

PRESCRIPTIONS FOR CHANGE: THE HATCH-WAXMAN ACT AND NEW LEGISLATION TO INCREASE THE AVAILABILITY OF GENERIC DRUGS TO CONSUMERS*

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INTRODUCTION

In 1984, Congress attempted to delicately balance the interests of innovator pharmaceutical companies (“innovators”) and generic drug manufacturers (“generics”) by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act.¹ Congress guaranteed innovators seventeen-year patent terms to encourage the research and development of valuable new drugs.² This aspect of the law may appear to delay generic competition on its face. Congress, however, eased the regulatory burden on generics by eliminating the need to repeat costly clinical trials to prove the effectiveness of generic drugs.³ Instead, the law enabled generics to establish the bioequivalence of generic drugs with brand drugs.⁴ As a result, generics are able to make lower-costing generic copies of brand drugs more widely available to consumers faster than if they were required to conduct clinical trials.

On the surface, the Hatch-Waxman Act appears to have accomplished this balance. Innovators increased their research and development (“R&D”) spending from \$3.6 billion in 1984 to over \$30 billion in 2001.⁵ They also developed more

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1. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

2. *See id.*

3. *See id.*

4. *See id.* Bioequivalence refers to the rate and extent that the body absorbs the active ingredients in a drug. GOODMAN AND GILMAN’S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 10 (Alfred Goodman Gilman et al. eds., 8th ed. 1990).

5. *Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. (June 13, 2001) [hereinafter *House Energy and Commerce Hearing*] (statement of Rep. Barbara Cubin, Member, House Comm. on Energy and Commerce). *See also* Press Release, Pharmaceutical Research and Manufacturers of America, Pharmaceutical Companies Made 32 New Treatments Available to Patients in 2001 and Invested an Estimated \$30.3 Billion in R&D (January 25, 2002) [hereinafter PhRMA Press Release] at <http://www.phrma.org/mediaroom/press/releases/25.01.2002.329.cfm>.

than 370 life saving medicines in the last ten years as compared to 239 in the previous decade.⁶ The Act has likewise played a pivotal role in spawning the birth of the generic industry. The Congressional Budget Office estimated that thirteen percent of total prescriptions filled in 1980 were for generic drugs.⁷ In contrast, by 1998, generics comprised fifty-eight percent of total prescriptions dispensed.⁸ Moreover, in ranking the top five drug distributors on the basis of prescriptions dispensed, three of the top five were generic companies, namely Watson, Mylan, and Teva.⁹

The balance may have, nonetheless, shifted in recent times because the law has enabled both innovators and generics to abuse the Hatch-Waxman Act. Generics accuse innovators of “patent evergreening” to preserve their monopolies.¹⁰ In addition, generics allege that innovators “game” the system by filing patent applications for peripheral aspects of inventions such as a drug’s color, label, or indication.¹¹ Thus, they contend that innovators block lower cost medications from reaching the public. For instance, generics point to consumers like Florence Rubin to exemplify their arguments. Ms. Rubin spends \$117 per month for the brand drug Prilosec to control a chronic digestive problem.¹² Ms. Rubin says, “It’s so costly. I don’t have a drug plan, and I pay full price.”¹³

To counter these allegations, innovators assert that many generics file frivolous Paragraph IV certifications in hopes of feasting upon the innovators’

6. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Dr. Gregory J. Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America). *See also* PhRMA Press Release, *supra* note 5 (noting that pharmaceutical and biotechnology companies added thirty-two new treatments—twenty-four drugs and eight biologics—in 2001 alone).

7. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Rep. Barbara Cubin, Member, House Comm. on Energy and Commerce).

8. *Id.*

9. *Id.* (statement of Bruce L. Downey, Chairman, Barr Laboratories, Inc., on behalf of the Generic Pharmaceutical Association).

10. *Id.* (statement of Rep. Gene Green, Member, House Comm. on Energy and Commerce). “Patent evergreening” refers to the combination practice of staggering the filings of a number of patent applications and at the same time, applying for patent term extensions. *See, e.g.,* Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD DRUG L.J. 245, 248-49 (1999).

11. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Rep. Gene Green, Member, House Comm. on Energy and Commerce); *see also id.* (statement of Bruce L. Downey, Chairman, Barr Laboratories, Inc., on behalf of the Generic Pharmaceutical Association) (describing Bristol-Myers Squibb’s (BMS) late-minute listing of a new Buspar metabolite patent one day prior to the entry of generic competition and patenting of methods of administration and stabilization for Taxol, a compound that BMS testified before Congress in 1991 was neither patented nor patentable).

12. Glenn Singer, *Drug Companies Battle in the War Over Generics; Patent Holders, Challengers Often Seem to Rely More on Lawyers Than on Scientists*, SUN-SENTINEL, Nov. 18, 2001, at 1H, available at LEXIS, Major Newspapers File.

13. *Id.*

profits.¹⁴ Moreover, innovators also seek to dispel the myth that generics dutifully guard consumers against the high prices set by innovators. To this end, innovators point out that generics are business entities formed to earn profit; they are not non-for-profit institutions designed to protect consumers' pocketbooks. For example, Watson enjoyed 2001 revenues of \$1,160,676,000 (net profit margin ten percent); Mylan's profits soared to \$1,070,100,000 (net profit margin twenty-two percent) that same year; and Barr earned \$959,651,000 in 2001 (net profit margin fifteen percent).¹⁵ Bruce Downey, Chairman and CEO of Barr Laboratories, even commented that "challenging patents protecting select branded products" is among Barr's three key business strategies and that such practice should yield a "steady cash flow with potential for exponential growth."¹⁶

Amidst the battle cries of innovators and generics, the Department of Justice ("DOJ") and Federal Trade Commission ("FTC") have initiated their own "drug war."¹⁷ That is, the FTC is closely scrutinizing settlement agreements made between innovators and generics during the pendency of patent litigation.¹⁸ The agencies are suspicious that such agreements are designed to prevent generic competition.¹⁹ As well, the FTC sent subpoenas to ninety pharmaceutical companies in 2001 to examine whether they improperly delayed the sale of generic drugs.²⁰

Meanwhile, in reaction to both pressure from generics to revamp the ANDA system and the recent Schering-Plough/Upsher Smith Laboratories-ESI Lederle settlement agreement, legislators are directly taking action in the "drug war."

14. In filing an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA), an applicant must certify that the drug for which approval is sought will not infringe any valid, enforceable patent that the holder of the new drug application (NDA) listed with the FDA. See 21 U.S.C. § 355(j)(2)(A)(viii)(I) to (IV) (2000); see also Terry Mahn & Jill B. Deal, *Orange Book Games*, FDLI UPDATE 2001, May-June 2001, at 8, available at http://www.fdl.org/pubs/Update/2001/Issue3/Mahn_Deal/article.html (discussing *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*, in which the district court found that Danbury had "no reasonable basis for challenging the validity of the patent at the time of certification"); see also *Yamanouchi Pharm. v. Danbury Pharmacal, Inc.*, 21 F. Supp. 2d 366 (S.D.N.Y. 1998) and *Eli Lilly and Co. v. Zenith Goldline Pharms, Inc.*, Cause No. IP 99-38-C H/K, 2001 U.S. Dist. LEXIS 25246 (S.D. Ind. Oct. 29, 2001) (both courts concluding that ANDA applicants have a duty of due care when to file Paragraph IV certifications only under an objective good faith belief that the patent is invalid).

15. FACTIVA.COM, at <http://global.factiva.com/en/arch/display.asp> (data current through Feb. 21, 2002).

16. Jayne O'Donnell, *Makers of Generic Drugs Take Some Legal Heat, Too*, USA TODAY, June 6, 2002, at 2, available at <http://www.usatoday.com/usatoday/20020606/4170222s.htm>.

17. Neal R. Stoll & Shepard Goldfein, *War on Drugs: The FTC v. Pharmaceutical Companies*, N.Y. L. J., May 15, 2001.

18. See Lisa Jarvis, *Collusion to Stall Generics is Subject of FTC Probe*, CHEM. MKT. REPORTER, Oct. 23, 2000, at 5, available at 2000 WL 24156402.

19. *Id.*

20. Melody Petersen, *Suits Accuse Drug Makers of Keeping Generics Off Market*, N.Y. TIMES, May 10, 2001, at C1, available at <http://www.nytimes.com>.

They introduced bills before both the 107th and 108th Congresses to reform the Hatch-Waxman system. Senators John McCain and Charles Schumer are sponsoring a version of the Greater Access to Affordable Pharmaceuticals Act²¹ ("GAAP"), which is aimed at amending the Federal Food, Drug, and Cosmetic Act to provide consumers with greater access to affordable pharmaceuticals.²² Senators McCain, Schumer, Ted Kennedy, and Judd Gregg have also introduced a second version of the GAAP with slightly different provisions.²³ In addition, Senator Patrick Leahy and Representative Henry Waxman backed the Drug Competition Act ("DCA")²⁴ to "expose" deals and subject them to immediate investigation and action by the FTC or DOJ for antitrust violations.²⁵ Given that products with collective annual sales of more than \$37 billion have lost or are due to lose patent protection between 2002 and 2005,²⁶ the proposed legislation

21. S. 54, 108th Cong. (2003). This bill was originally introduced to the 107th Congress as S. 812 where it passed in the Senate in July 2002. Vote Report; Greater Access to Affordable Pharmaceuticals Act of 2001, *available at* LEXIS, Legislative Politics File. Senators McCain and Schumer reintroduced it on January 7, 2003, to the 108th Congress. Press Release, Sen. Charles Schumer, Schumer, McCain Renew Generic Drug Efforts (Jan. 7, 2003), *at* <http://schumer.state.gov>.

22. *Id.*

23. Joanne Kenen, Key Senators Agree on Generic Drug Bill, (June 4, 2003), *available at* <http://www.forbes.com/newswire/2003/06/04/rtr991184.html>.

24. S. 754 & H.R. 1530, 107th Cong. (2001).

25. Leahy, Waxman Introduce Bills Targeting Sweetheart Deals That Delay Low-Cost Generic Drugs, U.S. NEWSWIRE, April 26, 2001, *available at* LEXIS, News File [hereinafter *Sweetheart Deals*].

26. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Bruce L. Downey, Chairman, Barr Laboratories, Inc., on behalf of the Generic Pharmaceutical Association); *see also* Eli Lilly & Company, *A Big Picture Perspective*, FOCUS MAGAZINE, Special Issue 2002, at 6 (on file with author).

Table 1: Major United States Patent Expirations

Year	Brand Name	Marketer	2001 worldwide sales (\$ millions)
2002	Claritin	Schering-Plough	3,159
	Augmetin	GlaxoSmithKline	2,046
	Intron A	Schering-Plough	1,447
2003	Cipro	Bayer	1,758
	Singulair	Merck & Co.	1,375
	Flovent	GlaxoSmithKline	1,317
2004	Lovenox	Aventis Pharmaceuticals	1,301
	Diflucan	Pfizer	1,066
2005	Zocor	Merck & Co.	6,670
	Prevacid	Tap Pharmaceuticals	2,951
	Zoloft	Pfizer	2,366
	Pravachol	Bristol-Myers Squibb	2,173
	Zithromax	Pfizer	1,506
	Biaxin	Abbott Laboratories	1,159

is timely and will offer a forum to formally address the intense Hatch-Waxman concerns of all players in the pharmaceutical industry.

Therefore, as change lurks in world of Hatch-Waxman, Section I of this Note explains the history of the Hatch-Waxman Act with particular focus on the original intent of the law. The reader must understand how the law was formed to fully appreciate the provisions of the GAAP and the DCA. Also, from this section, the reader will gain an awareness of the compromises made by innovators and generics and why even the slightest tip of the balance in favor of one side over the other causes vehement reaction.

Section II delves into aspects of antitrust law to explain why settlement agreements between innovators and generics potentially violate antitrust laws. Section III then highlights recent innovator-generic settlement agreements to elucidate these antitrust concerns. These two sections particularly show the egregious nature of settlements and their harsh impact on consumers.

Section IV explores key provisions of the GAAP and the DCA, and Section V evaluates whether these bills will return the state of the law to meet the intent of the Hatch-Waxman Act. This Note argues that the GAAP will suffocate not only innovators, but ultimately generics who will be unable to survive when innovators are forced to downsize. With this potential effect, this Note contends that the GAAP is a poison to the pharmaceutical industry. In contrast, this Note advocates that the DCA is exactly one of the supplements that the pharmaceutical industry needs to maintain good health. The DCA assures consumers that innovators and generics will not collude to fatten their profits margins at the expense of seniors, disabled persons, and the uninsured. Finally, this Note maintains that the true solution to accomplish greater access to affordable pharmaceuticals lies in the passage of a Medicare prescription drug benefit.

I. HISTORY AND APPLICATION OF THE HATCH-WAXMAN ACT

The 1962 Amendment of the Federal Food, Drug, and Cosmetic Act²⁷ required both innovators and generics to establish the safety and effectiveness of their drug products via human clinical trials prior to Food and Drug Administration approval.²⁸ The Amendment forbid a generic from merely relying on the testing performed by an innovator because trade secret laws protected the innovator's trial results.²⁹ Consequently, a generic would be forced to repeat extensive clinical trials, and these trials could not begin until the innovator's patents covering the drug expired.³⁰ To proceed otherwise, the generic risked

27. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.).

28. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 396-97 (1999); see also U.S. FOOD AND DRUG ADMINISTRATION, THE EVOLUTION OF U.S. DRUG LAW, at <http://www.fda.gov/fdac/special/newdrug/benlaw.html> (last visited Jan. 27, 2003).

29. Joseph P. Reid, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 314 (1999).

30. *Id.*

being sued by the innovator for patent infringement.³¹

A generic could, however, offer published data concerning the safety and efficacy of a previously approved drug to demonstrate that its product was safe and effective.³² Such data were not available for all drugs though.³³ Moreover, the Amendment did not prevent the FDA from requesting additional clinical studies to address adverse reactions or other data published after initial approval of the innovator's drug.³⁴ Thus, the 1962 Amendment essentially limited the number of generic drugs on the market and prolonged the time necessary to obtain approval for a new generic.

The generic industry received consolation for the 1962 Amendment with the *Roche Products, Inc. v. Bolar Pharmaceutical Co.* district court decision.³⁵ In efforts to prepare an NDA, Bolar Pharmaceutical Co. manufactured and tested a generic version of Roche Products, Inc.'s patented prescription sleeping pill Dalmare.³⁶ Roche filed a patent infringement action against Bolar, alleging that Bolar initiated clinical trials before the expiration of the Dalmare patent. In response, Bolar asserted that the manufacture and testing was permissible under the law because it was for the purposes of obtaining FDA approval. The district court agreed with Bolar and permitted the experimentation before Roche's patent expired.³⁷

In light of the tensions in the pharmaceutical industry, the stage was set for legislation to expedite generic drug approvals and to stimulate competition between innovators and generics. Both houses of the 97th Congress (1980-82) introduced bills³⁸ to provide patent-term extensions of up to seven years to compensate innovators for lost marketing time caused by governmental delays in assessing the safety and efficacy of drugs.³⁹ This legislation, however, lacked any provision to counter the *Roche v. Bolar* decision and thus allowed generics to engage in drug development prior to expiration of an innovator's patent without the risk of an infringement action.⁴⁰ Nevertheless, it failed to streamline the drug approval process for generics.⁴¹ Despite 250 votes in favor of passage, this legislation did not earn the required two-thirds majority.⁴²

During the 98th Congress (1983-1985), Representative Henry Waxman and members of the innovator and generic drug industries, namely the Pharmaceutical Manufacturers Association ("PMA") now known as the Pharmaceutical Research and Manufacturers Association ("PhRMA") and the Generic Pharmaceutical

31. *Id.*

32. Engelberg, *supra* note 28, at 397.

33. *Id.*

34. *Id.*

35. 572 F. Supp. 255 (E.D.N.Y. 1983).

36. *Id.* at 256.

37. *Id.* at 258.

38. Patent Term Restoration Act, S. 255 and H.R. 1937, 97th Cong. (1980-82).

39. Engelberg, *supra* note 28, at 397.

40. *Id.* at 398.

41. *Id.*

42. *Id.* (noting that Reps. Henry Waxman and Albert Gore, Jr. cast the critical "no" votes).

Industry Association (“GPIA”), began negotiations to reach a compromise.⁴³ Senator Orrin Hatch later joined Representative Waxman in these negotiations and championed the proposed legislation in the Senate.⁴⁴ Hatch-Waxman legislation “was predicated on the desire to enhance the growth of the generic drug industry, while simultaneously extending patent protection for brand-name drugs developed by the research-based industry.”⁴⁵ Accordingly, representatives from PMA and GPIA thrashed out provisions to benefit their respective interests. The initial draft provided for an expedited generic drug approval process, codified the *Roche v. Bolar* decision, and amended patent law to provide for patent term extensions.⁴⁶ PMA was especially concerned with a streamlined drug approval process because most generics were quite small and could not afford to pay damages if they were found guilty of infringement.⁴⁷ Nevertheless, the catalyst that triggered the ultimate rift occurred when the Court of Appeals for the Federal Circuit (“Federal Circuit”) reversed the district court’s decision in *Roche v. Bolar* in mid-1984.⁴⁸ The Federal Circuit held that Bolar’s actions were not limited to scientific inquiry, but instead extended the experimentation for business reasons and thereby infringed Roche’s patent.⁴⁹ In response to this ruling, several large pharmaceutical members, including Merck, Johnson & Johnson, Hoffman LaRoche, and American Home Products, balked at the initial draft because it contained an experimental use exception.⁵⁰

Senator Hatch returned to the bargaining table and resumed arbitration between PMA and GPIA in the summer of 1984.⁵¹ Ultimately, the compromise left the Bolar exemption intact, but several new provisions were added to compensate innovators. The Senate and House approved S. 2748 and H.R. 3605, respectively, in September 1984.⁵² President Ronald Reagan signed the Hatch-Waxman Act into law on September 24, 1984.⁵³

Title I of the Act, codified as Title 21 of the United States Code,⁵⁴ favored the interests of generics by authorizing a novel mechanism for rapid generic FDA approval, namely the ANDA.⁵⁵ It also limited the scope of data that the FDA required in ANDAs to only bioavailability results.⁵⁶ ANDA applicants were no longer required to repeat the expensive and lengthy clinical trials previously

43. *Id.* at 398-99.

44. *Id.* at 401.

45. *Bill To Ease Way for Generics Is Introduced in the House*, CHAIN DRUG REV., June 4, 2001, at RX11, available at LEXIS, News File.

46. Engelberg, *supra* note 28, at 401.

47. *Id.* at 399.

48. *Roche Prod. v. Bolar Pharm.*, 733 F.2d 858, 867 (Fed. Cir. 1984).

49. *Id.* at 863.

50. Engelberg, *supra* note 28, at 404.

51. *Id.* at 405.

52. *Id.* at 407.

53. *Id.*

54. See H.R. REP. NO. 857 (Part I), 98th Cong., 2nd Sess. at 14 (1984).

55. See 21 U.S.C. § 355(j)(4)(f) (2000).

56. See *id.* § 355(j)(4)(f).

mandated by federal law.⁵⁷ In addition, the law required an ANDA applicant to show that its product had the same active ingredient, route of administration, dosage form, strength, and labeling requirements as the brand drug approved in a New Drug Application (NDA).⁵⁸

In turn, the holder of an approved NDA must inform the FDA, under 21 U.S.C. § 355, of any patent that could reasonably be asserted to cover the drug in question.⁵⁹ Specifically, the holder must “list” the patent number and expiration date of any patent claiming the drug or a method of using the drug and upon which the NDA holder could file a claim of patent infringement if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.⁶⁰ Process patents were not covered under 21 U.S.C. § 355, and therefore, information about them does not have to be submitted. The FDA is required to then publish the submitted patent information in a document called “Approved Drug Products with Therapeutic Equivalence Evaluations,” more commonly known as the Orange Book.⁶¹ The FDA will not review the patents submitted by the NDA holder or assess whether the claims in these patents cover the approved drug.⁶² In addition, the FDA will not determine if a claim for patent infringement could reasonably be asserted against the unauthorized use of the patented drug.⁶³ “The FDA has determined that Congress intended the filing requirement to provide notice to potential NDA or ANDA applicants of patents that may protect the pioneer drug product.”⁶⁴

In order to secure FDA approval in light of these listings, the ANDA applicant must then certify to the FDA, pursuant to 21 U.S.C. § 355, that their generic version of the approved drug will not interfere with any patents that the NDA holder was required to “list.”⁶⁵ That is, the ANDA applicant must certify one of the following: (i) that such patent information has not been filed; (ii) that such patent has expired; (iii) the date such patent will expire; or (iv) that such patent is invalid or will not be infringed by the generic product.⁶⁶ These options are designated as Paragraph I, II, III, or IV certifications, respectively, in the

57. See *id.* § 355(j); see also 21 C.F.R. § 314.94(a)(3) (2000).

58. See 21 U.S.C. §§ 355(j)(2)(A)(iii), (j)(4)(D)(i)-(ii); see also 21 C.F.R. § 314.92(a)(1) (indicating the categories of drug products for which an ANDA may be filed).

59. See 21 U.S.C. § 355.

60. See *id.*; see also 21 C.F.R. § 314.53.

61. See 21 U.S.C. § 355(b)(2) & (j)(7)(A).

62. *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the Senate Comm. on the Judiciary*, 107th Cong. (May 24, 2001) [hereinafter *Senate Judiciary Hearing*] (statement of Gary Buehler, Acting Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration).

63. *Id.*

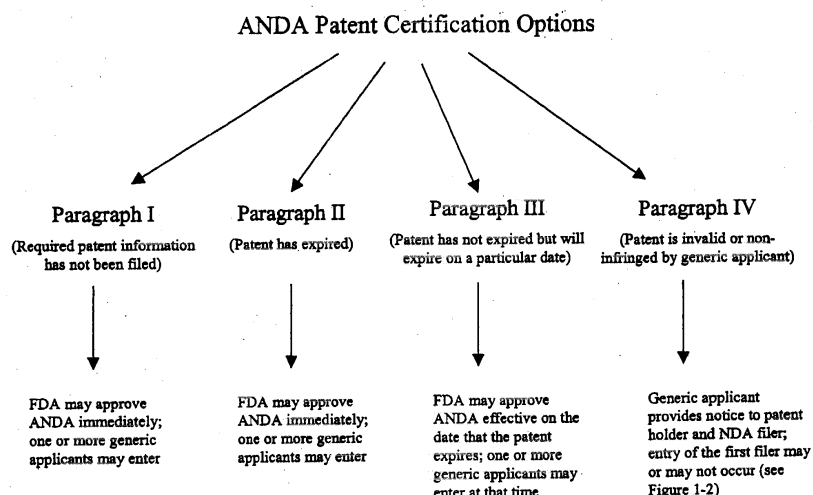
64. Brian D. Coggio & Francis D. Cerrito, *The Application of the Patent Laws to the Drug Approval Process*, ANDREWS PHARMACEUTICAL LITIGATION REPORTER, Aug. 1997, available at WESTLAW, News File.

65. See 21 U.S.C. § 355(j)(2)(vii); see also 21 C.F.R. § 314.94(a)(12).

66. See 21 U.S.C. 355(j)(2)(A)(vii)(I) to (IV).

Hatch-Waxman system. They are depicted graphically in Figure 1-1 below.⁶⁷

Figure 1-1 ANDA Patent Certifications



With a Paragraph I or II certification, the FDA may grant approval as soon as it is satisfied that the product is safe and effective.⁶⁸ Under a Paragraph III certification, the FDA may grant approval as soon as the patent on the innovator's drug expires.⁶⁹ Paragraph IV certifications present a more unique situation. The timing for FDA approval depends on the actions taken by both the NDA holder and patent holder in response to a Paragraph IV certification notice.

Filing an ANDA with a Paragraph IV certification is a "technical" or "artificial" act of infringement under 35 U.S.C. § 271 and gives rise to a case or controversy under patent laws.⁷⁰ Consequently, the ANDA applicant must explain why a generic version of the approved drug would not infringe the patent covering the approved drug or why such patent is invalid.⁷¹ In response, the patent holder has the option of filing a patent infringement action within forty-five days after receiving such notice.⁷² If the patent holder fails to bring suit, then the FDA may approve the ANDA. On the other hand, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either thirty months or until a court rules that the patent is invalid or not

67. Federal Trade Commission, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 6* (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter *FTC STUDY*].

68. See 35 U.S.C. § 271(j)(5)(B)(i) (2000).

69. See *id.* § 271(j)(5)(B)(ii).

70. See *id.* § 271(e)(2).

71. See *id.* § 271(j)(2)(B)(i); see also 21 C.F.R. § 314.95 (2000).

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

infringed, whichever occurs first.⁷³ The drafters allotted thirty months for the stay period in order to allow ample time for the ANDA approval process and any litigation.⁷⁴ Thus, the purpose of a Paragraph IV certification was to ensure adjudication of the rights of a patent holder before any economically damaging competition.⁷⁵

Incentive to file an ANDA or engage in a patent infringement suit exists because the first filer is awarded a 180-day period of market exclusivity beginning either from the date the generic begins commercial marketing of the generic drug product or from the date of a court decision.⁷⁶ “The purpose of the 180-day exclusivity provision was to insure that one generic competitor would not get a free ride on the litigation effort of another generic competitor until the party who . . . [financed] the cost and risk of litigation had a fair opportunity to recover its litigation costs.”⁷⁷ Interestingly, the courts and FDA differ on what qualifies as a “court decision” capable of triggering the 180-day exclusivity period. The courts have held that a “court decision” is any district court ruling that a patent is invalid, unenforceable, or will not be infringed by the generic drug product.⁷⁸ In contrast, the FDA originally interpreted this phrase to mean a ruling from which no appeal was possible to avoid subjecting generics to treble damages in the event that an appellate court ruled in favor of the patent holder.⁷⁹ Today, however, the FDA has adopted the court’s position and acknowledges that the “court decision” trigger is satisfied by a district court decision.⁸⁰ During the 180-day exclusivity period, the FDA cannot approve any subsequently submitted ANDA for the same drug.⁸¹ Therefore, the ANDA applicant who receives the exclusivity will block all generic competition for the innovator.⁸² Figure 1-2 below graphically shows how the thirty-month stay and 180-day exclusivity provisions affect FDA approval of an ANDA.⁸³

73. *See id.*

74. *See Engelberg, supra* note 28, at 422.

75. *See id.* at 414-15.

76. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II).

77. Engelberg, *supra* note 28, at 423.

78. *Senate Judiciary Hearing, supra* note 62 (statement of Gary Buehler, Acting Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration).

79. *Id.*

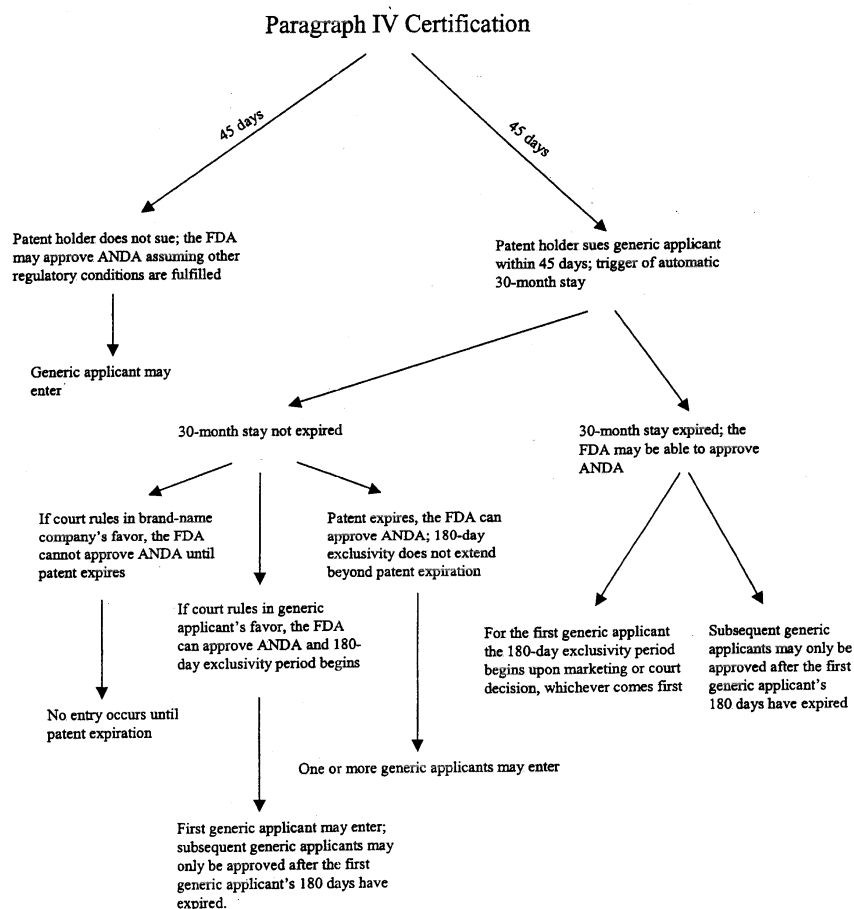
80. *See Mylan Pharm., v. Shalala*, 81 F. Supp. 2d 30, 34 (D.D.C. 2000) (noting that the FDA’s original interpretation of “court decision” was challenged).

81. *See Senate Judiciary Hearing, supra* note 62 (statement of Gary Buehler, Acting Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration).

82. *See id.*

83. FTC STUDY, *supra* note 67, at 8.

Figure 1-2 Paragraph IV Certifications



Title II of the Act, codified as Title 35 of United States Code,⁸⁴ favored the interests of innovators by granting patent term extensions and guaranteeing five-years of data package exclusivity for new chemical entities (NCEs). Particularly, the innovator receives a term extension equal to one-half of the time period from the start of human clinical trials to NDA approval.⁸⁵ The maximum extension period equals five years, and the total marketing exclusivity time cannot exceed fourteen years.⁸⁶

The innovator also receives a data package exclusivity period commencing on the day of NDA approval and continuing for five years thereafter.⁸⁷ A generic may not file an ANDA during this period unless it contains a Paragraph IV

84. See H.R. Rep. No. 857 (Part I), 98th Cong., 2nd Sess. at 15 (1984).

85. See 35 U.S.C. § 156 (2002).

86. See *id.*

87. See *id.*

certification.⁸⁸ With such certification, the ANDA may be filed after four years from the date of NDA approval.⁸⁹

Beyond question, the five-year non-patent exclusivity . . . was key to the compromise. This provision assured innovators of a reasonable opportunity to recoup development costs and to make profit irrespective of the existence of patents. It did not deprive generic manufacturers of any important economic right since there is no real incentive to develop a generic drug until a market has been established and any post-approval issues of safety and efficacy have been resolved by broad use in the general population.⁹⁰

II. ANTITRUST CONCERNS

A. General Principles

Similar to the balance struck in Hatch-Waxman system, antitrust law seeks to balance the exclusionary rights needed to fuel innovation with those that strive to maintain competition.⁹¹ Hence, both antitrust law and intellectual property law are predicated on advancing innovation.

[Intellectual property] law, properly understood preserves incentives for . . . innovation. Innovation benefits consumers through the development of new and improved goods and services, and spurs economic growth. Similarly, antitrust law, properly understood, promotes innovation and economic growth by combating restraints on vigorous competitive activity. By deterring anti-competitive arrangements and monopolization, antitrust law also ensures that consumers have access to a wide variety of goods and services at competitive prices.⁹²

Thus, the DOJ and FTC issued “Antitrust Guidelines for the Licensing of Intellectual Property” (“Guidelines”) in 1995 to provide standards for assessing whether a business practice is anti-competitive.⁹³ These Guidelines focus on whether there would have been competition in the marketplace absent an agreement between the competitors not to compete with each other. They fail,

88. *See id.*

89. *See id.*

90. Engelberg, *supra* note 28, at 406.

91. Sheila F. Anthony, Riddles and Lessons for the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Address at the ABA “Antitrust and Intellectual Property: The Crossroads” Program (June 1, 2000), at <http://www.ftc.gov/speeches/anthony/sfip000601.htm>.

92. Press Release, Federal Trade Commission, Muris Announces Plans for Intellectual Property Hearings (Nov. 15, 2001), at <http://www.ftc.gov/opa/2001/11/iprelease.htm>.

93. *See* U.S. Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, at <http://www.usdoj.gov/atr/public/guidelines/guidelin.htm> (last visited Jan. 27, 2003) [hereinafter Antitrust Guidelines].

however, to address the particular anti-competitive nature of patent settlements in the context of Paragraph IV Hatch-Waxman litigation.

The Guidelines embody three central tenets. First, the DOJ and FTC apply the same general antitrust principles to intellectual property as they apply to conduct involving any form of tangible or intangible property.⁹⁴ Intellectual property is not accorded a status either completely free from scrutiny or completely susceptible to it.⁹⁵ The Agencies thus scrutinize conduct involving intellectual property to the same degree as conduct involving any form of private property.⁹⁶

Second, the Agencies do not presume that intellectual property creates market power, despite the fact that a patent confers the right to exclude others with respect to a specific patentable invention.⁹⁷ Rather, they recognize that market power resulting solely from a superior product, business acumen, or historic accident does not violate antitrust laws.⁹⁸ Nonetheless, the Agencies do acknowledge that if market power was acquired or maintained illegally, then a property owner could adversely harm competition.⁹⁹

Third, the FTC and DOJ generally consider intellectual property to be procompetitive.¹⁰⁰ They are aware that licensing, cross licensing, or otherwise transferring intellectual property may benefit consumers and introduce new products.¹⁰¹ Nevertheless, when a licensing arrangement creates a horizontal relationship¹⁰² in a relevant market to restrain trade, the Agencies grow concerned about the anti-competitive potential of such agreements.¹⁰³ They recognize that the existence of a horizontal relationship does not, in itself, indicate that the relationship is anti-competitive, but they use this relationship type merely to aid in determining whether the agreement has anti-competitive effects.¹⁰⁴

94. *Id.* § 2.1.

95. *Id.*

96. *Id.*

97. *Id.* § 2.2.

98. *Id.*

99. *Id.*

100. *Id.* § 2.3.

101. *Id.* The text provides an example of a synergistic license: the patent owner of a machine and the patent owner of the process for using the machine, each blocking the other's use of the invention, may form a cross-license to develop new technology which would not have occurred but for the cross-license.

102. *Id.* § 3.3. The FTC and DOJ treat the relationship between two parties, such as between a licensor and licensee or between two licensees, as "horizontal" when the parties would have been actual or likely competitors in a relevant market in the absence of an agreement.

103. *Id.* § 3.1.

104. Federal Trade Commission, *An Antitrust Primer*, at <http://www.ftc.gov/bc/compguide/antitrst.htm>. (last visited Jan. 27, 2003).

B. Rule of Reason

Using these tenets as a source of direction, the DOJ and FTC typically use either a “rule of reason” or an unlawful “per se” analysis scheme.¹⁰⁵ To determine which scheme is appropriate, the DOJ and FTC ask whether the restrictive provision found in the agreement aids an efficiency-enhancing integration of economic activity.¹⁰⁶ If there is no efficiency-enhancing integration and if the agreement is one that has been accorded per se treatment by the Agencies previously, then the Agencies will challenge the agreement as unlawful per se.¹⁰⁷ Under per se treatment, they do not inquire into the likely competitive effect of the agreements.¹⁰⁸

Otherwise, the Agencies utilize the rule of reason analysis scheme, which is a multi-step evaluation.¹⁰⁹ Initially, the DOJ and FTC ask whether the agreement is likely to adversely affect competition in the relevant market and investigate market conditions.¹¹⁰ If they determine that the agreement has no anti-competitive effects in the market, then they will treat it as reasonable and end their analysis.¹¹¹ Alternatively, finding a possible anti-competitive effect, the Agencies inquire whether such anti-competitive effect is reasonably necessary to achieve pro-competitive benefits or efficiencies. Essentially, the answer to this inquiry depends on whether the balance tips in favor of the pro-competitive benefits or efficiencies.¹¹² The DOJ and FTC further examine whether the agreement appears to always, or almost always, reduce output or increase prices, and at the same time whether the reduction or increase, respectively, is unrelated to the pro-competitive benefits/efficiencies.¹¹³ If this is the situation, then the Agencies will bring a challenge and not consider industry circumstances surrounding the formation of the agreement.¹¹⁴

C. Section 5 of the Federal Trade Commission Act

Once agreements are found to be of an anti-competitive nature, the Commission may bring specific charges based on the Federal Trade Commission Act (“FTC Act”). Section 5 of this Act provides that “unfair methods of competition . . . and unfair or deceptive acts or practices . . . are hereby declared unlawful.”¹¹⁵ A violation of the Act is enforced through administrative

105. Antitrust Guidelines, *supra* note 93, at § 3.4.

106. *Id.*

107. *Id.*

108. *Id.* Among those restraints held “per se” unlawful are: 1) naked price fixing; 2) agreements to restrict output or maintain minimum resale price; and 3) market divisions among horizontal competitors.

109. *Id.*

110. *Id.* §§ 4.1-4.3.

111. *Id.* § 3.4.

112. *Id.*

113. *Id.*

114. *Id.*

115. 15 U.S.C. § 45(a) (2002).

proceedings before the FTC.¹¹⁶ If the Agency determines that the Act has been violated, it issues a “cease and desist” order.¹¹⁷ These orders are subject to federal judicial review.¹¹⁸

Traditionally, the Sherman and Clayton Antitrust Acts are thought to embody antitrust law. Both are felony statutes that bring criminal penalties of up to three years imprisonment and several million dollars in corporate fines.¹¹⁹ In contrast, the FTC Act is a civil statute. As well, unlike the Sherman and Clayton Acts, the FTC Act does not give rise to private actions or to treble damages.¹²⁰ Because of key differences between these statutes, the FTC Act is more workable in testing new extensions of established antitrust law such as innovator-generic settlement agreements.

The concept of unfair methods of competition encompasses four broad categories of anti-competitive behavior, and categories that violate the Sherman or Clayton Antitrust Acts also violate the FTC Act.¹²¹ Prohibited practices include: 1) horizontal price fixing; 2) vertical price fixing; 3) horizontal market allocations; 4) commercially-motivated boycotts; 5) exclusive dealing; 6) monopolization; 7) attempted monopolization; and 8) conspiracies to monopolize.¹²² Section 5 also covers actions that are not literal “letter” violations of either the Sherman Act or Clayton Act, but instead are considered “incipient” antitrust violations.¹²³

Furthermore, Section 5 includes practices that violate the policies behind the Sherman and Clayton Acts. Although Section 5 “was intended by Congress to ‘fill in the gaps in the other antitrust laws, to round them out and make their coverage complete,’”¹²⁴ this policy rationale is typically applied as an alternative or supplement to outright antitrust violations.¹²⁵ Finally, Section 5 reaches actions deemed inherently unfair.¹²⁶ This category offers the FTC broad discretion in determining what practices constitute unfair methods of competition. Therefore, Congress explicitly stated that the FTC has no authority

116. WILLIAM C. HOLMES, INTELLECTUAL PROPERTY AND ANTITRUST LAW § 10.01 (2001).

117. *Id.*

118. *Id.*

119. 15 U.S.C. §§ 1-2 (2002).

120. HOLMES, *supra* note 116, § 10.01.

121. *Id.*

122. *Id.* § 10.02.

123. *Id.* § 10.03. *See* FTC v. Brown Shoe Co., Inc., 384 U.S. 316 (1966) (noting that this Supreme Court decision gave birth to the incipency doctrine); *see also* Boise Cascade Corp v. FTC, 637 F.2d 573 (9th Cir. 1980) (noting that both the court and FTC impose a restriction application on the use of the incipency doctrine).

124. HOLMES, *supra* note 116, § 10.04 (quoting Neil W. Averitt, *The Meaning of “Unfair Methods of Competition” in Section 5 of the Federal Trade Commission Act*, 21 B.C.L. REV. 227, 251 (1980)).

125. *Id.* (noting that Section 5 historically was used to strike down practices proscribed by the Clayton Act, but outside of its literal reach); *see generally* Grand Union Company v. FTC, 300 F.2d 92 (2nd Cir. 1962).

126. HOLMES, *supra* note 116, § 10.05.

to declare an action unlawful on unfairness grounds unless the act “causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition.”¹²⁷

III. FIRST GENERATION FTC LITIGATION:¹²⁸ SETTLEMENTS BETWEEN INNOVATORS AND GENERICS AND THEIR ANTITRUST IMPACTS

Innovators may settle patent infringement lawsuits resulting from Paragraph IV certifications with generics in lieu of engaging in extensive patent litigation. Notably, the “Hatch-Waxman [Act] is silent on the question of what happens in a patent infringement action if it’s resolved by settlement as opposed to going to the judge. Some have called this a loophole in the law.”¹²⁹ Consequently, these settlements have drawn the attention of the DOJ and FTC as potential antitrust risks. The Agencies are concerned such settlements fundamentally may be agreements not to compete.¹³⁰ “[I]t’s not the fact that settlements have taken place that is our concern; rather, the commission has become concerned that there are incentives created quite inadvertently under Hatch-Waxman that have led to settlements on anti-competitive terms.”¹³¹ The FTC specifically appears to object to three particular kinds of settlement provisions. These include provisions that provide for: (1) “reverse” payments; (2) restrictions on a generic’s ability to enter the market with non-infringing products; and (3) restrictions on a generic’s ability to assign or waive its 180-day marketing exclusivity period.¹³² Moreover, legislators worry that the agreements may delay market entry of new products that offer benefits, such as lower prices, to consumers and thereby frustrate the Act’s intent.¹³³ Three recent examples of objectionable settlements will be dissected as case studies in the sections to follow.

127. *Id.* (quoting 15 U.S.C. § 45(n) (1994)).

128. The FTC refers to patent settlements between innovators and generics for the purpose of delaying the entry of a generic drug into the market as “first generation litigation.” *See* Pharmaceutical Industry Testimony: Before the Committee On Commerce, Science, and Transportation, 107th Cong. (Apr. 23, 2002) (statement of Timothy J. Muris, Chairman, Federal Trade Commission). “Second generation litigation” focuses, in turn, on improper Orange Book listings. *Id.* As such, the FTC considers the unilateral actions of an innovator, not the collusion of an innovator and a generic, as first generation litigation. *Id.*

129. *Senate Judiciary Hearing, supra* note 62 (statement of Mark Shurtleff, Attorney General, State of Utah).

130. *See Sweetheart Deals, supra* note 25.

131. *Senate Judiciary Hearing, supra* note 62 (statement of Molly Boast, Director, Bureau of Competition, Federal Trade Commission).

132. Prepared Statement of The Federal Trade Commission Before the Committee on Commerce, Science, and Transportation, 107th Cong. (Apr. 23, 2002) (statement of Timothy J. Muris, Chairman of the Federal Trade Commission) at <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>.

133. *See Sweetheart Deals, supra* note 25.

A. Abbott/Geneva

The FTC first alleged antitrust violations in the Hatch-Waxman context in a settlement between Abbott Laboratories and Geneva Pharmaceuticals involving Abbott's drug Hytrin. Abbott's Hytrin was approved to treat hypertension and benign prostatic hyperplasia (BHP).¹³⁴ Hytrin amounted to \$542 million (over eight million prescriptions) of U.S. sales in 1998.¹³⁵ BHP afflicts fifty percent of men over age sixty and results in 1.7 million office visits to a physician each year.¹³⁶

Geneva was the first generic to file ANDAs for generic versions of Hytrin in tablet and capsule forms.¹³⁷ In conjunction with its applications, Geneva filed Paragraph IV certifications, stating that these products did not infringe any Abbott patent because the patent was invalid.¹³⁸ Within forty-five days of Geneva's certification, Abbott sued on the tablet form, but failed to sue on the capsule form.¹³⁹ As a result, the thirty-month stay applied only to the tablet form, not the capsule form.¹⁴⁰ The FDA granted approval to market the capsules in March of 1998.¹⁴¹

According to the complaint, Geneva contacted Abbott on the day it received FDA approval for the capsules and announced that it would launch generic capsules unless Abbott paid to preclude market entry.¹⁴² On April 1, 1998, Abbott and Geneva entered into an interim agreement pending resolution of the patent litigation.¹⁴³ Geneva agreed not to enter the market with any version of Hytrin, even a non-infringing form, until the earlier of: 1) final resolution of the patent litigation involving the tablet formulation, including appeal to the United States Supreme Court; or 2) entry of another generic product.¹⁴⁴ In addition, Geneva agreed not to transfer, assign, or relinquish its 180-day exclusivity right.¹⁴⁵ By blocking Geneva's 180-day exclusivity period from tolling, these

134. Analysis to Aid Public Comment, *In re Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, File No. 981 0395 (Federal Trade Commission 2000), available at <http://www.ftc.gov/os/2000/03/genevaabbptanalysis.htm> (last visited Jan. 27, 2003) [hereinafter Abbott/Geneva Analysis to Aid Public Comment].

135. Alvin J. Lorman, *FDA/Patent Law Intersection: What's New With Hatch-Waxman*, PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES 337, 452 (Practicing Law Institute 2001).

136. Complaint, *In re Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, File No. 981 0395 (Federal Trade Commission 2000), available at <http://www.ftc.gov/os/2000/03/abbottcmp.htm> (last visited Jan. 27, 2003) [hereinafter Abbott/Geneva Complaint].

137. Abbott/Geneva Analysis to Aid Public Comment, *supra* note 134.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.*

provisions ensured that no other generic could enter the market after obtaining FDA approval for a generic version of Hytrin during the term of the agreement.¹⁴⁶ In exchange, Abbott agreed to pay Geneva \$4.5 million per month until the district court decision in the infringement action.¹⁴⁷ If the court found in favor of Geneva, Abbott further agreed to pay \$4.5 million monthly into an escrow account during the appeal process.¹⁴⁸

The terms of this deal were quite favorable to both sides. Geneva projected earnings of \$1 million to \$1.5 million per month if they entered the market with a generic.¹⁴⁹ With the deal in place, Geneva would earn \$3 million to \$3.5 million above its projections. Abbott, in turn, forecasted that they would lose \$185 million in Hytrin sales during the six months subsequent to generic entry.¹⁵⁰ Thus, Abbott preserved their earnings by settling with Geneva.

In the fall of 1999, the FTC initiated an investigation into the Geneva/Abbott settlement. Adopting a “rule of reason” analysis,¹⁵¹ the FTC’s complaint stated that the parties’ conduct unreasonably restrained and injured competition by preventing and discouraging entry of a generic form of Hytrin.¹⁵² The FTC did not find the agreement to be justified by any countervailing efficiency.¹⁵³ Additionally, the FTC found that the agreement exceeded any likely remedy available to the parties under a court-ordered preliminary injunction.¹⁵⁴ Finally, the complaint alleged that the agreement was formed without weighing the equities or considering whether Abbott would succeed on the merits of the infringement suit or suffer any irreparable harm.¹⁵⁵ Hence, the FTC brought violations under Section 5 of the FTC Act that included: an unreasonable restraint of trade, monopolization of the relevant market by Abbott, conspiracy to monopolize the relevant market on the part of Abbott and Geneva, and unfair methods of competition.¹⁵⁶ In light of the FTC’s action, Geneva and Abbott terminated their agreement.¹⁵⁷

The parties entered into a consent agreement to remedy the unlawful conduct charged in the complaint.¹⁵⁸ Under the consent order, Abbott and Geneva are barred from entering into agreements in which the first ANDA filer agrees to 1)

146. Lorman, *supra* note 135, at 452.

147. Abbott/Geneva Analysis to Aid Public Comment, *supra* note 134.

148. *Id.*

149. *Id.*

150. *Id.*

151. M. Howard Morse, *FTC Challenges Payments by Branded Drug Manufacturers to Generic Manufacturers to Stay Out of Market*, FDLI UPDATE, Oct. 2000, at 23, available at <http://www.fdpi.org/pubs/Update/2000/issue5.pdf> (contending that the FTC utilized a “rule of reason” rather than a “per se” analysis in evaluating the Abbott/Geneva settlement agreement).

152. Abbott/Geneva Complaint, *supra* note 136.

153. *Id.*

154. Abbott/Geneva Analysis to Aid Public Comment, *supra* note 134.

155. *Id.*

156. *Id.*

157. Abbott/Geneva Complaint, *supra* note 136.

158. Abbott/Geneva Analysis to Aid Public Comment, *supra* note 134.

relinquish or transfer its 180-day exclusivity period or 2) not bring a non-infringing product to market.¹⁵⁹ In addition, the court must approve any agreement, which contains terms involving payments to keep a generic off the market, created during the pendency of patent litigation and involving either Abbott or Geneva as a party.¹⁶⁰ The parties must notify the FTC of any such agreements thirty days in advance of forming the agreement.¹⁶¹ Lastly, Geneva was required to waive its 180 days of exclusivity, thereby enabling other generics to market a generic form of Hytrin.¹⁶²

B. Aventis/Andrx

Another FTC antitrust investigation involved an agreement between Aventis, formerly Hoechst Marion Roussel, and Andrx Corporation. Andrx was the first to file an ANDA for a generic version of Cardizem CD, a once-a-day diltiazem product used to treat hypertension and angina pectoris.¹⁶³ The FTC charged that Aventis paid Andrx over \$80 million to refrain from marketing any competing product—infringing or non-infringing—during the pendency of patent litigation.¹⁶⁴ The complaint noted that Aventis preserved its Cardizem CD sales, which amounted to more than \$700 million per year, by forming this interim agreement with Andrx.¹⁶⁵ In addition, the complaint further alleged that Andrx agreed not to withdraw its pending ANDA or to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity.¹⁶⁶ Similar to a term in the Abbott/Geneva agreement, this term would block another of generic Cardizem CD from entering the market for the agreement period. Applying Section 5 of the FTC Act to the conduct of the parties, the FTC lodged violations that mirrored those in the Abbott/Geneva case.¹⁶⁷ Likewise, the ultimate consent orders entered against Aventis and Andrx contain relief similar to that offered to Abbott/Geneva.¹⁶⁸

C. Schering-Plough/Upsher-Smith Laboratories/American Home Products

More recently, on March 30, 2001, the FTC filed an administrative complaint

159. Decision and Order, *In re Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, File No. 981 0395 (Federal Trade Commission 2000), available at <http://www.ftc.gov/os/2000/03/abbott.do.htm> (last visited Jan. 27, 2003).

160. *Id.*

161. *Id.*

162. *Id.*

163. Administrative Complaint, *In re Hoechst Marion Roussel, Inc.; Carderm Capital L.P.; and Andrx Corporation*, File No. 981 (Federal Trade Commission 2000), available at <http://www.ftc.gov/os/2000/03/hoechstandrexcomplaint.htm> (last visited Jan. 27, 2003) [hereinafter *Aventis/Andrx Complaint*].

164. Lorman, *supra* note 135, at 348.

165. *Aventis/Andrx Complaint*, *supra* note 163.

166. *Id.*

167. *See id.*

168. *See id.*

against Schering-Plough, Upsher-Smith Laboratories and ESI Lederle, a division of American Home Products (“AHP”), for agreements involving Schering’s K-Dur 20 drug product. K-Dur 20 is a potassium chloride supplement used to treat patients with low potassium levels.¹⁶⁹ This condition commonly occurs in people taking drugs to treat high blood pressure. Low potassium levels may lead to cardiac problems.¹⁷⁰ Schering’s 1998 sales of K-Dur 20 exceeded \$220 million,¹⁷¹ and the company projected that the first year of generic competition would reduce sales by \$30 million.¹⁷²

The FTC alleged that Schering and Upsher-Smith settled a patent infringement lawsuit by private agreement.¹⁷³ Under the terms of such agreement, Upsher-Smith agreed not to sell the product for which it sought FDA approval or any other generic version of K-Dur 20 until September 2001.¹⁷⁴ In exchange, Schering paid Upsher-Smith \$60 million.¹⁷⁵ Schering also received licenses to market five Upsher-Smith products.¹⁷⁶ The FTC contended that these products were, however, of little value to Schering¹⁷⁷ and that the \$60 million payment had little relation to these products.¹⁷⁸

Through a second agreement, Schering settled another patent infringement action against AHP. Schering paid up to \$30 million to AHP in exchange for AHP’s promise not to market any generic version of K-Dur 20 until January 2004.¹⁷⁹ In addition, ESI Lederle agreed to market only one formulation of K-Dur 20 between January 2004 and September 2006 and to refrain from assisting any other company in studies necessary for an ANDA.¹⁸⁰ Schering also purchased licenses for two of AHP’s generic products.¹⁸¹ The FTC asserted that payment was really made for AHP’s delayed entry, not for the value of the products.¹⁸²

169. Press Release, Federal Trade Commission, FTC Charges Schering-Plough over Allegedly Anticompetitive Agreements with Two Other Drug Manufacturers (Apr. 2, 2001), at <http://www.ftc.gov/opa/2001/04/schering.htm>.

170. *Id.*

171. Administrative Complaint, *In re* Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products, Docket No. 9297, at 5 (Federal Trade Commission 2001), available at <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf> (last visited Jan. 27, 2003).

172. *Id.*

173. *Id.* at 6.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.* (noting that Schering never sold four of the five licensed products, made minimal sales of the fifth, and did not expect to sell any more of the five products).

178. *Id.*

179. *Id.* at 7-8.

180. *Id.* at 8.

181. *Id.*

182. *Id.* (noting that Schering made no sales of the two products as of the date of the complaint).

The FTC's complaint against the three parties contained charges similar to those made against Abbott/Geneva and Aventis/Andrx. It charged that Schering, Upsher-Smith, and AHP violated Section 5 of the FTC Act by attempting to unreasonably restrain trade and conspiring to monopolize the potassium chloride supplement market in the United States.¹⁸³

Trial against the parties commenced on January 23, 2002, before Administrative Law Judge ("ALJ") D. Michael Chappell.¹⁸⁴ The FTC entered into a consent agreement with AHP in February 2002.¹⁸⁵ The agency agreed to drop charges that AHP signed an illegal patent deal with Schering in exchange for AHP's promise to avoid making potentially anti-competitive agreements with other drug companies and to notify the FTC before entering into certain other types of agreements in the future.¹⁸⁶ More specifically, the proposed orders prohibit AHP from entering two categories of conduct: (1) agreements in which the NDA holder makes payments to the first ANDA filer and this filer agrees not to market its product for some period of time (except in certain limited circumstances); and (2) agreements between the NDA holder and ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing generic product.¹⁸⁷ These proposed orders apply to AHP in its role as either an NDA holder or an ANDA filer. In April 2002, the FTC approved the order, thereby withdrawing its litigation against AHP.¹⁸⁸

In June 2002, ALJ Chappell rendered an initial decision against Schering and Upsher-Smith.¹⁸⁹ The opinion dismissed all allegations that the two companies engaged in unfair methods of competition. Similarly, ALJ Chappell also dismissed similar separate charges against Schering stemming from an agreement with AHP.¹⁹⁰ He held that the complaint counsel did not "prove or properly define" the relevant product market and that Schering did not have a monopoly power in the relevant market as properly defined.¹⁹¹ In addition, ALJ Chappell found that the evidence failed to prove that the agreements delayed competition

183. *Id.* at 9.

184. Initial Decision, *In re* Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products, Docket No. 9297 (Federal Trade Commission 2002), *available at* <http://www.ftc.gov/os/ajsp/d9297/020627.pdf> (last visited Apr. 6, 2003) [hereinafter Schering/Upsher-Smith/AHP Initial Decision].

185. Press Release, Federal Trade Commission, FTC Agreement with American Home Products Corp. Would Protect Consumers from Anticompetitive Practices, Feb. 19, 2002, *at* <http://www.ftc.gov/opa/2002/02/ahp.htm>.

186. *Id.*

187. Decision and Order, *In re* Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products, Docket No. 9297 (Federal Trade Commission 2002), *available at* http://www.ftc.gov/os/2002/04/schering-plough_do.htm (last visited Mar. 27, 2003).

188. Schering/Upsher-Smith/AHP Initial Decision, *supra* note 184.

189. Press Release, Federal Trade Commission, Administrative Law Judge Dismisses FTC Allegations of Anticompetitive Conduct by Schering-Plough and Upsher-Smith (July 2, 2002) *at* <http://www.ftc.gov/opa/2002/07/schering.htm>.

190. *Id.*

191. *Id.*

or that the payments from Schering to Upsher-Smith and AHP, respectively, were not to settle the infringement case and for drugs licensed to Schering.¹⁹² The FTC immediately appealed this decision. The appeal is currently pending.

D. From the Perspective of Innovators and Generics: Why Settle?

Beyond the specifics of these three case studies, settlements are attractive to both innovators and generics for economic reasons. Innovators hope to delay the entry of generic competitors to preserve their profit margins.¹⁹³ For example, Glaxo earns nearly \$4.4 million for every day—approximately \$3,044 for each minute—that their antidepressant Paxil avoids generic competition.¹⁹⁴ The price of the first generic drug to enter the market is lower than the price of the approved drug. Studies indicate that the first generic typically enters the market at seventy to eighty percent of the price of the corresponding brand.¹⁹⁵ Subsequent generics cause the price to drop even lower. According to the Generic Pharmaceutical Association, “[w]hen they first hit the market, generics typically cost about [twenty-five] percent less than brand-name equivalents. But after the six-month exclusivity period often granted to the first generic firm to receive approval, the price drops within the next two years to about [forty] percent less”¹⁹⁶ For instance, Barr Laboratories earned \$365 million from sales of a generic version of Prozac during its period of exclusivity.¹⁹⁷ In the three months after its exclusivity period ended, Barr’s Prozac sales fell to \$2.5 million. Nevertheless, innovators typically do not lower prices to meet those offered by generics in an effort to thwart generic competition.¹⁹⁸ From the generics’ perspective, they will not enjoy the same profit margin as innovators for the same volume of sales because of the flood of generic products to the market after the initial exclusivity period ends.¹⁹⁹ This creates an incentive for the generic manufacturer to settle because the first generic to enter a market may share the innovator’s profits, rather than compete with the innovator and ultimately, other generics.

Innovators also hesitate to expose the validity of a patent in a litigation

192. *Id.*

193. See Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II*, Address at the American Bar Association Healthcare Program (May 17, 2001) at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm> (last visited Jan. 27, 2003).

194. Charles Ornstein, *Law Keeps Generics In Limbo; Drug Makers Deny Abusing Patent Rules*, DALLAS MORNING NEWS, June 24, 2001, at 1A, available at LEXIS, News File.

195. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), available at <http://www.cbo.gov/Studies&Rpts.cfm>.

196. Singer, *supra* note 12.

197. Christopher Elser, *Generic Drugmakers May Outpace Rivals as Patents End*, Sept. 4, 2002, at <http://quote.bloomberg.com>.

198. Leary, *supra* note 193; see also *Senate Judiciary Hearing*, *supra* note 62 (statement of Molly Boast, Director, Bureau of Competition, Federal Trade Commission).

199. See Leary, *supra* note 193.

setting. If the patent is truly valid, then the innovator is entitled to monopoly profits.²⁰⁰ A settlement in this situation will transfer a portion of the innovator's profits to a generic challenger, undercutting those rightfully claimed by the innovator. If a patent is invalid, however, then the patent holder is not rightfully entitled to such monopoly profits.²⁰¹ Thus, a settlement readily avoids exposing an invalid patent.²⁰² An undercut of profits in this context is, consequently, the lesser of two evils for an innovator; consumers will continue to pay monopoly profits and innovators will continue to receive such improper profits.

Furthermore, generics may be reluctant to engage in patent litigation, regardless of the strength or weakness of its validity or non-infringement position, because of the risk of losing the suit.²⁰³ If a generic loses, it may be held liable for damages and potentially for attorney fees or treble damages if the court find the infringement to be willful. At the same time, innovators may shy away from litigating against generics in fear that the generics will be unable to pay damages.²⁰⁴

E. From the Perspective of the FTC: Response to Settlement Agreements

To address both the serious questions raised by the Abbott/Geneva, Aventis/Andrex, and Schering-Plough/Upsher-Smith Laboratories/ESI Lederle investigations and recent statistics concerning the number of generics to enter the market prior to patent expiration, the FTC designed a study to assess the practices of innovators and generics.²⁰⁵ Particularly, "[t]he purpose of the study [was] to examine the extent to which the 180-day marketing exclusivity and thirty-month stay provisions of the [Hatch-Waxman] Act have encouraged generic competition or facilitated the use of anti-competitive strategies."²⁰⁶ It therefore focused solely on the procedures to achieve generic drug market entry prior to expiration of the patents protecting the brand-name drug. It did not address other ways for generic entry or the patent term restoration features of the Hatch-Waxman Act.

In April 2001, the Office of Management and Budget approved the study, and the FTC issued seventy-five special subpoenas to twenty-eight innovators and over fifty generics for documents and information pursuant to Section 6(b) of the

200. Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Address at Sixth Annual Health Care Antitrust Forum, Northwestern University School of Law (Nov. 3, 2000), at <http://www.ftc.gov/speeches/leary/learypharma.htm> (last visited Jan. 27, 2003).

201. *Id.*

202. *Id.*

203. *Id.*

204. *House Energy and Health Hearing*, *supra* note 5 (statement of Dr. Gregory Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

205. FTC STUDY, *supra* note 67, at ii.

206. Federal Trade Commission, Agency Information Collection Activities; Submission for OMB Review; Comment Request, at <http://www.ftc.gov/os/2001/02/v000014.htm> (last visited Oct. 13, 2001).

FTC Act.²⁰⁷ For innovators, the subpoenas focused on brand-name drugs that were the subject of Paragraph IV certifications filed by generic competitions.²⁰⁸ In turn, the subpoenas for generics centered on drug products for which ANDA applications containing Paragraph IV certifications had been filed.²⁰⁹

Based on the collected data, the FTC released its report in July 2002 and suggested two primary changes to the Hatch-Waxman Act. First, it recommended that the Hatch-Waxman Act be amended to permit only one automatic thirty-month stay per drug product per generic entry application.²¹⁰ The study discovered that an innovator may receive multiple thirty-month stays if the it lists additional patents in the Orange Book after a generic files its first ANDA. The generic must re-certify to each later-listed patent. Upon notice of this re-certification, the innovator may then sue again on each patent within forty-five days to trigger additional thirty-month stays for resolution of this subsequent litigation.

The FTC found that this situation has occurred for eight drugs since 1992, resulting in four to forty months delay beyond the first thirty-month stay.²¹¹ And, in all four of the cases decided before a court thus far, it noted that the additional patent has been found either invalid or not infringed by the ANDA.²¹² The FTC consequently concluded that a single thirty-month stay does not pose significant delay to generic drug entry because the FDA typically needed this amount of time to review and approve the ANDA.²¹³ Nevertheless, it determined that multiple thirty-month stays would prevent generic entry, given the four to forty month delays seen thus far.²¹⁴ It also concluded that allowing a single thirty-month stay per drug would eliminate improper Orange Book listings made only to avail unwarranted thirty-month stays.²¹⁵

Second, the FTC supported the DCA, which mandates innovators to give copies of certain agreements that relate to the 180-day exclusivity to the FTC and DOJ.²¹⁶ The FTC found that the FDA granted the 180-day exclusivity for thirty-one of the 104 ANDA filings containing Paragraph IV certifications from 1992 through 2000.²¹⁷ Moreover, during this period, it found that the parties settled the ANDA-patent litigation on twenty occasions, fourteen of which had the potential to delay the start of the generic's exclusivity.²¹⁸ Because the FDA may not

207. Lorman, *supra* note 135, at 455.

208. *Id.* The brand-name drugs included: Capoten, Cardizem CD, Cipro, Claritin, Lupron, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa. FTC STUDY, *supra* note 67, at ii.

209. *Id.*

210. *Id.* at iii.

211. *Id.*

212. *Id.*

213. *Id.* at iv.

214. *Id.*

215. *Id.* at v.

216. *Id.* at vi. See *infra* Section IV, Part B.

217. FTC STUDY, *supra* note 67, at vi.

218. *Id.* at vii.

approve other ANDAs until the first 180-day exclusivity period tolls, the FTC determined that the 180-day exclusivity period in itself does not create a bottleneck to subsequent generic entry.²¹⁹ Rather, it determined that such a bottleneck may result when an innovator and generic agree to avoid triggering the 180-day exclusivity by entering a entering private settlement.

After the release of the FTC recommendations, President George W. Bush acted by proposing a new FDA regulation to speed generic drug approvals. He introduced this legislation on October 21, 2002. President Bush explained in support of his proposal that “[t]he average brand name drug costs more than \$72 per prescription” while “the average price for generic drugs . . . was less than \$17 per prescription.”²²⁰

This regulation contained three key provisions. The first provision implemented the FTC’s recommendation to allow only one thirty-month stay per generic drug application.²²¹ The second provision tightened the Orange Book patent listing process in attempt to ensure that only appropriate patents are listed.²²² Specifically, patents that claim packaging, metabolites, intermediates, and unapproved uses may not be submitted under proposed regulation because they do not claim the approved drug product.²²³ Where packaging is integral to the delivery of the approved drug, however, a patent directed to such product may be listed. This provision would continue to permit patents on active ingredients, formulations, and uses of a drug to be submitted.²²⁴ The third provision sought to clarify the requirements for submission of patent information into the Orange Book, and thereby eliminate ambiguity and improper listings.²²⁵ Particularly, this provision requires an innovator to supply specific information and complete a checklist format for each patent listed. Declarations containing false information will be sent to the DOJ for review. The FDA approved this regulation in its entirety, and it will become effective on August 18, 2003.

219. *Id.* at viii. The FTC did suggest clarifying the circumstances that trigger the 180-day exclusivity, namely: (1) specifying that marketing includes the first generic’s marketing of the brand-name drug; (2) codifying that any court decision is sufficient to start the running of the 180-day exclusivity; and (3) clarifying that a court decisions dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a “court decision” to start the running of the 180-day exclusivity. *Id.* at ix-xi.

220. President George W. Bush, Remarks by the President on Prescription Drugs (Oct. 21, 2002), available at <http://www.whitehouse.gov/news/releases/2002/10/print/20021021-2.html>.

221. Applications for FDA Approval to Market a New Drug Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed; Proposed Rule 21 C.F.R. §§ 314.94(a) & 314.52(a) (2002).

222. *Id.* §314.53(a).

223. *Id.*

224. *Id.* § 314.53(b).

225. *Id.* § 314.53(c).

IV. PROPOSED LEGISLATION BEFORE THE 107TH AND 108TH CONGRESSES

A. *The Greater Access to Affordable Pharmaceuticals Act*²²⁶

In the face of ballooning price differences between brand-name and generic drugs,²²⁷ Senator Charles Schumer introduced bi-partisan legislation, known as S. 54 or more commonly as the McCain-Schumer proposal, before the 108th Congress on January 7, 2003.²²⁸ Twenty-one other senators are co-sponsoring this bill.²²⁹ It will reform the Hatch-Waxman system by amending the Federal Food, Drug, and Cosmetic Act. According to the language of the GAAP, it is intended “1) to increase competition, thereby helping all Americans, especially seniors and the uninsured, to have access to more affordable medications; and 2) to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anti-competitive action or actions that tend to unfairly restrain trade.”²³⁰ The Congressional Budget Office estimates that this legislation would reduce drug spending by \$60 billion over the next ten years.²³¹ Given its broad purpose and support, it may catalyze changes in the Hatch-Waxman system that have been sought by generics and discouraged

226. The GAAP, originally sponsored by Senators John McCain and Charles Schumer and Representatives Sherrod Brown and JoAnn Emerson, was first introduced before the 107th Congress in May 2001. *Hatch-Waxman Reform Will Benefit Industry and Patients*, DRUG STORE NEWS (Aug. 20, 2001) [hereinafter Hatch-Waxman Reform]. It was designated S. 812 and H.R.1862, respectively, by the Senate and House. It passed in the Senate in July 2002 and was forwarded to the House for introduction in September 2002. House Democrats launched a discharge petition to force a floor vote on the bill. Julie Rovner, *US Lawmakers Try to Force Vote on Generic Drug Bill*, Sept. 18, 2003, available at <http://abcnews.com>. Simultaneously, innovators ran newspaper advertisements featuring a photo of a child getting drugs injected through an intravenous line with the comment, “Pray for a miracle, because generic drugs will never cure him.” *Id.* The GAAP was held at the desk and not introduced to the House prior to session close.

227. Hatch-Waxman Reform, *supra* note 226 (noting that the difference in average price between a brand and a generic is \$46 compared to \$17 ten years ago); *see also* Press Release, Sen. John McCain, McCain, Schumer Unveil Initiative to Save Consumers \$71 Billion on Prescription Drugs (May 1, 2001), at <http://mccain.senate.gov/mccain>. The press release stated that consumers save sixty percent over average when they choose a generic over a brand drug. Under the generic scheme, consumers could purchase a generic version of Prilosec, an ulcer medicine, for \$57.60 instead of a brand prescription for \$143.99. Likewise, a consumer could spend \$49.88 for a generic version of Zocor, a cholesterol lowering medication, rather than \$124.71 for a brand prescription.

Id.

228. Schumer Press Release, *supra* note 21.

229. Co-sponsoring senators include: Jeff Bingaman, Susan M. Collins, Mark Dayton, Richard J. Durbin, Russell D. Feingold, Edward M. Kennedy, Mary Landrieu, John McCain, Bill Nelson, John F. Reed, Debbie Stabenow, Hillary Rodham Clinton, Thomas A. Daschle, Byron L. Dorgan, John Edwards, Tim Johnson, Herb Kohl, Patrick J. Leahy, Zell Miller, Mark Lunsford Pryor, and Jay Rockefeller.

230. S. 812, 107th Cong. § 2(b) (2001).

231. Schumer Press Release, *supra* note 21.

by innovators for years.

The proposed bill contains numerous provisions designed to make delayed entry of generic drugs quite difficult. First, the bill requires the first ANDA applicant to forfeit the 180-day exclusivity period to the next-filed applicant if the first applicant 1) reaches a financial settlement with an innovator to stay out of the market until the patents expire; 2) fails to market their generic within ninety days from the date that the ANDA becomes effective; 3) withdraws their ANDA application; 4) fails to obtain FDA approval within thirty months; 5) fails to challenge a new patent within sixty days; or 6) is found to have engaged in anti-competitive activities.²³² Second, the bill eliminates the automatic thirty-month stay for subsequently issued patents, in effect allowing only one thirty-month stay per brand-name drug.²³³ Third, the bill requires patent holders to list all of a drug's relevant patents in the FDA's Orange Book and to certify that the list is complete and accurate.²³⁴ Fourth, the bill bars an applicant from filing a civil action for patent infringement if the applicant failed to timely register its patents with the FDA.²³⁵ Fifth, the bill permits a generic to file a civil action to correct or delete patent information in the Orange Book.²³⁶ Finally, the bill disregards an applicant's ability to pay damages from a court's consideration of whether to provide injunctive relief before the expiration of the thirty-month stay.²³⁷

While the GAAP as embodied in S. 54 presently stands before the Senate Committee on Health, Education, Labor, and Pensions,²³⁸ Senators McCain, Schumer, Kennedy, and Gregg introduced a revised bipartisan version of the GAAP as S. 1225 on June 10, 2003, before the Senate Committee on Health, Education, Labor, and Pensions.²³⁹ This revision, referred to as the Gregg-Schumer proposal, attempts to address a number of the criticisms lodged against the McCain-Schumer proposal. Senator Schumer said,

This legislation uses a market-based approach that doesn't cost the government a penny and gives the drug industry a desperately needed dose of competition. It's all about easing the burden on everyday people who are forced to rely on higher-priced name brand drugs because no cheaper alternative is available.²⁴⁰

232. S. 54, 108th Cong. § 5(a)(2) (2003).

233. *Id.* § 4(a)(1).

234. *Id.* § 3(a)(2).

235. *Id.* § 3(a)(1).

236. *Id.* § 4(a)(1).

237. *Id.* § 6.

238. S. 54 Bill Summary & Status, at <http://thomas.loc.gov/cgi-bin> (last visited Mar. 17, 2003).

239. Joanne Kenen, *Key Senators Agree on Generic Drug Bill*, *Forbes*, June 4, 2003, available at <http://www.forbes.com/newswire/2003/06/04/rtr991184.html>.

240. Press Release, Sen. Charles Schumer, Gregg-Schumer Generic Drug Amendment Passes Full Senate (June 19, 2003) at http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/PR01804.pf.html.

Particularly, S. 1225 simplifies S. 54 into four key sections. First, the bill, like S. 54, permits an innovator to utilize only one thirty-month stay.²⁴¹ Second, it creates forfeiture provisions for the 180-day exclusivity period similar to S. 54.²⁴² Third, unlike S. 54, the bill enables the FDA to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream.²⁴³ Lastly, S. 1225 does not specify which patents may be listed in the Orange Book. Nevertheless, to ensure that innovators do not list frivolous patents to stall generic competition, the bill permits generics to file counter-claims against an innovator if the innovator sues them for violating a listed patent.²⁴⁴ In essence, this provision establishes an enforcement mechanism to regulate Orange Book listings. S. 54 did not provide for such enforcement. This proposal was overwhelmingly passed in the Senate on June 19, 2003, by a vote of 94-to-1.²⁴⁵

B. The Drug Competition Act

Besides the GAAP, several legislators also introduced the DCA, which targets “sweetheart deals”²⁴⁶ that delay the entry of low-cost generics onto the market. The Senate bill, S. 754, was sponsored by Senator Patrick Leahy, the ranking member of the Senate Judiciary Committee, and co-sponsored by Senator Herb Kohl, the ranking member of the panel’s Antitrust Subcommittee, and Senators Charles Schumer, Richard Durbin, and Russell Feingold.²⁴⁷ On the House side, the bill, H.R. 1530, was co-sponsored by Representative Henry Waxman, the ranking member of the House Government Reform Committee and a senior member of the House Commerce Committee, and co-sponsored by Representatives Marion Berry, Peter Deutsch, Fortney “Pete” Stark, and Sherrod Brown.²⁴⁸ Senator Leahy said, “If Dante were writing *The Inferno* today he would find a special place for those who devise anti-consumer conspiracies to gouge the public. Stifling competition hurts seniors and families and cheats healthcare providers, and it hits taxpayers through higher Medicare and Medicaid costs.”²⁴⁹ Senator Waxman further commented, “This drug company collusion against consumers has got to stop. These payoffs from one company to another help no sick people get well. They just make patients’ medical bills higher. The first step to stopping this collusion is to expose it. Once it’s public, no one can defend it.”²⁵⁰ Thus, the DCA was crafted

241. S.1225, 108th Cong. §2(C) (2003).

242. *Id.* § 3.

243. *Id.* § 4.

244. *Id.* § 2(aa).

245. Schumer Press Release, *supra* note 240.

246. *Sweetheart Deals*, *supra* note 25.

247. *Id.*

248. *Id.*

249. *Id.*

250. *Id.*

1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding branded drugs and companies which could manufacture generic versions of such branded drugs; and 2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.²⁵¹

In terms of application, the new bill will allow the FTC and DOJ to monitor private sales or marketing agreements between innovators and generics in the context of an ANDA with a Paragraph IV certification and subject them to immediate FTC and DOJ investigation and action.²⁵² That is, an innovator and a generic, which enter into a private agreement regarding either (1) the manufacture, marketing, or sale of a generic that potentially would compete with either the brand name drug or (2) the 180-day exclusivity period, must file the texts of such agreements with the FTC and the Attorney General.²⁵³ In addition, the parties must explain purpose and scope of the agreement and discuss whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture, or sale of the generic in question.²⁵⁴ Moreover, the parties must file this explanation and discussion within ten business days after the agreement is executed.²⁵⁵ Otherwise, the parties may be subject to a civil penalty of \$10,000 per day of non-compliance.²⁵⁶

On October 18, 2001, the Senate Judiciary Committee approved the DCA by voice vote.²⁵⁷ The FTC then specifically recommended passage of this bill when it released its report on the generic pharmaceutical marketplace in July 2002.²⁵⁸ The Senate, in turn, passed the DCA on November 18, 2002 and referred it to the House Committee on the Judiciary.²⁵⁹ Congress closed session, however, before the House voted on this bill.

251. S. 754, 107th Cong. § 3 (2001).

252. Lorman, *supra* note 135, at 348.

253. S. 754 § 5.

254. *Id.*

255. *Id.* § 6.

256. *Id.* § 7.

257. *Senate Panel Approves Bill on Generic Drug Availability*, NAT'L J. CONG. DAILY, Oct. 18, 2001 [hereinafter Senate Panel].

258. *See infra* Section III, Part E.

259. Press Release, Sen. Patrick Leahy, Senate Passes Leahy Bill Targeting Sweetheart Deals That Delay Low-Cost Generic Drugs (Nov. 19, 2002), at <http://www.senate.gov/~leahy/press/200211/111902.html>.

V. FULL CIRCLE: DO THE INTENTIONS BEHIND THE
HATCH-WAXMAN ACT SURVIVE?

A. *The Greater Access to Affordable Pharmaceuticals Act—Poisoning
the Hatch-Waxman System*

Today, the U.S. pharmaceutical market is robust, competitive, and working to the benefit of consumers and patients. As such, the Hatch-Waxman balance has not tipped in favor of either generics or innovators. The reconstructive surgery proposed by Senators McCain, Schumer, and Gregg is simply not necessary. In fact, the changes contained in the GAAP may destroy the tender compromise achieved in 1984.²⁶⁰

Generics flourish as a result of the Hatch-Waxman Act. The 1984 law revoked the trade secret status accorded to an innovator's safety and efficacy data and allowed a generic to show only bioequivalence to the innovator product. As a result, a generic may avoid the huge expense of clinical trials and only spend a small fraction of that amount to show bioequivalence. Further, in overruling the *Roche v. Bolar* decision, the Hatch-Waxman Act enabled generics to establish bioequivalence during the patent life of the innovator's product. Thus, a generic may be prepared to market as soon as the patent protection around an innovator's product expires. Moreover, the Hatch-Waxman Act instituted the ANDA process to facilitate generic entry into market.

Before 1984, generic competition did not begin until three to five years after the innovator's patent expired.²⁶¹ When the law took effect, generics flooded the FDA with 800 applications in the first seven months.²⁶² Today, generic copies are almost immediately available as soon as an innovator's patent expires.²⁶³ In fact, "[o]f the approximately 10,000 brand name prescriptions drugs available, 9,000 have generic equivalents."²⁶⁴ Additionally, the generic industry's share in the prescription drug market has jumped from less than twenty percent to almost fifty percent since 1984.²⁶⁵ Given that pharmacists fill more than one billion prescriptions with generic medications, generics are eating a larger serving of the profits.²⁶⁶ In fiscal year 2000, Barr Laboratories and Teva Pharmaceutical

260. Provisions to be analyzed in this section are common to both S. 54 and S. 1225. Accordingly, use of the term "the GAAP" hereafter may refer to either proposed bill.

261. *House Energy and Commerce Hearing*, supra note 5 (statement of Dr. Gregory Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

262. Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition; How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, available at <http://www.nytimes.com/library/national/science/health/072300hth-generic-drugs.html>.

263. *Id.*

264. Marjorie Wertz, *Consumers Question Generic Drugs; Doctor Knows Best*, PITT. TRIB.-REV., Feb. 4, 2002, available at http://www.pittsburghlive.com/x/tribune-review/health/s_15624.html.

265. *House Energy and Commerce Hearing*, supra note 5 (statement of Dr. Gregory Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

266. Wertz, supra note 264.

Industries, two of the largest generics, realized a return on revenues of ten percent and 8.5%, respectively.²⁶⁷ Comparatively, the eleven firms in the Fortune 500 drug industry earned an 18.6% return.²⁶⁸ Thus, both their speed to market and revenue earnings suggest that generics are not struggling anorexically behind the innovator drug companies.

The Hatch-Waxman system also preserved incentives for innovators while nourishing the generic industry. The 1984 law allows for partial patent term restoration for the time lost in clinical testing and FDA review. The total time is, however, limited to a maximum of five years, even if this amount of time is lost during drug development and review. In addition to the partial restoration, the 1984 law prohibits the FDA from approving a generic copy of an innovator's new chemical entity ("NCE") until five years after the NCE's approval date. Furthermore, the law also creates a procedure for litigating patent disputes prior to FDA approval of an infringing generic.

Indeed, innovators continue to develop novel and efficacious medications. In 2001 alone, pharmaceutical and biotechnology companies developed thirty-two new medicines—twenty-four drugs and eight biologics—to combat diseases that cost society over \$250 billion a year in other health care costs, lost productivity, and wages.²⁶⁹ Presently, innovators have over 1000 new medicines in the development pipeline—these include more than 400 for cancer, more than 200 to meet the special needs of children, more than 100 each for heart disease and stroke, mental illnesses, and AIDS, twenty-six for Alzheimer's disease, nineteen for arthritis, sixteen for Parkinson's disease, and fourteen for osteoporosis.²⁷⁰ As well, "America not only leads the world in investing in medical research and development, it is also the nation where patients benefit the from that research the fastest."²⁷¹ A survey of new drug launches in twenty-two developed countries revealed that all of the one hundred new medicines developed by American pharmaceutical companies were launched in the United States from 1997 to 1999. In contrast, sixty-six of those drugs reached patients in the United Kingdom, and only forty-three reached patients in Canada during that same three year period. Thus, innovators are steadily turning scientific advances into life-saving medicines for the benefit of ailing patients.

Nevertheless, if the GAAP is adopted, it will introduce various provisions into the law to suffocate innovation. First, it will limit an innovator to avail only a single automatic thirty-month stay regardless of the number of separate patents challenged by generics. The 1984 law afforded, however, special treatment to patent litigation in the ANDA context because the Hatch-Waxman Act overruled the *Roche v. Bolar* decision. Under the holding of *Roche v. Bolar*, a generic

267. *Generic Drugs. The Stalling Game*, 66 CONSUMER REPORTS 36, July 2001, available at LEXIS, News File.

268. *Id.*

269. PhRMA Press Release, *supra* note 5.

270. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Dr. Gregory Glover, Partner, Ropes & Gray on behalf of Pharmaceutical Researchers and Manufacturers of America).

271. Pharmaceutical Research and Manufacturers of America, *Americans Patients Have More Timely Access to New Medicines*, at <http://www.phrma.org/updates/2002-02-19.346.phtml>.

would have been barred from conducting any form of product development that could potentially have been deemed patent infringement until the innovator's patent expired. Congress designed the thirty-month stay provision as a trade-off for enabling generics to engage in product development prior to the expiration of the innovator's patent. No other United States industry offers a competitor such a competitive advantage.²⁷² Thus, Senators McCain, Schumer, and Gregg cannot reasonably assert that the special provision for patent litigation should be limited and, at the same time, advocate that a generic may continue development activities that would otherwise constitute patent infringement.

Moreover, if a subsequent generic challenger is not forced to adhere to the thirty-month stay, then such generic may enter the market as soon as the FDA grants ANDA approval. Subsequent generics consequently have greater incentives to file ANDAs with Paragraph IV certifications and trigger litigation under the proposed the GAAP than in the present system. An innovator's only recourse, in turn, is to file for a preliminary injunction to block the subsequent generic until a court decision on the merits of the infringement suit.

The Federal Circuit applies a four-factor test in deciding whether to grant preliminary injunctive relief in a patent infringement suit. "[A] party must prove four factors: (1) its reasonable likelihood of success on the merits; (2) irreparable harm to its interests; (3) the balance of hardships tipping in its favor; and (4) public interest."²⁷³ In proving its probability of success on the merits, the patent holder must meet the standard of a "clear showing."²⁷⁴ The holder may do so by establishing evidence of either (1) prior adjudication of validity in a suit by the patent holder against another party or (2) acquiescence by the industry to the patent holder.²⁷⁵ In addition, the patent holder must show that the generic's product will infringe²⁷⁶—one of the central issues in the ensuing Hatch-Waxman litigation spawned by the Paragraph IV certification. Additionally, to evaluate the proof of infringement offered by the patent holder, the court may need to engage in a patent claim construction exercise.²⁷⁷ Such exercise may involve an in-depth, time-consuming review of the specification, inquiry into the scope of the invention, investigation of the prior art, and consideration of the prosecution history.²⁷⁸ Finally, the patent holder must establish that he will suffer irreparable harm if the injunction is denied. If the patent holder can obtain full compensation through money damages, then the court will deem that holder will not suffer such harm.²⁷⁹ This determination may indeed be difficult for a court to make given the speculative nature of monetary damages.

Once a patent holder establishes both probable success and irreparable harm,

272. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Dr. Gregory Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

273. *Glaxo v. Ranbaxy Pharm.*, 262 F.3d 1333, 1335 (Fed. Cir. 2001).

274. *See Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 1233 (Fed. Cir. 1985).

275. DONALD S. CHISUM, *CHISUM ON PATENTS* § 20.04 (2001).

276. *Id.*

277. *Id.*

278. *Id.*

279. *Id.*

then the trial court has great discretion whether to issue an injunction.²⁸⁰ The court balances the hardships that the parties will suffer from granting the injunction versus withholding the injunction.²⁸¹ In addition, the court will consider the effects on third parties and the public interest. Typically, the public interest will not seriously be effected by the grant or denial a preliminary injunction in a patent infringement case, even the in the pharmaceutical industry.²⁸² Specifically, in *Eli Lilly and Company v. Premo Pharmaceuticals Labs*, the court reasoned that

[a]lthough companies such as Premo . . . might be able to undercut the prices offered by pharmaceutical manufacturers . . . this type of short-term competition does not, at least in the considered opinion of Congress, serve the public interest. Instead, Congress has determine that it is better for the nation in the long-run to afford the innovators of novel, useful, and nonobvious products short-term monopolies.²⁸³

Additionally, preliminary injunctions may be a risky maneuver for the patent holder based on statistical data. A study surveyed 252 patent disputes across six federal district courts between January 1, 1990, and June 30, 1991, and found that forty-eight patent holders (nineteen percent) requested preliminary injunctions.²⁸⁴ The courts granted this relief in only twelve of the twenty-three cases (fifty-two percent) that proceeded through a ruling on the request. Thus, an innovator will bear a heavy and risky burden since the “preliminary injunction may be the most striking remedy wielded by contemporary courts.”²⁸⁵

If the court refuses to grant a preliminary injunction, then a generic may opt to market their version of the branded drug. The innovator’s profit margin of the innovator will plummet as a result of this generic competition. Thus, an innovator will suffer unjustly in many ways if the court ultimately upholds the validity of the challenged patent in favor of the innovator. First, the innovator will lose both profits from the sales of its patented drug for the period of the infringement and the loyalty of the patient population who convert to the generic. Second, despite its right to force the generic to withdraw its infringing product from the market, the innovator will unlikely to resort to such action for ethical reasons. Specifically, the innovator is, in theory, entitled to reclaim its market share wrongfully disturbed by the generic. However, in reality, enforcement by the innovator would only hurt patients who by then rely on the lower-cost generic.

Therefore, faced with inequitable treatment under the law and threat of increased litigation resulting from the thirty-month stay limitation, innovators

280. *Id.*

281. *Id.*

282. *Id.*

283. 630 F.2d 120, 138 (3d Cir. 1980).

284. Jean O. Lanjouw & Josh Lerner, *Tilting the Table? The Use of Preliminary Injunctions*, 44 J. LAW & ECON. 573, 594-95 (Oct. 2001).

285. John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 HARV. L. REV. 525, 525 (1978).

may decrease the number of dollars dedicated to R&D. This is especially probable because innovators will potentially encounter these challenges in as little as four years after a drug hits the market. For example, although Eli Lilly and Company's compound and method patent for Zyprexa, a schizophrenia treatment drug, does not expire until 2011 in the United States, already three patent challengers have filed ANDAs between the fourth and fifth year post-product launch.²⁸⁶ The innovator will only be in the early stages of recouping development costs for a particular drug at this four-year time point, and such costs are quite staggering. In 2002, Tufts University researchers targeted the figure to be \$897 million from inception to market launch.²⁸⁷ Thus, while still recouping these R&D costs, innovators will be forced to bear the extreme cost of patent litigation. Bruce L. Downey, Chairman and CEO of Barr Laboratories acknowledged, "We invest literally millions of dollars in these patent challenges."²⁸⁸ Likewise, Robert A. Armitage, Senior Vice President and General Counsel for Eli Lilly and Company, said that a full-blown patent litigation can cost a drug manufacturer \$5 million to \$10 million in outside attorney fees alone.²⁸⁹ Hence, in direct frustration of the intent of the original Hatch-Waxman Act, the \$30 billion spent on bringing life-saving medications to market will undoubtedly dwindle with each new patent challenge.

Second, in addition to limiting the thirty-month stay, the GAAP will require the first ANDA applicant to forfeit the 180-day exclusivity period to the next-filed applicant if the first applicant delays market entry of the generic. From the innovator's perspective, this provision will also injure innovation and aggravate the goals of the Hatch-Waxman Act. The 180-day exclusivity is a precious bounty awarded to the first ANDA applicant to either commercially market a generic product or receive a favorable court decision in a patent infringement action. Presently, "multiple challenges to the same patent have become commonplace."²⁹⁰ Three, four, or sometimes five generics may line up to challenge patents on blockbuster drugs, even though only the first generic to challenge is eligible for the exclusivity.²⁹¹ If this bounty is transferable as it will be under the GAAP, an even larger number of generics will file ANDAs in hopes

286. Prescription Pharmaceuticals and Biotechnology (also known as "The Pink Sheet"), available at <http://www.thepinksheet.com>.

287. Press Release, Tufts Center for the Study of Drug Development, Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 Million (May 13, 2003), at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp>; see also Press Release, Tufts Center for the Study of Drug Development, Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million (Nov. 30, 2001), at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp>. The average cost of new drug development in 1987 was \$231 million. Had costs only increased at the rate of inflation, the average cost would have been \$318 million in 2000.

288. *House Energy and Commerce Hearing*, *supra* note 5.

289. Morrison, *supra* note 287.

290. Engelberg, *supra* note 28, at 416.

291. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Rep. W.J. "Billy" Tauzin, Chairman, House Committee on Energy and Commerce).

of winning the 180-days of exclusivity directly, or alternatively, of standing as the first runner-up in the event that the first ANDA delays market entry. As well, many of these generics will file Paragraph IV certifications in their ANDAs. Innovators, consequently, will be confronted with a steady stream of patent challengers. As mentioned earlier in this section, patent litigation is intensely expensive and will quickly deplete the dollars that innovators have available for R&D.

Thus, the GAAP deliberately overturns tradeoffs so tenuously negotiated by representatives from PMA and GPIA in the summer of 1984. “There is almost nothing in McCain-Schumer that is going to create more innovation.”²⁹² The true solution to enable all Americans, especially seniors, disabled persons, and the uninsured, to have greater access to more affordable pharmaceuticals is a Medicare prescription drug benefit. Uninsured persons, like Ms. Rubin,²⁹³ are not criticizing innovators for developing new medications. Instead, such persons are really concerned with the cost of these new medications. Recall that Ms. Rubin said, “It’s so costly. I don’t have a drug plan, and I pay full price.”²⁹⁴ Affordability is the predominant issue for Americans, not the thirty-month stay or 180-day exclusivity provisions. Affordability may be turned into a reality through good prescription drug insurance. Congress therefore should be focused on enacting a bill to accomplish this coverage. Their present efforts with the GAAP are misdirected.

B. The Drug Competition Act—Supplementing the Hatch-Waxman System

The DCA contains much narrower legislation than the GAAP. It does not aim to amend the Hatch-Waxman Act or slow down the drug approval process.²⁹⁵ Rather, according to Senator Orrin Hatch, it seeks to enable “government . . . [to] take a hard look at efforts to keep generic drugs off the market.”²⁹⁶ Particularly, the bill singles out private agreements between innovators and generics and subjects these agreements to scrutiny by the FTC and DOJ. In scrutinizing agreements, the Agencies will not squelch the right to contract, but will block those settlements that gouge antitrust and competition principles. Therefore, the motivation behind the DCA parallels the purpose of the Hatch-Waxman Act, which sought to make lower-costing generic copies of brand drugs more widely available to consumers.

Indeed, the time is past due for such legislative action to keep the spirit of Hatch-Waxman strong. The recent glamorized settlements between Abbott/Geneva, Aventis/Andrx, and Schering/Upsher-Smith/ESI Lederle²⁹⁷ have simply called the public’s attention to a long-standing abuse of antitrust law.

292. Morrison, *supra* note 287 (quoting Robert A. Armitage, Senior Vice President and General Counsel for Eli Lilly and Company).

293. *See supra* notes 12-13 and accompanying text.

294. *Id.*

295. *Sweetheart Deals*, *supra* note 25.

296. Senate Panel, *supra* note 257.

297. *See infra* Section II.

Deals between innovators and generics started shortly after the Hatch-Waxman Act was passed in 1984. For example, one of the earliest Hatch-Waxman skirmishes involved Merck & Company's popular muscle relaxant Flexeril. Merck accused Schein Pharmaceuticals of patent infringement pursuant to a Paragraph IV certification. In the patent litigation, the district judge ruled in favor of Schein. According to Mr. Albert B. Engelberg, the attorney who represented Schein and who also represented generic manufacturers in writing the Hatch-Waxman Act, the victory changed the legal dynamic surrounding Hatch-Waxman.²⁹⁸ In the wake of Schein's victory, Mr. Engelberg said that an innovator offered to settle a separate case by giving Schein cash payments to stay off the market, a tactic similar to the one used by Abbott with Geneva.²⁹⁹ He also revealed that the settlement was kept secret and therefore, he would not disclose the details.³⁰⁰

On the other hand, Congress's heightened concern may not be justified. The FTC and DOJ are adequately and actively monitoring settlements between innovators and generics for anti-competitive terms under existing law as demonstrated by the recent actions taken against Abbott/Geneva, Aventis/Andrx, and Schering/Upsher-Smith/ESI Lederle. Next, the number of Hatch-Waxman patent challenges from 1984 through January 2001 was quite small compared to the number of ANDA applications. Generics filed 8259 ANDA applications, but only 478 of these applications raised a patent issue, either challenging patent validity or claiming non-infringement.³⁰¹ Additionally, only fifty-eight court decisions involving just forty-seven patents have been issued to resolve generic challenges to innovator patents.³⁰² As well, only three of the patent disputes involving a settlement between the innovator and generic companies have been challenged by the FTC,³⁰³ namely Abbott/Geneva, Aventis/Andrx, and Schering/Upsher-Smith/ESI Lederle. In other words, a scant 0.036% of the ANDA applications filed in the past seventeen years have resulted in settlements challenged by the FTC. Considering these actual figures, perhaps the media has incited needless worry by overdramatizing the volume of settlements.

Public policy typically favors settlements. Court dockets are overcrowded, and settlements lower transaction costs for the parties by avoiding the expenses of litigation.³⁰⁴ Mr. Charles T. Lay, a former vice president and chief executive at Geneva, stated that litigation drives up the cost of developing a generic from \$500,000 a decade ago to more than \$5 million today.³⁰⁵ Settlements may likewise create results that accommodate the mutual interests of both parties.³⁰⁶

298. Stolberg & Gerth, *supra* note 262.

299. *Id.*

300. *Id.*

301. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Dr. Gregory J. Glover, Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

302. *Id.*

303. *Id.*

304. *Id.*

305. Stolberg & Gerth, *supra* note 262.

306. *House Energy and Commerce Hearing*, *supra* note 5 (statement of Dr. Gregory J. Glover,

In contrast, litigation generally favors only the interest of one party. Also, without the distraction and costs of litigation, innovators can focus on researching and developing new drug products. This innovator R&D, in turn, translates into growth of the generic industry. Thus, consumers ultimately benefit by having both new innovator medicines and generic copies available.

Countervailing arguments exist though to show why settlements in the context of Hatch-Waxman differ from settlements in regular patent litigation. In normal litigation, the public trusts an alleged infringer to be the strongest competitor of a patent holder in favor of consumers.³⁰⁷ Generics no longer favor consumers in Hatch-Waxman settlements. Their interests diverge from consumers' interests as soon as innovators drop dollars into their pocketbooks.³⁰⁸ Effectively, generics are paid to be weak competitors.³⁰⁹ For this reason alone, public policy cannot truly support settlements stemming from Hatch-Waxman litigation.

What is more, if the FTC and DOJ scrutinize agreements under the DCA, then the validity of the patent underlying the whole dispute will undoubtedly surface. If such patent is valid, then private agreements with generics not to compete are not anti-competitive because innovators have the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."³¹⁰ Private agreements may actually benefit generics and consumers by providing additional funds to generics that may be devoted to developing other generic drugs. Hence, innovators may actually fund generics to become stronger competitors. Indeed, in this context, the goals of Hatch-Waxman are readily advanced.

The true problem surfaces, however, when the patent is either clearly invalid or its validity is uncertain. In these circumstances, innovators do not have exclusionary rights, and agreements not to compete are likely violations of antitrust laws. Patent validity is not readily ascertainable though; it involves complex legal determinations. According to Thomas B. Leary, former FTC Commissioner,

[T]he Commission is extremely ill equipped to determine on its own whether patents are valid or not. Theoretically, it could decide the issue on the basis of the parties' own evaluations, as disclosed by internal documents or testimony. . . . [However], [c]ompanies with sophisticated counsel can generate documents that are helpful either in patent litigation or in defense of a settlement.³¹¹

Partner, Ropes & Gray, on behalf of Pharmaceutical Researchers and Manufacturers of America).

307. Dr. Suzanne Michel, Address at Antitrust in the Pharmaceutical Industry: A Brown Bag Series, *Cutting Edge Issues in Government Pharmaceutical Investigations and Litigation: An In-Depth Look at In the Matter of Schering-Plough Corporation et. al., New York v. Bristol-Myers Squibb Co. and What Comes Next* (Feb. 20, 2002) (notes on file with author).

308. *Id.*

309. *Id.*

310. 35 U.S.C. § 154(a)(1) (2000).

311. Leary, *supra* note 193.

Conclusively, because of the integral nature of patent validity in determining the anti-competitive nature of an agreement and the difficulty in assessing such validity, the FTC and DOJ will be subjected to a sincerely complex task. This task quickly may overwhelm their systems.

Lastly, if an innovator pays a generic to delay market entry, the public must consider the length of this delay. The public cannot automatically presume terms that mention delay make the agreement anti-competitive. If the delay does not preclude market entry beyond the date when a generic could enter if victorious in patent litigation, then it is not anti-competitive. The generic really would have no right to enter the market until a court rules that its drug product would not infringe the innovator's patent or that such patent is invalid. Nevertheless, a delay that postpones generic entry beyond the point when a generic could enter the market if victorious in the patent litigation would certainly be anti-competitive. The innovator in such instance will maintain market power illegally because the generic has a right to enter the market and in this manner adversely harm competition.

CONCLUSION

Living in the aftermath of the Hatch-Waxman Act for seventeen years, innovators and generics are sounding cries of abuse across the United States. In Washington, D.C., the FTC and DOJ are likewise ringing alarms at private treaties formed between innovators and generics to govern the entry of generic drugs onto pharmacy shelves. In response, the 107th and 108th Congresses are considering legislation to reform the Hatch-Waxman system, restore the provisions of the 1984 law to meet the original intent of the drafters, and quiet industry players.

The GAAP seeks to increase competition, ensure fair marketplace practices, and deter innovators and generics from engaging in anti-competitive practices or actions that tend to unfairly restrain trade. This proposed legislation severely fails to preserve the tender Hatch-Waxman balance achieved in 1984. It instead unreasonably tip the balance toward the generics' side. Such a tip is unnecessary because the Hatch-Waxman Act is working efficiently to both encourage generics and embrace innovators.

On the other hand, the DCA supplements the original Hatch-Waxman Act by protecting the availability of lower-costing generic copies of brand drugs through enforcement of antitrust and competition principles. Congress need not wait until ninety-nine percent of all ANDA applications result in private settlements before taking action. Any settlement that delays generic entry inevitably thwarts the original drafters' intent. Congress needs, however, to include more guidance to the FTC and DOJ on how to evaluate settlements for anti-competitive terms given the intricate patent validity considerations and particular ways that delays may be used.

In conclusion, the 108th Congress will not facilitate innovation by passing the GAAP. They will instead poison the pharmaceutical industry. When the House considers this proposed legislation in the coming months, hopefully they will vote against it. To truly accomplish greater access to affordable pharmaceuticals, the 108th Congress should pass a Medicare prescription drug

benefit. Seniors, disabled persons, and the uninsured will then be able to directly rely on insurance to pay for their prescription drugs. Additionally, the 108th Congress should resurrect and pass the DCA to keep competition alive in the drug marketplace.