹

A. Blocking Generic Competition Through Groundless Infringement Lawsuits and Questionable Patent Listings

Often a pharmaceutical company will submit to the FDA for listing in the Orange Book a new method of use, new labeling or a new patent, which is so similar to a previous patent that it covers a generic copy of the

46. *Id.* at 35 U.S.C. § 154(c)(1).

47. *Bristol-Myers Squibb Co. v. Royce Lab.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995). The court said a generic drug can be approved and prepare to enter the market during this period if the patented drug it copies did not have a patent in effect or pending on June 8, 1995.

48. *Merck v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996). Uruguay Rounds Agreement Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994). 35 U.S.C. § 154.

49. *Merck*, 80 F.3d at 1544. The restoration did not apply to the five patents that were still in force in 1996 due to the 1984 law. See also CBO, *Increased Competition*, *supra* note 21, at Chap. 3, 3. (stating that between fifty and sixty applications for patent restoration are filed with the United States Patent and Trade-mark Office each year and of the 101 drugs containing new chemical compounds between 1992 and 1995, fifty-one of them received extensions, which on average lasted 2.9 years. The total patent term for these drugs was on average was 11.5 years).

50. *Merck*, 80 F.3d at 1544.

51. Testimony of Timothy Muris, Chairman of the Federal Trade Commission, before the Senate Commerce, Science and Energy Committee, April 23, 2002, available at <http://commerce.senate.gov/hearings/042302muris.pdf>.

first patent.⁵² The company will time its submission of a new listing to occur immediately before a generic drug firm has planned to launch the introduction of its product into the market, thereby triggering the thirty-month stay on this competition by bringing an infringement lawsuit.⁵³ This strategy guarantees the brand name drug years of additional unfettered market exclusivity and millions of dollars in profits.

For example, Eli Lilly ("Lilly") engaged in this conduct to protect its popular brand name drug, Prozac.⁵⁴ In December 1995, Barr Laboratories, Inc. ("Barr") filed an ANDA to produce and sell an antidepressant consisting of fluoxetine hydrochloride, which is an active ingredient in Prozac.⁵⁵ In April 1996, Lilly brought an infringement action in the United States District Court for the Southern District of Indiana against Barr.⁵⁶ Because of Lilly's claim, the FDA could not approve Barr's ANDA application for thirty months or until the court issued a decision, even though the court later rejected Lilly's lawsuit.⁵⁷ The Federal Circuit Court of Appeals found that Lilly had two patents for essentially the same drug: one for the compound fluoxetine hydrochloride and one for the administration of fluoxetine hydrochloride.⁵⁸ It concluded that Lilly staggered the timing of its patents in 1974 and 1986 to extend its monopoly beyond the usual seventeen years and requested to patent the drug for a second use to extend exclusive marketing rights.⁵⁹

Lilly generated \$2.7 billion selling Prozac domestically in 2000 alone.⁶⁰ Meanwhile, more than three years passed between the time of filing the infringement suit and the first court decision, and five years passed between the time of filing the infringement suit and the final appellate decision.⁶¹ Even though the patent was invalid, the infringement lawsuit

52. Chris Adams and Gardiner Harris, *Drug Makers Face Battle to Preserve Patent Extensions—Governors Join Businesses, Labor Unions in Effort to Hasten Generics to Market*, WALL ST. J., March 19, 2002, at A24. Brand name drug makers also commonly file citizen petitions raising safety questions about a potential competitor, which are often without merit and can delay approval. Between 1990 and 2000, eighty percent of these petitions were substantially rejected by the FDA or were withdrawn.

53. *Id.* See also Muris, *supra* note 51, at 17. The majority of patents subject to Paragraph IV certifications that result in patent infringement litigation involve formulation and method of use. These are not the patents on the active ingredient contained in the drug product, but the patents on how the product is formulated – for example, into tablets – or how the product will be used to treat certain health problems.

54. *Eli Lilly & Co. v. Barr Lab.*, 251 F.3d 955 (Fed. Cir. 2001).

55. *Id.* at 958.

56. *Id.* Lilly subsequently sued Geneva Pharmaceuticals, Inc., Apotex, Inc., and Bernard C. Sherman, all of whom had also filed ANDA applications with the FDA, and the actions were consolidated.

57. *Id.* at 968.

58. *Id.* at 959.

59. *Id.* at 968-69.

60. Rafael Gerena-Morales, *Substitute Will Push Up Co-Payments for Prozac*, TAMPA TRIB., July 31, 2001, at 1.

61. *Eli Lilly*, 251 F.3d at 958. The first decision was issued on January 10, 1999 and the appellate decision was issued on May 30, 2001.

triggered an automatic two and one-half years of no ANDA approval along with no opportunity to bring the cheaper generic to the market.⁶² This delay provided a significant marketing and profit advantage to the name brand company which it fully exploited while forestalling the availability of a cheaper, generic alternative available to the public.

Similarly, AstraZeneca, another large pioneer drug firm, filed an infringement suit to protect its blockbuster heartburn drug, Prilosec, commonly known as the “purple pill” in its advertising campaign.⁶³ On June 6, 2000, Mutual Pharmaceutical Company (“Mutual”) filed an ANDA seeking FDA approval to market a generic ten milligram felodipine tablet, and, following an amendment, a 1.5 milligram tablet and a five milligram tablet.⁶⁴ The ANDA contained three Paragraph IV certifications.⁶⁵ On September 18, 2000, AstraZeneca exercised its right to bring an infringement action, arguing that Mutual’s notice letters failed to include a complete and detailed explanation on how the generic product would not infringe upon its patent.⁶⁶ While the United States District Court for Eastern Pennsylvania acknowledged the notice was “far from exemplary,” it concluded that AstraZeneca did not show prejudice or that inadequate notice constitutes an actionable violation under the Hatch-Waxman Act.⁶⁷ Moreover, AstraZeneca admitted that there was neither precedent nor a statute establishing a legal remedy for an incomplete ANDA notice.⁶⁸

As with Lilly, this lawsuit, regardless of merit or the lack of a possible legal remedy, triggered the thirty-month stay on the ANDA and enabled the name brand drug company to generate huge additional profits. At \$4 per pill, Prilosec accounted for \$3.7 billion in sales in the United States in 2001 and \$26 billion in the past five years.⁶⁹ Moreover, the Prilosec patent expiration date was initially set for April 2001, yet no

62. Joseph Brown, *Prozac for the Long Term*, WASH. TIMES, Jan. 15, 2002, at A4. In anticipation of losing its market power on the August 2003 patent expiration date, which had already been extended with a pediatric six-month exclusivity period, Lilly launched Sarafem, a new brand name for fluoxetine, which is the active chemical in Prozac in August 2000. In March 2001, it also launched Prozac Weekly, the first and only prescription medication administered weekly for the treatment of depression. Prozac Weekly has patent protection until 2017 and therefore, can serve as the successor drug to dominate the drug market. *Id.*

63. AstraZeneca AB v. Mutual Pharm. Co., Inc., No. CIV.A.00-4731, 2002 W.L. 393119 (E.D. Pa. Mar. 12, 2002).

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* at 5.

68. *Id.*

69. Ronald D. White, *Key Drug Patent Ruling Nears; Courts: Effort to Block Generic Versions of Prilosec Could Set Trend in the Industry*, L.A. TIMES, May 28, 2002, at B1; Gardiner Harris, *Drug Prices – Why They Keep Soaring – Fast Relief; As a Patent Expires, Drug Firm Lines Up Pricey Alternative – Prilosec’s Maker Is Switching Users to a Lookalike Pill While It Thwarts Generics – Mr. Young Scrapes to Afford It*, WALL ST. J., June 6, 2002, at A1.

generics have been launched due to seven years of planning by marketers, lawyers and scientists at AstraZeneca.⁷⁰ The ANDA infringement lawsuit was just one of many approaches to delaying generic entry into the market.⁷¹ The combined effort ensured that AstraZeneca was generously compensated while it impeded the Hatch-Waxman goal of making generic drugs available to consumers.⁷²

A third example of aggressive strategies to avoid generic competition through questionable patent listings and infringement lawsuits is Bristol-Myers Squibb's ("BMS") actions in protecting its monopoly over the sale of BuSpar for the treatment of anxiety.⁷³ In 1980, BMS obtained a patent covering the use of buspirone, which it has sold as BuSpar since 1986.⁷⁴ On November 21, 2000, less than one day before the patent expired, BMS listed a newly-obtained patent in the Orange Book covering what buspirone becomes when swallowed and indicated that a reasonable claim of patent infringement could be asserted against generic producers of the drug.⁷⁵ On the same day, it filed a Paragraph IV ANDA infringement lawsuit to trigger the thirty-month stay.⁷⁶

In response to this last minute patent filing, generic drug makers seeking to enter the buspirone market, direct purchasers of buspirone products, end-payors who have purchased buspirone, consumer protection organizations, and thirty states all filed an antitrust action against BMS.⁷⁷ Among the plaintiffs' claims were that BMS tried to extend its monopoly by inappropriately listing a subsequent patent in the Orange Book so it could file an infringement lawsuit and obtain thirty additional months of market exclusivity.⁷⁸ The Southern New York District Court concluded that there was no basis for BMS to claim that its second patent covered the use of buspirone or that it could have been valid if it did.⁷⁹ "Bristol-Myers's creative legal arguments to the contrary cannot breathe life into claims that

70. Harris, *supra* note 69, at A1 (explaining that AstraZeneca obtained an additional six-month pediatric exclusivity).

71. *Id.* In March 2001, AstraZeneca established a successor heartburn drug, called Nexium. It spent \$478 million on an advertising and promotional campaign in 2001 to switch Prilosec users to Nexium, "today's purple pill, from the makers of Prilosec," according to their advertisements. By April 2002, Prilosec's share of heartburn prescriptions dropped to twenty-five percent from forty-nine percent in 2000 and Nexium had already acquired nineteen percent. Nexium is half of the Prilosec molecule so it is essentially the same drug in a smaller dosage.

72. White, *supra* note 69, at B1.

73. *In re Buspirone Patent Litig./In re Buspirone Antitrust Litig.*, 185 F.Supp.2d 363, 365 (S.D.N.Y. 2002).

74. *Id.*

75. *Id.* at 366.

76. *Id.*

77. *Id.* at 366.

78. *Id.* at 378.

79. *Buspirone*, 185 F.Supp.2d at 376.

have no basis.”⁸⁰ There was neither scientific innovation nor legal grounds for filing the second patent; just innovative legal maneuvering.

The court summarized how and why a company might abuse the Hatch-Waxman system:

Bristol-Myers could have listed the ‘365 Patent [the second patent] in the Orange Book without subsequently bringing infringement suits against Mylan and Watson, and Bristol-Myers could have brought these suits without relying on its Orange Book listing. What listing does is simply provide the owner of a patent with a number of additional and automatic benefits under the Hatch-Waxman Amendments. For example, by listing a patent that allegedly covers a listed drug or a method of using a listed drug, a pioneer drug company obtains (i) the right to receive notice of any ANDA from applicants seeking FDA approval of a generic form of the drug who have filed a Paragraph IV certification with regard to the patent in question; (ii) a grace period of forty-five days in which to bring a patent infringement suit against any such applicant before the applicant can file a declaratory judgment action; and (iii) if the pioneer drug company brings such a lawsuit, a stay of up to thirty months of the FDA’s approval of the ANDA.⁸¹

The court’s assessment of the ways in which BMS’s decision to list in the Orange Book, despite the groundless nature of its infringement suit, illustrates how the brand name drug companies can abuse the Hatch-Waxman system to their advantage and to the disadvantage of consumers.⁸² The Federal Circuit did reverse this opinion, but only because the statute did not provide a private right of action to compel de-listing of a patent from the Orange Book.⁸³

Since 1986, when BMS began selling BuSpar, the blockbuster drug has generated \$700 million in annual sales.⁸⁴ During the four months it took for the court to rule in favor of the generic companies, BMS made

80. *Id.*

81. *Id.* at 372. Mylan and Watson also sought to produce generic drugs.

82. Susan R. Miller, *Protecting Patents: Some Giant Brand-Name Drug Makers Using Delay Tactics to Keep Generic Competitors at Bay*, MIAMI DAILY BUS. REV., May 20, 2002, at A10. BMS used similar aggressive tactics to hold up the release of Ivax Corporation’s generic version of its cancer drug, Taxol, and to obtain an additional three and one-half years of market exclusivity for its diabetes drug Glucophage by trying unsuccessfully to convince Congress to carve out a special exception to the law in the reauthorization of the pediatric exclusivity law. See also Harris, *supra* note 69, at A1 (stating that in June 2002, twenty-nine state attorney generals sued BMS for using frivolous patents to delay generic competition to Taxol).

83. Muris, *supra* note 51, at 10.

84. *Id.*

approximately \$200 million.⁸⁵ As with Lilly and AstraZeneca, BMS brought a valuable drug to the market and instead of playing by the Hatch-Waxman rules, submitted a last minute patent to stave off generic competition, ensure market domination, and generate more company profits.⁸⁶

At least twelve pioneer drug companies are actively taking advantage of the ability to trigger a thirty-month stay of generic competition.⁸⁷ In most cases, the newly filed patent is no different from the initial patent. AstraZeneca's Nexium, for example, is merely a half molecule of Prilosec, which in the company's own studies had virtually identical healing rates.⁸⁸ In one study, Nexium achieved a ninety percent healing rate as compared to eighty-seven percent by Prilosec for the same dosage.⁸⁹ Refusing to release detailed descriptions of two other negative studies on Nexium, AstraZeneca filed its patent and cited the one positive study to doctors and consumers as grounds for why Nexium was a newer, better drug.⁹⁰

This practice of selling something as new that lacks genuine innovation and improvement over previous drugs is replicated throughout the industry. Two-thirds of new drugs approved from 1989 to 2000 used active ingredients already on the market.⁹¹ Over this twelve-year period, only fifteen percent (153) of all new drug approvals were medicines that used new active ingredients and provided significant clinical improvement over currently marketed products.⁹² In addition, over the past six years, eighty percent of the drugs approved by the FDA were deemed "standard drugs," and therefore, similar to what already exists.⁹³

Every pioneer drug company has the legal right to bring an infringement claim and protect its intellectual property. However, these suits must be based on the legitimate threat of infringing a valid patent, and not on a mere reformulation of a pill or dosage strength that is designed to

85. *Bitter Medicine: Pills, Profit and the Public Health*, ABC News, available at http://www.abcnews.go.com/onair/ABCNEWSpecials/pharmaceuticals_020529_pjr_feature.html (May 29, 2002).

86. *But see id.* (citing the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the nation's research-based pharmaceutical and biotechnology companies, stating that between 1984 and January 1, 2001, only 478 of the 8,259 generic drug applications filed with the FDA involved patent disputes).

87. Miller, *supra* note 82.

88. Harris, *supra* note 69, at A1.

89. *Id.*

90. *Id.*

91. Nat'l Inst. for Health Care Mgmt., *Changing Patterns of Pharmaceutical Innovation*, 7-8, <http://www.nihcm.org.innovations.pdf> (May 28, 2002).

92. *Id.* *But see* Alan F. Holmer, *Innovation is Key Mission*, USA TODAY, May 31, 2002, at 11A (arguing that the pharmaceutical industry spends more than \$30 billion annually on research and development, with eighty percent of this investment dedicated to the advancement of scientific knowledge and the development of products, compared to twenty percent that is devoted to improving and/or modifying existing drugs.).

93. *Bitter Medicine: Pills, Profit and the Public Health*, ABC NEWS, available at http://abcnews.go.com/onair/ABCNEWSpecials/pharmaceuticals_020529_pjr_feature.html (May 29, 2002).

trigger the automatic thirty-month stay on generic competition. The purpose of Hatch-Waxman was to stimulate innovation and improvement of new prescription medications, not to just sell the old drugs in new dosages with new labels and advertising schemes. Automatically rewarding a pioneer drug company with this thirty-month period of additional market exclusivity simply for filing an infringement suit that is unmediated by merit makes this improper conduct all too easy. Moreover, the lack of patent law expertise of the FDA, which presumes all submissions for listing are valid, facilitates the regular exploitation of the Hatch-Waxman system.⁹⁴ When pioneer drug makers are allowed to essentially duplicate their drugs to stretch out their market exclusivity, their conduct is an abuse of Hatch-Waxman and an obstruction of its twin goals. This practice perpetuates the tendency of pioneer drug makers placing profits over innovation and keeps low cost generic drugs off the market and inaccessible to consumers.

B. Using Patent Extensions to Maintain Market Control and High Profits

The patent term extension provisions in Hatch-Waxman and in the aforementioned orphan drug and pediatric exclusivity laws increase the already hefty pioneer drug profits secured through even longer market exclusivity periods and ANDA infringement suits. At the time Hatch-Waxman formed the pipeline drug provisions creating the patent extensions for pending FDA applications, Congress assumed that these drugs were close to completion and would be approved within one or two years.⁹⁵ However, many of these drugs were not close to completion and did not obtain FDA approval for another eight years, and therefore applied for and received other extensions.⁹⁶ Some of the extended time in the market free from generic competition includes not just the thirty-month stay for the ANDA, but another six months through the pediatric exclusivity provision. As of February 15, 2002, thirty-one different prescription drugs had received the pediatric exclusivity periods, including popular products by Bristol-Myers Squibb, AstraZeneca and Schering-Plough.⁹⁷

94. See *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442, 2001 U.S. Dist. LEXIS 2477, at *7-*8 (D. Md. Jan. 17, 2001) (stating "It [FDA] has no expertise—much less any statutory franchise—to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to the coverage . . .").

95. Mossinghoff, *supra* note 17, at 3.

96. *Id.*

97. The complete list of products receiving this exclusivity is available at <http://www.fda.gov/cder/pediatric/labelchange.htm>.

In addition, the Uruguay Round Agreements Act⁹⁸ led to the delay of generic versions of more than 100 prescription drugs—including Glaxo Wellcome's Zantac for ulcers, Merck's Mevacor for cholesterol, and Bristol-Meyer Squibb's Capoten for heart conditions—for up to two additional years.⁹⁹ These patent extensions can lead to overwhelming profits for pioneer drug firms. For instance, the extension for the G.D. Searle & Co. patent on the arthritis drug Daypro resulted in approximately \$280 million in sales in 1996, and the Schering-Plough patent for allergy medication Claritin generated annual sales of approximately \$2.2 billion.¹⁰⁰

In sum, brand name drug manufacturers have succeeded in stretching out the patent terms for their high profit, blockbuster drugs in addition to finding ways to list new patents in the Orange Book, triggering a thirty-month stay on generic competition and lengthening their market exclusivity periods. These astute efforts to game the Hatch-Waxman system contradict the Act's goals of balancing innovation with affordability. Some critics, including the FTC, no longer classify some of these actions as merely aggressive legal maneuvers, but rather, illegal violation of antitrust laws.¹⁰¹

C. Creating Anticompetitive Agreements to Protect Monopoly Power in the Prescription Drug Market

In response to recent settlements between brand name and generic drug companies disputing infringement claims, the FTC has begun to challenge the legality of paying generic firms millions of dollars to keep their products out of the market during their 180-day exclusivity periods.¹⁰² Because generic entry into the market lowers prices so dramatically, generic companies gain substantially less in profits than what the brand name companies lose in profits.¹⁰³ As a result, both parties can benefit from colluding to delay generic entry.¹⁰⁴ The FTC has become engaged in "first generation litigation" to block anticompetitive agreements¹⁰⁵ and "second generation litigation" to stop improper listings of patents and exclusive

98. 35 U.S.C. § 154.

99. Celia Wexler, *Prescription for Power: How Brand-Name Drug Companies Prevailed Over Consumers in Washington*, A Report from the Common Cause Education Fund, Common Cause, 11, available at <http://commoncause.org/publications/june01/phrma/061201.pdf> (June 2001).

100. *Id.* See also Families USA, *The Drug Industry Facts and Figures*, <http://www.familiesusa.org/factsheet.pdf> (April 2002) (describing sales revenues for leading drugs in 2000).

101. See *id.* (stating that in just one four-month period, November 2000 to March 2001, these companies accumulated at least \$160 million in additional sales by illegally manipulating the Hatch-Waxman system).

102. See *Muris*, *supra* note 51.

103. *Id.* at 6.

104. *Id.*

105. *Id.* at 3.

distributorship and market division agreements that illegally control the market.¹⁰⁶

The two leading collusion cases in which the FTC has intervened successfully, resulting in consent orders, are Abbott/Geneva and Hoechst/Andrx.¹⁰⁷ In the first case, the FTC alleged that Abbott paid Geneva approximately \$4.5 million per month to delay bringing its generic version of the hypertension drug, Hytrin, to the market.¹⁰⁸ It also claimed that Geneva agreed to not transfer its 180-day market exclusivity rights and to not introduce any generic Hytrin product (even if it did not infringe the patent) until the patent infringement litigation was finally resolved or another generic Hytrin manufacturer entered the market.¹⁰⁹ “In the second case, the FTC alleged that Hoechst Marion Roussel (“Hoesht”) paid Andrx \$10 million per quarter, beginning in July 1998, when Andrx gained FDA approval for its generic version of Cardizem CD, a widely prescribed drug for treatment of hypertension and angina. The FTC also alleged that Hoechst had agreed to pay Andrx an additional \$60 million per year from July 1998 to the conclusion of the lawsuit if Andrx won. This anticompetitive agreement kept Andrx from entering the market with its generic drug and from transferring its 180-day exclusivity period to another generic company.¹¹⁰ The consent orders for both of these cases prohibited the respondents from entering into brand name/generic agreements where the first ANDA filer agrees to not enter the market with a non-infringing product or transfer its 180-day market exclusivity rights.¹¹¹ They also required advance notice to the FTC as well as court approval for any interim settlement agreements during patent infringement litigation that provided payments to generics to stay out of the market.¹¹²

106. *Id.*

107. Complaint, *Abbott Labs. and Geneva Pharm.*, FTC Dkt. No. C-3945 (May 22, 2000), available at <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; Complaint, *Geneva Pharm.*, FTC Dkt. No. C-3946 (May 22, 2000), available at <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; Complaint, *Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corp.*, FTC Dkt. No. 9293 (Mar. 16, 2000), available at <http://www.ftc.gov/os/2000/03/hoeschtandrxcomplaint.htm>.

108. Complaint, *Abbott Labs.*, at ¶ 27.

109. *Id.* at ¶ 26.

110. Complaint, *Hoechst*, at ¶ 23; See also Press Release, Federal Trade Commission, Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp. (April 2, 2001) available at <http://www.ftc.gov/opa/2001/04/hoechst.htm>

111. *Id.*

112. Consent Order, *Abbott Labs. and Geneva Pharm.*, FTC Dkt. No. C-3945 (May 22, 2000), available at <http://www.ftc.gov/os/2000/05/c3945.do.htm>; Consent Order, *Geneva Pharm.*, FTC Dkt. No. C-3946 (May 22, 2000), available at <http://www.ftc.gov/os/2000/03/genevad&0.htm>; Consent Order, *Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corp.*, FTC Dkt. No. 9293 (Mar. 16, 2000). <http://www.ftc.gov/os/1999/9912/hoechstagree.htm> See also Complaint, *Schering-Plough Corp.*, No. 9297 (Mar. 30, 2001), available at <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf> (addressing similar issues in a pending case).

A principal focus of the FTC's "second generation" litigation is improper Orange Book listings.¹¹³ The FTC first raised concerns about the possible anticompetitive effect of improperly listing¹¹⁴ in *American Bioscience v. Bristol-Myers Squibb*.¹¹⁵ It filed an amicus brief to request that the United States District Court for the Central District of California not issue an order requiring Bristol-Myers Squibb ("BMS") as the patent holder for the cancer drug, Taxol, to list American Bioscience's new patent in the Orange Book. The FTC wanted to avoid an improper listing and argued that a court-ordered listing would assign *validity* to the new patent that had not yet been proven.¹¹⁶ While the court did order the listing, it was later vacated and BMS withdrew the original submission, suggesting it knew the patent was invalid.¹¹⁷ During appellate motions, the court found American Bioscience was not substantially likely to succeed on the merits.¹¹⁸ The court battle did not end there. Ivax Corporation, the affiliate for the generic competitor filing the ANDA, Baker Norton, then charged BMS and American Bioscience of colluding to keep the generic drug off the market.¹¹⁹ This latter suit is still pending. The FTC's actions were aimed at preventing the court from assigning legitimacy to an improper listing.

In another "second generation" lawsuit, the FTC announced a proposed consent order with Biovail Corporation to settle charges that it illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book to block generic competition to its brand name drug, Tiazac.¹²⁰ This is the first enforcement action by the FTC to remedy the effects of an allegedly anticompetitive Orange Book listing.¹²¹ Before the complaint was issued, Andrx filed an ANDA, was sued by Biovail for infringement, and then prevailed in court.¹²² However, Biovail acquired a newly issued patent from a third party and listed it in the Orange Book as claiming Tiazac, forcing Andrx to amend its ANDA certification and triggering another thirty-month stay on generic competition.¹²³ The FTC accused Biovail of knowing that its new patent did not cover the form of

113. Muris, *supra* note 51, at 9.

114. *Id.* at 9 n.36.

115. *Am. Bioscience v. Bristol-Myers Squibb, et al.*, Dkt. No. CV-00-08577, 2000 WL 1278348 *1, (C.D. Cal. Sept. 7, 2000).

116. *Id.* See Sara Beliveau, *FDA: Approval of Generic Drug Reversed by U.S. Court of Appeals*, 30 J.L. MED. & ETHICS, 120, 120 (Mar. 22, 2002).

117. *Am. Bioscience*, 2000 WL 1278348 at *1.

118. *Id.* at 1083.

119. Beliveau, *supra* note 116, at 121.

120. The FTC complaint against Biovail is available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

121. Muris, *supra* note 51, at 12.

122. *Id.*

123. *Id.*

Tiazac it had been marketing, and Biovail later admitted that the newly listed patent covered a new formulation of Tiazac that Biovail developed only after it obtained and listed the patent so it did not cover the FDA-approved version of Tiazac.¹²⁴ The FDA told Biovail that the new patent lacked FDA approval and it would be de-listed unless Biovail certified that the patent claimed the approved ANDA version of the drug, which the company has still failed to do.¹²⁵ The FTC proposed a consent order that would require Biovail to divest the illegally acquired patent to its original owner, except as to new product developments outside the Tiazac market; to dismiss its infringement suit against Andrx; to end the generic thirty-month stay; to refrain from any action that would trigger any further thirty-month stays; to prohibit Biovail from unlawfully listing patents in the Orange Book, and to require it to give FTC notice of future listings.¹²⁶ Again, the FTC is attempting to ensure the proper use of the Orange Book and related Hatch-Waxman provisions.

In addition to drafting these consent orders for pending litigation, the FTC is scrutinizing other versions of anticompetitive agreements. Specifically, it is monitoring exclusive distributorship arrangements where a second generic drug company agrees to become the exclusive distributor of the first generic company's drug instead of bringing a competing generic to the market, which gives the second generic an agreed-upon share of the market.¹²⁷ Another anticompetitive agreement of concern for the FTC involves dividing the market segments.¹²⁸ For instance, one company might market its product exclusively in one strength while another company agrees to market its product exclusively in another, thus making competition noticeably less vigorous.¹²⁹

The FTC's attempts to crack down on collusive, anticompetitive activity have sparked the attention of the drug industry, Congress, and the media. This summer, the FTC is expected to announce findings from a comprehensive study of business relationships between brand name and generic drug manufacturers to better understand anticompetitive impediments to bringing low cost generics to the market and into hands of consumers.¹³⁰ These findings may provide additional insight as to the nature and extent of Hatch-Waxman abuses.

124. *Id.* at 13.

125. *Id.* at 13 n.54.

126. *Id.*

127. Muris, *supra* note 51, at 14.

128. *Id.*

129. *Id.*

130. *Id.* at 15.

The combination of redundant submissions of patents to the FDA, filing of lawsuits to block generic entry, continual extensions of drug patents, and the negotiation of questionable anticompetitive agreements between brand name and generic firms have upset the Hatch-Waxman equilibrium. Hatch-Waxman, as currently applied, favors the brand name drug companies and hinders the ability of generic competitors to provide the public with less expensive pharmaceutical products. The simultaneous advertising campaigns make the pioneer drug makers all the more powerful.

V. EXACERBATING THE IMBALANCE: DIRECT TO CONSUMER ADVERTISING

Beyond the legal maneuvering, pioneer drug firms have also launched persuasive DTC advertising campaigns to enhance their blockbuster drug profits. Today's vast marketing of name brand drugs is unprecedented and the techniques employed to convince consumers and doctors that only the latest brand name drug can truly alleviate heartburn, high blood pressure or even a headache are deceptive and misleading. As explained previously, most "new drugs" today are the same drugs of yesterday, and some have generics in the market. Due to the recent relaxing of FDA rules on advertising, brand name drugs have been able to dominate the market not only with market exclusivity and patent extensions, but with DTC advertising as well.

The FDA requires manufacturers, packers, and distributors (sponsors) who advertise prescription drugs to disclose in advertisements "information in brief summary relating to side effects, contraindications, and effectiveness."¹³¹ For forty years, the FDA has forbidden false or misleading prescription drug advertisements and the omission of material facts.¹³² The advertisements are defined in one of three categories.¹³³ First, "product claim" advertisements make claims about a product and must provide a fair balance of risks and benefits as well as convenient access to this information.¹³⁴ Second, "help-seeking" advertisements discuss a disease or condition, advise the public to "see your doctor" and are not FDA-regulated because they are not advertising a drug.¹³⁵ Third, "reminder" advertisements

131. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040 (1938) (now codified at 21 U.S.C. § 352(n)).

132. Testimony of Janet Woodcock, Director of the FDA Center for Evaluation and Research, before the House Commerce Subcommittee on Health, June 13, 2001, ("Woodcock") at 4, *available at* <http://energycommerce.house.gov/107/hearings/06132001Hearing276/Woodcock412.htm>.

133. *Id.*

134. *Id.*

135. *Id.*

are targeted at health professionals and cannot make claims or recommend dosages because they are exempted from the risk disclosure requirement.¹³⁶

From 1983 to 1985, the FDA requested the suspension of DTC advertising due to concerns raised about promotions directed toward non-health care professionals.¹³⁷ It lifted the moratorium, concluding that the required inclusion of information on drug effectiveness and potential risks in advertisements sufficiently protected consumers.¹³⁸ By the early 1990s, name brand print advertising began to accelerate. These ads included brief summaries regarding the adverse effects of a drug that were hard for consumers to understand.¹³⁹ By the mid-1990s, the television advertising began with “reminder” ads targeting health care professionals.¹⁴⁰ But like the print ads, they also confused consumers since they only mentioned the name of the drug without further explanation.¹⁴¹

Responding to this problem, in August 1997, the FDA announced guidelines to clarify how sponsors can offer convenient access to the advertised product’s approved labeling in accordance with the existing law.¹⁴² In August 1999, the FDA issued the Guidance for Industry: Consumer-Directed Broadcast Advertisements, which confirmed the 1997 announcement.¹⁴³ The regulations required broadcast advertisements to include a toll-free telephone number, referral to a print advertisement in a concurrently running publication, access to product brochures in convenient outlets, or referral to a healthcare provider or Internet web page.¹⁴⁴ Brand name drug companies could now produce “product claim” advertisements for blockbuster drugs without having to list the benefits and risks in the advertisement.

Consequently, since the 1997 regulatory change, spending on mass media advertising for prescription drugs more than doubled from \$1.1 billion to \$2.5 billion in 2000.¹⁴⁵ The drugs most heavily prescribed by doctors

136. *Id.* at 5.

137. *Id.*

138. *Woodcock* at 5. The FDA withdrew the moratorium on September 9, 1985, stating that the “current government regulations governing prescription drug advertising provide sufficient safeguards to protect consumers.” (citing 50 Fed. Reg. 36,677).

139. *Id.*

140. *See Id.*

141. *Id.*

142. *Id.* at 6. (By referring to a toll-free number, a website address, a concurrently running print advertisement or health care professionals in the broadcast advertisement, the ad would meet the legal standard of convenient access to the product’s approved labeling.).

143. Guidance for Industry: Consumer-Directed Broadcast Advertisements, 21 C.F.R. § 202.1 (1999), 64 Fed. Reg. 43,197.

144. *Id.* (These measures satisfy the “adequate provisions” requirement.).

145. Nat’l Inst. for Health Care Mgmt., *Prescription Drugs and Mass Media Advertising, 2000*, at <http://www.nihcm.org/DTCbrief2001.pdf> (Nov. 2001). Advertising is just one part of the pharmaceutical industry’s drug promotion campaigns, on which they spent \$15.7 billion in 2000. *Id.* at 5.

between 1997 and 1999 were those most heavily advertised.¹⁴⁶ In fact, eighty percent of the FDA-approved drugs that were marketed the most to consumers over the past several years were in the top twenty percent of drugs physicians prescribed.¹⁴⁷ Doctors are also prescribing more drugs for their patients than in the past. For instance, in 1999 they prescribed 146 drugs for every 100 office visits compared to 109 drugs per 100 office visits in 1985.¹⁴⁸ Moreover, when asked by patients, many physicians prescribe a name brand drug.¹⁴⁹

Members of Congress have reported similar findings and drawn striking conclusions about the small number of blockbuster drugs leading these advertising campaigns. The Ranking Member on the House Energy and Commerce Subcommittee on Health stated, “[i]n 2000, the drug industry advertised one percent of its 10,000 available prescription drugs. Ninety-five percent of all direct to consumer advertising was spent on just fifty of these 10,000 drugs.... [T]hose fifty drugs... were responsible for half of the \$21 billion increase in prescription drug spending.”¹⁵⁰ The Ranking Member on the House Ways and Means Subcommittee on Health added,

[D]TC advertising expenditure will reach seven billion dollars annually. This increased spending correlates with increased prices of prescription drugs. Like any other commodity, greater product recognition leads to increased demand, and higher prices.... [L]arge-scale advertising may also lead consumers to demand drugs that may not be medically necessary or appropriate for the patient's condition. According to the National Institute for Health Care Management, eighty-six percent of patients who request a prescription for Claritin from their doctor receive one.... [M]ost of the money spent on DTC drug advertisements goes to heartburn, allergy medications, and vanity drugs like those that prevent hair loss. These advertisements promote consumers to seek expensive treatment for conditions that they might not have felt the need for treatment in the past.¹⁵¹

146. *Id.* at 6.

147. *Id.*

148. *Id.* at 4.

149. *See Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals* before the House Commerce Subcommittee on Health, 107th Congress (June 13, 2001), available at <http://energycommerce.house.gov/107/hearings/06132001Hearing276/Woodcock412.htm>. *See also* testimony of Janet Woodcock, Director of the FDA Center for Evaluation and Research (Testifying that a 1999 FDA telephone interview found that eighty-six percent of consumers surveyed said drugs advertisements helped make them aware of new drugs, eighty-one percent of those who spoke to their doctors about a prescription drug said their doctor welcomed the question, seventy-nine percent of this latter group said the doctor discussed the drug with them and fifty percent of these patients said their doctor gave them the medication discussed.).

150. 107 CONG. REC. H659-01 (daily ed. March 5, 2002) (statement of Rep. Sherrod Brown).

151. 147 CONG. REC. E1225-04 (daily ed. June 27, 2001) (statement of Rep. Fortney Pete Stark).

Without a doubt, today's DTC advertising for blockbuster drugs is unprecedented. The degree to which these ads are shaping consumer demand and doctor supplied name brand drugs is still being determined.¹⁵² Consumers are so familiar with television commercials for the fifty leading brand name drugs promising to alleviate common ailments, such as arthritis and allergies that they can ask their doctors for prescriptions by name. Moreover, with new patents obtained and marketed as the successor drugs to the popular initial branded drug, as with Clarinex replacing Claritin and Nexium replacing Prilosec, the public is exposed to new advertisements suggesting newer and better drugs.¹⁵³ With little knowledge as to the meaning of bioequivalence, much of the public is swayed by the advertisements.¹⁵⁴ Doctors are given access to only published studies on new drugs, treated to endless free samples of blockbuster drugs, and want to meet the demands of their patients.¹⁵⁵ Therefore, doctors often start out with a name brand prescription for their patients, getting patients accustomed to the name brand drug early in the marketing process. Just as submitting last minute, so-called "new" patents to the FDA that offer no improvement over past medications, advertising so-called "new" brand name drugs as better than old ones is often a deceptive manipulation of a process gone awry.

VI. TIME FOR CHANGE

Prescription drugs have become a central part of the practice of medicine. National expenditures on drugs continues to grow at an astronomical pace, raising concerns about the pharmaceutical industry's manipulation of the drug approval process as well as its disproportionate spending on marketing and lobbying as opposed to research and development. Eighteen years after the enactment of Hatch-Waxman, which now operates in a changed health care environment of increased prescription drug usage, reform is needed.

152. *Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results*, Food and Drug Administration, available at <http://www.fda.gov/cder/ddmac/Presentations/KitDIA2002out2/KitDIA2002out2.PPT> (June 18, 2002) (noting 2002 FDA phone survey of 943 people who had visited their doctor in the past three months found eighty-one percent said they recalled seeing or hearing a drug advertisement in past three months, and ninety-seven percent reported that this ad was on television). See also *supra* note 149.

153. Melody Peterson, *2 Big-Selling Arthritis Drugs Are Questioned*, N.Y. TIMES, June 4, 2002, at C12.

154. *Id.* (The article states that Celebrex and Vioxx, two heavily advertised medicines for arthritis, are over prescribed because they have not been shown to fight pain better than older drugs like ibuprofen and naproxen, which are available in generic and over-the-counter versions for a fraction of the price. It also states that the heavy promotion of these drugs on television and to doctors as well as the misperception that the new drugs are always better may cause the excessive prescribing.).

155. Harris, *supra* note 69, at A1.

A. Escalating Drug Expenditures

Today, more Americans are using prescription drugs. Between 1992 and 1998, the number of prescription drugs sold increased thirty-seven percent¹⁵⁶ and the three billion prescriptions sold in 2000 are expected to rise to four billion by 2004.¹⁵⁷ Americans use an average of ten drug prescriptions per year while Medicare beneficiaries use eighteen.¹⁵⁸ The regular use of prescription drugs has led to spiraling health expenditures. Drug prices rose 306 percent between 1981 and 1999.¹⁵⁹ More recently, prescription drug spending, largely on name brand drugs,¹⁶⁰ has risen fifteen percent or more per year over the past several years.¹⁶¹ The rising cost is shouldered by health care insurers and providers and increasingly by seniors and uninsured individuals. Most employer-sponsored health care plans cover prescription drugs; however, if no generic drug exists for a prescription, some patients may still pay a large portion of the drug out-of-pocket once reaching their annual deductibles. Medicare does not provide any outpatient prescription drug coverage. For those who are not Medicaid eligible,¹⁶² or cannot obtain health insurance through their employer, paying out-of-pocket for ten to eighteen prescriptions per person per year can be costly.¹⁶³ Therefore, high brand name drug prices and the inability to access cheaper drug equivalents impacts consumers and drives the public demand for controlling the cost of what has become a vital part of modern medicine.

156. Celia Wexler, *How Brand-Name Drug Companies Prevailed Over Consumers in Washington*, A Report from the Common Cause Education Fund, Common Cause, at 16, available at <http://rxpolicy.com/studies/ccausephrma0601.pdf> (June 2001).

157. Dana A. Elfin, *Pharmaceuticals: Drug Cost Debate Continues, But Drug Industry Eschews Price Controls*, Bureau of National Affairs, Vol. 8, No. 19, 749 (May 8, 2000) [hereinafter Elfin, *Pharmaceuticals*].

158. *The Profit in Pills: A Primer on Prescription Drug Prices*, Alliance for Retired Americans, 13 http://www.retiredamericans.org/news_theprofitinpills.htm (May 2001) [hereinafter *Profit in Pills*]. Medicare beneficiaries are sixty-five and older or are disabled. See generally Senate Finance Subcommittee on Health Hearing on Reimbursement and Access to Prescription Drugs Under Medicare Part B, Mar. 14, 2002, available at <http://finance.senate.gov/sitepages/hearing031402.htm> (discusses Medicare and prescription drug coverage).

159. Elfin, *Pharmaceuticals*, *supra* note 157, at 749.

160. See Nat'l Inst. for Health Care Mgmt., *Prescription Drug Expenditures in 2001* 6-7 (May 2002), available at <http://www.nihcm.org> (The average price for a prescription rose ten percent from \$45.27 in 2000 to \$49.84 in 2001, but the average price for the fifty best-selling drugs in 2001 was \$71.56. Only five generic drugs were in this group. The fifty top selling drugs also accounted for 44.4 percent of total outpatient retail drug sales in 2001 and sales of these drugs grew 21.4 percent in the same year.).

161. Katharine Levit et al., *Inflation Spurs Health Spending in 2002*, HEALTH AFFAIRS, Vol. 21, No. 1, 172-81 (Jan./Feb. 2002). See also Nat'l Inst. for Health Care Mgmt., *Changing Patterns of Pharmaceutical Innovation* 3 (May 28, 2002), available at <http://www.nihcm.org> (explaining that drug spending rose from \$64.7 billion in 1995 to \$132 billion in 2000); Nat'l Inst. for Health Care Mgmt., *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* 363 (March 29, 2002), available at <http://www.nihcm.org> (listing factors contributing to the recent growth in drug expenditures).

162. Medicaid eligibility is based on income level as a percentage of poverty and varies from state to state.

163. See generally *Profit in Pills*, *supra* note 158.

B. Pharmaceutical Revenues and Expenditures

Despite the Hatch-Waxman goal of spurring innovation, brand name pharmaceutical companies currently spend more on marketing than on research and development. Although developing a drug takes eleven to twelve years and costs about \$200 million per successful product,¹⁶⁴ the most popular blockbuster drugs garner tremendous profits for brand name companies.¹⁶⁵ However, these companies dedicate just twelve percent of their revenues to research and development, compared to thirty percent to marketing and administration.¹⁶⁶ Moreover, the twelve drug companies with the highest revenues spent three times as much on marketing as on research and development in 2000.¹⁶⁷ In addition, over the past five election cycles, PhRMA and its members spent approximately \$360 million on political contributions, lobbying, and advertising campaigns.¹⁶⁸

While marketing is key to selling products, the disproportionate spending on this activity in conjunction with efforts to list improper patents, file unmeritorious patent infringement suits to trigger the thirty-month stay on generic competition, and establish agreements to pay generic companies not to compete raises important questions about the current drug approval process. Pioneer drug firms are not investing in innovation close to the extent promoted by Hatch-Waxman. Instead, they spend millions of dollars on advertising and promotional campaigns of successor drugs to ensure high profits and choke off access to cheaper generics. Consumers frustrated with the inaccessibility of low cost drugs are among the toughest, most vocal critics of pioneer drug firms today. In recent years, consumers have created advocacy groups to lobby for better access to prescription drugs, scrutinize the pharmaceutical industry, and to file lawsuits against the drug industry.¹⁶⁹ Congress, the FTC, and both previous and current White House

164. CBO, *Increased Competition*, *supra* note 21, at Chap. 3, 3.

165. *The Profit in Pills: A Primer on Prescription Drug Prices*, Alliance for Retired Americans (May 2001), available at http://www.retiredamericans.org/news_theprofitinpills.htm (providing that in 2000, pharmaceutical companies had after-tax median profits of 18.6 percent, compared with five percent for all other Fortune 500 companies combined).

166. *Id.*

167. *Id.*

168. *Id.* at 4.

169. Some of the leading advocacy groups pushing for legislation to lower the cost of drugs and leading the class action lawsuits against pioneer drug companies for thwarting competition from generics include: Prescription Action Litigation ("PAL") Project, which was created April 2001, available at <http://www.prescriptionaccesslitigation.org>; Stop Patient Abuse Now, which was created in February 2000, available at <http://www.spancoalition.org>; Alliance for Retired Americans, which was created in January 2001; and the AARP, which on May 29, 2002 joined three lawsuits initiated by PAL against Bristol-Myers Squibb, Schering-Plough and AstraZeneca. See generally Denise Gellene, *Pharmaceuticals Targeted for Class-Action Suits*, L.A. TIMES, June 10, 2001, at A1; Robert Pear, *AARP Joins Three Lawsuits Against Large Drug Companies*, N.Y. TIMES, May 30, 2002, at A17.

administrations have all joined in this critique, suggesting the opportunity for meaningful reform of the Hatch-Waxman imbalance may exist.¹⁷⁰

VII. CONGRESSIONAL REFORM OF HATCH-WAXMAN

In order to restore balance to the drug approval process, the Hatch-Waxman reforms must include setting higher standards for patent infringement suits, eliminating the automatic thirty-month stay on generic competition, discouraging excessive DTC advertising, providing more information to patients and doctors on new brand name drugs, and ending the aggressive marketing tactics that induce doctors to provide name brand drugs instead of cheaper generic drugs. Two legislative proposals would implement some of these recommendations.

The Greater Access to Affordable Pharmaceuticals Act would block brand name drug manufacturers from withholding cheaper, generic equivalents from consumers.¹⁷¹ It would allow a generic drug to be considered a bioequivalent to a listed drug if the effects of such drug and the listed drug do not show a significant difference.¹⁷² It also would alter the ANDA procedures by allowing a settlement, and not just a court decree, to end the thirty-month delay imposed on generic drug companies.¹⁷³ Moreover, it would require the FDA to approve an ANDA forty-five days after the forty-five day notice period even if the brand name company files a lawsuit, unless the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides its patent validity.¹⁷⁴ Finally, the bill would permit a patent holder to obtain a declaratory judgment as to whether the patent that claims the listed drug or a method of using the drug is valid or will be infringed.¹⁷⁵

This legislation would discourage pioneer drug firms from filing infringement lawsuits every time an ANDA is filed by expanding the means to end the thirty-month stay on generic competition to include settlements

170. Elfin, *Pharmaceuticals*, *supra* note 157, at 749. See also Harris, *supra* note 69, at A1.

171. H.R. 1862, 107th Cong. (2001). The House Committee of Jurisdiction has not held hearings to examine this bill, but a companion bill, S. 812, 107th Cong. (2001), was reviewed in a Senate Committee on Health, Education, Labor, and Pensions hearing, "Closing the Gaps in Hatch-Waxman: Assuring Greater Access to Affordable Pharmaceuticals," which occurred on May 8, 2002. Testimonies are available at <http://labor.senate.gov/Hearings-2002/may2002/050802pwit/050802pwit.htm>. See Adams, *supra* note 52, at A24. Chairman of the House Energy and Commerce Committee, W.J. Tauzin does not support reopening the Hatch-Waxman Act and Chairman of the Senate Health, Education, Labor and Pensions Committee has not made this a priority issue.

172. H.R. 1862.

173. *Id.*

174. *Id.*

175. *Id.*

and mandating ANDA approval within forty-five days after the forty-five day notice to the brand name drug competitor unless a court intervenes with a preliminary injunction. However, allowing settlements to end the thirty-month stay may still permit the anticompetitive agreements about which the FTC is concerned because brand name and generic drug companies could carry on a lawsuit for years, then settle with an agreement that the brand name company reimburse the generic company for the time lost in the market. Moreover, even with the approximately ninety day ANDA approval (at the earliest), the cost of losing an infringement suit is so high that many generic drug companies may still delay marketing and selling their products. This legislation also could be strengthened by requiring a patent holder to obtain a declaratory judgment on whether the infringement claim is valid before it can file an infringement suit against a generic drug company, as opposed to merely permitting this action. This provision would further discourage unmeritorious infringement claims that unnecessarily delay making cheaper generics available to consumers. The Greater Access to Affordable Pharmaceuticals Act would effectively promote the initial Hatch-Waxman goal of making generic drugs more accessible to consumers.

Another bill that would help restore balance to the current Hatch-Waxman system is the Fair Advertising and Increased Research ("FAIR") Act, which targets excessive direct-to-consumer advertising.¹⁷⁶ This bill would limit the tax deductions that pharmaceutical companies could take for advertising expenses to the amount they deduct for research and development costs.¹⁷⁷ In other words, a drug company would not be able to deduct any amount of money spent on marketing that exceeds the aggregate amount spent on research and development for the taxable year.¹⁷⁸

For example, if a company spends \$110 million on advertising, promoting or marketing FDA approved prescription drugs, but spends only \$100 million on research and development in one year, the company would not be able to deduct \$10 million of advertising expenses in that year. Any savings resulting from this legislation would be credited to the Medicare Trust Fund.¹⁷⁹

176. Fair Advertising and Increased Research Act, S. 2486, 107th Cong. (2001). See 148 CONG. REC. S4065-01 (daily ed. May 8, 2002) (statement of Senator Debbie Stabenow describing the reasoning for the FAIR Act and stating that American taxpayers contribute about \$16 billion a year to pharmaceutical research through the National Institutes of Health and drug companies spend nearly \$16 billion a year on advertising, marketing, and promotion of prescription drugs). No congressional hearings have been held to examine this bill.

177. S. 2486.

178. *Id.*

179. 48 CONG. REC. S4065-01 (daily ed. May 8, 2002) (statement of Senator Debbie Stabenow).

Not only would this legislation discourage excessive DTC advertising, it would also promote the initial Hatch-Waxman goal of spurring innovative research and development of new and improved pharmaceutical products. Rewarding the industry for ending the practice of pouring \$15.7 billion into marketing and promotional campaigns would encourage increased research and development expenditures.¹⁸⁰ While the level of funding subtracted from marketing and added to research and development would be at the company's discretion, this bill would serve as a powerful impetus for shifting these expenditures and restoring the emphasis on innovation to the Hatch-Waxman system.

The final policy recommendation of providing more information to patients and doctors on new brand name drugs is not currently included in congressional proposals. Since the drugs most heavily prescribed by doctors are the very same drugs that are most heavily advertised, an examination of drug advertising practices may lead to increased patient usage of more costly brand name drugs, even when a more affordable generic alternative is available, needs to occur.¹⁸¹ Marketing campaigns directed at doctors also affect drug usage. Drug marketing activities include handing out free drug samples, citing only positive studies on the new drug, making regular visits to physicians to ensure they prescribe brand name drugs, trips, and other lucrative gifts.¹⁸²

Valuable information to counter misleading marketing could be made available to consumers and doctors through educational efforts such as a toll-free hotline number and a media campaign similar to the ones launched to stop teen smoking and drug use. Public service announcements ("PSAs") providing guidelines to consumers and doctors should emphasize the importance of asking questions about the differences between new and older drugs, between generics and name brand drugs, and the possibility of not taking drugs to solve every ailment. The toll-free hotline number could serve as a resource to get these specific questions answered in an objective, easy-to-understand manner. In addition, establishing a system to monitor and crack down on the unnecessary and questionable practice of providing doctors with lucrative gifts, regular visits, constant re-supplies of free samples, and misleading information would alleviate the intense pressure to prescribe brand name drugs over cheaper generic equivalents. These proposals may not end the practice of prescribing the most heavily

180. Nat'l Inst. for Health Care Mgmt., *Prescription Drugs and Mass Media Advertising: 1999-2000*, 5 (Nov. 2001), available at <http://www.nihcm.org>.

181. *Id.*

182. Harris, *supra* note 69, at A1 (describing a typical interaction between a doctor and a Prilosec salesman via computer and in person).

advertised drugs, but it would help inform the public and doctors alike and encourage informed decision-making.

Moreover, a reexamination of the timelines for patent terms, extensions, and market exclusivity periods is also necessary — particularly since when Hatch-Waxman was enacted, these numbers were arbitrarily selected.¹⁸³ Assessing the appropriate time in a non-competitive market necessary to compensate the pioneer drug firms, but not to deter making generic versions available as soon as reasonably possible, is a key first step. In making this assessment and in formulating a comprehensive reform proposal, Congress must address the contemporary factors, such as unprecedented advertising and accelerated prescription drug use that are contributing to the imbalanced system.

VIII. CONCLUSION

The cunning legal tactics of the pioneer drug makers have squashed contemporary, meaningful implementation of Hatch-Waxman and ensured that brand name drugs maintain monopolistic control over the prescription drug market by blocking generic competition. The ANDA process, which was designed to bring generic drugs to the market faster, has been abused by excessive use of questionable new patent listings in the Orange Book and related infringement lawsuits. The invalid patent listings, which do not represent any improvement over the current patented drug, contradict the Hatch-Waxman goal of stimulating innovative research and development. Moreover, the infringement lawsuits often serve no other purpose than to stave off generic competition for thirty months through the automatic stay or through anti-competitive agreements that include payments to generic companies in exchange for no competition.

In addition, the 180-day market exclusivity provision for the first ANDA filer offers a mix of benefits and risks that keep generics from utilizing it. The generic drug company may win in district court after thirty months, but risks losing on appeal 180 days later, thereby facing huge damages for selling its products during the market exclusivity period. The market exclusivity period for brand name drugs can last even longer through the Hatch-Waxman patent extensions as well as the pediatric exclusivity provisions. Combining patent extensions with additional periods of market exclusivity can make the DTC advertising of blockbuster drugs all the more potent because it can dominate the airwaves for even longer, unfettered by generic competition. Effective advertising is producing results for brand

183. Mossinghoff, *supra* note 17, at 2.

name drug makers—the most frequently prescribed medications are the most heavily advertised. Coincidentally, and perhaps consequently, prescription drug use overall has grown exponentially over the past several years, which is precisely why accessibility and innovation remain present-day necessities.

Neither of Hatch-Waxman's goals is being met effectively under the current system, and with growing consumer frustration, public debate, and congressional criticisms of pioneer drug makers, the time is ripe for change.¹⁸⁴ Meaningful reform of Hatch-Waxman involves setting higher standards for patent infringement suits, eliminating the automatic thirty-month stay on generic competition, discouraging excessive DTC advertising, and providing more information to patients and doctors on new brand name drugs. The Greater Access to Affordable Pharmaceuticals Act and FAIR would implement many of these recommendations and effectively reform the system for drug approval and marketing of new drugs. Adding a provision to educate the public and doctors alike through informative television PSAs and print advertisements in physician publications and to end the aggressive sales tactics that induce doctors to provide name brand drugs instead of cheaper generic drugs would strengthen this reform.

In the next five years, the patents of several major prescription drugs, including Claritin, Prilosec, and Glucophage, will expire.¹⁸⁵ This may seem to ensure significant savings to consumers who have used these drugs on a regular basis, but if the current system is not reformed, brand name manufacturers will continue to replace these expiring drugs with new, successor drugs that contain little improvements but enticing DTC advertisements. By continuing to file patents based on slightly altered formulas, dosages or manufacturing processes, backed by a persuasive advertising blitz and constant infringement lawsuits, pioneer drug makers will continue to persuade consumers and physicians that the new drugs are improved and better than generic equivalents. If Congress does nothing to reform the Hatch-Waxman system, the biggest loser is the American public and the entire health care system. Both innovation and accessibility will continue to be stymied by profit-based decision-making by the pharmaceutical industry.

184. Elfin, *Pharmaceuticals*, *supra* note 157, at 749. See N.Y. TIMES, *Gaming the Drug Patent System*, June 10, 2002, at A24.

185. Taren Grom, *Generics Best Years to Come*, MED. AD NEWS, Oct. 1, 1999, at 7; Jerry Hirsch, *Patent Fight Delays Cheaper Drug*, L.A. TIMES, Sept. 6, 2000, at A1.