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ANALYSIS OF RECENT PROPOSALS TO RECONFIGURE HATCH-WAXMAN

*Laura J. Robinson**

The rising costs of prescription medicines are of great concern to many Americans, especially our nation's growing population of seniors. As the prices of brand name prescription drugs rise astronomically,¹ many citizens and politicians are pushing for legislative or regulatory changes that would increase access to more affordable generic alternatives. Although the desire to increase the availability of lower priced drugs is a legitimate goal, it is important to recognize the tremendous costs involved in the invention and development of new brand name drugs, which are estimated to be between \$800 million and \$1 billion per drug.² Therefore, when making changes to the existing drug patent laws, legislators and administrators should seek to maintain a balance between increasing access to cheaper generic drugs and ensuring the continued development of new drugs by our nation's pharmaceutical companies through the preservation of strong patent rights.

The 1984 Drug Price Competition and Patent Term Restoration Act, commonly referred to as Hatch-Waxman,³ was enacted to achieve this important balance between generic manufacturers and brand name pharmaceutical companies. It was designed to assist the entry of generics onto the market while simultaneously protecting the brand name manufacturer's incentive to invent.

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¹ Last year, according to a Congressional Budget Office (CBO) study, these costs were estimated to be \$438 billion over ten years. The CBO was created by the Congressional Budget and Impoundment Control Act of 1974, and it began operating on February 24, 1975. The CBO's mission is to provide the Congress with the objective, timely, nonpartisan analyses needed for economic and budget decisions and with the information and estimates required for the congressional budget process.

² Fed. Trade Comm'n Generic Drug Entry Prior to Patent Expiration: An FTC Study, i (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter An FTC Study].

³ Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.) (amending the Federal Food Drug and Cosmetics Act (FDCA) Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-397 (2000))).

For the most part, Hatch-Waxman has been successful in achieving its goal of assisting generics onto the market, as generics now comprise more than forty-seven percent of the market as opposed to only nineteen percent prior to the law's enactment.⁴ In addition, generics are projected to comprise fifty-seven percent of the market by 2005.⁵

In effect, the Hatch-Waxman amendments created the modern generic drug industry. As a result of the Act, generic manufacturers can avoid the huge costs associated with developing a new drug. Bringing a generic drug to market costs only about \$1 million, as opposed to the \$800 million to \$1 billion required to bring a new brand name drug to market.⁶ Because of the benefits that Hatch-Waxman provides to generic companies, the generic industry continues to thrive.⁷

In the almost twenty years since its enactment, however, there has been increasing criticism that pharmaceutical companies attempt to evade the spirit of Hatch-Waxman by manipulating loopholes that exist in the law to extend the lives of their patents and delay the entry of generics onto the market. In response, Congress recently proposed changes to Hatch-Waxman. The most sweeping proposal, The Greater Access to Affordable Pharmaceuticals Act (GAAP), was approved in the Senate by a vote of 78-21 on July 31, 2002.⁸ The proposal received little attention in the House last year, but it was reintroduced by the 108th Congress on January 7, 2003.⁹ New regulatory changes have also been proposed by the Bush administration. In October 2002, at a surprise Rose Garden ceremony, President George W. Bush proposed new Federal Drug Administration (FDA) regulations that would alter the delicate compromise that Hatch-Waxman sought to achieve between pharmaceutical companies and their generic competitors.¹⁰ These new FDA rules were finalized in June 2003.¹¹

⁴ An FTC Study, *supra* note 2, at i.

⁵ Pharmaceutical Research Manufacturers of America (PhRMA), *The Hatch-Waxman Act in Perspective* at 5 (2002), available at <http://www.anon.mindsharespeedera.net/anon.mindshare/phrmadev/publications/policy/2002-06-24.435.pdf>.

⁶ *Id.* at 4.

⁷ *Id.*

⁸ The Greater Access to Affordable Pharmaceuticals Act S. 812, 107th Cong. (2002). There is other related legislation proposed in the House as well, such as The Greater Access to Affordable Pharmaceuticals Act H.R. 1862, 107th Congress (2002) and The Prescription Drug Affordability Act H.R. 5311, 107th Cong. (2002), but the Senate bill is the one most often discussed and the only one that was voted on and approved.

⁹ The Greater Access to Affordable Pharmaceuticals Act S. 54, 108th Cong. (2003). The new bill was re-introduced by Senators McCain and Schumer and referred to the Committee on Health, Education, Labor and Pensions.

¹⁰ 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, 67 Fed. Reg. 65448 (proposed Oct.

Part I of this Article provides an overview of the objectives of the Hatch-Waxman Act and the balances it seeks to establish between generic manufacturers and brand name pharmaceutical companies. Part II outlines the various strategies that pharmaceutical companies have devised to evade the spirit of Hatch-Waxman and keep generics off the market and how generic companies attempt to game the system as well. Part II also includes an analysis of recent case law involving abuse of Hatch-Waxman's 180-day exclusivity provision and abuse of Hatch-Waxman's thirty-month stay provision through improper listings in the Orange Book.¹² For discussion of the 180-day exclusivity provision, case law analysis will focus on *Abbott v. Geneva*, *Hoechst Marion Roussel v. Andrx*, and *Schering-Plough v. Upsher-Smith*.¹³ For discussion of the thirty-month stay provision, case law analysis will focus on *Mylan Pharmaceuticals v. Thompson*¹⁴ and *Andrx Pharmaceuticals v. Biovail Corporation*.¹⁵ This section also addresses the role the Federal Trade Commission (FTC) played in these cases.¹⁶

24, 2002) (to be codified at 21 C.F.R. pt. 314). The deadline for comments to the FDA was December 23, 2002. The FDA had also proposed regulatory changes to the 180-day exclusivity provision back in 1999, but a final rule never issued. 64 Fed. Reg. 42873. *See also* Steve Seidenberg, *Rule on Generics Faces Hurdles: As proposed by Bush, the regulation would change provisions of Hatch-Waxman*, 26 NAT'L L.J. 12, Nov. 11th, 2002 at 3 (commenting on the peculiarity of a presidential Rose Garden ceremony to announce on FDA regulatory proposal).

¹¹ Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated Certifying that a Patent Claiming the Drug is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) [hereinafter *New Drug Application—Final Version*]. *See also* *Bush Releases Final FDA Drug Patent Rule*, 2003 WL 10134624 WASHINGTON DRUG LETTER, June 16, 2003 (announcing release of new FDA rule, with reactions to some of its provisions).

¹² The Orange Book is another name for the listings of approved drug patents. It is also known as the Approved Drug Products with Therapeutic Equivalence Evaluations publication. 21 U.S.C. § 355(b)(1) (2000); 21 C.F.R. § 314.53(b) (2002).

¹³ Complaint, *In re* Abbott Labs. & Geneva Pharm. (FTC Dkt. No. C-3945) (May 22, 2000). Complaint, *In re* Hoechst Marion Roussel, Inc. & Andrx Corp. (FTC Dkt. No. 9293) (Mar. 16, 2000). Complaint, *In re* Schering-Plough Corp. & Am. Home Prod. (FTC Dkt. No. 9297) (Mar. 30, 2001). It is important to note that these three examples all arose out of patent infringement litigation between the pharmaceutical company and the generic company, but none of these cases ever reached court. Instead, each settled by entering into alleged anticompetitive agreements, and this section discusses the FTC actions that arose as a result of the alleged anticompetitive settlements. On the other hand, the disputes involving the thirty-month stay provision were actually litigated in court in addition to having the FTC component.

¹⁴ *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 60 U.S.P.Q.2d (BNA) 1576 (Fed. Cir. 2001).

¹⁵ *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 61 U.S.P.Q.2d (BNA) 1414 (Fed. Cir. 2002).

¹⁶ Federal Trade Commission's mission: "The Commission seeks to ensure that the nation's markets function competitively, and are vigorous, efficient, and free of undue restrictions." *See* FTC, *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, at 1, available at <http://www.ftc.gov/ogc/brfouvrw.htm> (Sept. 2002) (discussing the role and authority of the

The remainder of this Article considers abuse of the thirty-month stay provision. Part IV summarizes the recent FTC study, which discusses the abuse of the thirty-month stay provision and establishes that the abuse is simply not that prevalent.¹⁷ Part V analyzes two of the recent proposals to amend the thirty-month stay provision of Hatch-Waxman. This final section compares The Greater Access to Affordable Pharmaceuticals (GAAP) Act¹⁸ with President Bush's new FDA rules. In particular, it discusses the effects that each would have on the careful balance established by Hatch-Waxman and argues that the GAAP Act goes too far in shifting that balance toward generics while the proposed new FDA rules will be unenforceable and ineffective. Finally, this section suggests increased FDA and FTC involvement as an alternative proposal to police the more flagrant abuses. Ultimately, the best solution would create greater access to more affordable generic prescription medications while preserving the patent rights of brand name manufacturers so that they continue to have proper incentives for developing new life-saving and life-enhancing pharmaceutical drugs.

I. HISTORY AND OBJECTIVES OF THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG AND COSMETICS ACT

The Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetics Act were enacted to encourage the entry of more affordable generics onto the market while protecting the incentives for brand name drug manufacturers to invent. The Amendments seek to achieve this goal by providing benefits for generic companies to encourage them to bring their generic drugs to market while preserving the rights of the brand name patent holders.

The Hatch-Waxman Amendments have been very successful, and both the generic industry and the pharmaceutical industry continue to thrive. Within seven months of Hatch-Waxman's enactment, the FDA received eight hundred new applications for generic drugs.¹⁹ From the date of enactment in 1984, over ten

FTC).

¹⁷ An FTC Study, *supra* note 2, at ii. The study focused on instances between the years of 1992 to 2000 in which generic applicants filed applications with the FDA seeking to make and sell a drug before the brand name drug patent expired. To accomplish this, the Commission subpoenaed documents and information from brand name manufacturers and generic manufacturers. The brand name drug products included in the study include the following blockbuster drugs: Capoten, Cardizem CD, Cipro, Claritin, Lupron, Neurontin, Paxil, Pepcid, Pravacol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zolof, and Zyprexa.

¹⁸ S. 812, 107th Cong. (2002), S. 54 108th Cong. (2003).

¹⁹ ROY LEVY, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, BUREAU OF ECONOMICS 12 (1999) (The Bureau of Economics helps the FTC evaluate the economic impact of its actions by providing economic analysis and support to antitrust and consumer protection investigations).

thousand new generic drugs have entered the American pharmaceutical market, and today almost one hundred percent of brand name drugs that have gone off patent have at least one generic counterpart available.²⁰ Since generic drugs are on average half the price of their brand name counterparts, the consumer savings are considerable.²¹ The Congressional Budget Office (CBO) has estimated that the availability of generic drugs in 1994 alone saved consumers between \$8 billion and \$10 billion.²² With more patents set to expire over the next few years, these consumer cost savings are expected to increase significantly.²³

The reason for Hatch-Waxman's success is the balance it achieves between pharmaceutical companies and their generic competitors. The following discussion outlines some of the counterbalancing benefits that the Amendments provide to both generic manufacturers and brand name pharmaceutical manufacturers.

A. BENEFITS TO GENERIC MANUFACTURERS

Hatch-Waxman provides three major benefits to generic manufacturers: (1) the abbreviated new drug application (ANDA);²⁴ (2) the right to make and test the generic version of a drug before the expiration of the brand name patent;²⁵ and (3) the incentive of receiving 180 days of exclusivity for being the first generic on the market.²⁶

²⁰ *Promoting Availability of Lower Cost Generic Drugs Before Comm. on Senate Judiciary* (2003) (Statement of Dan Troy, Chief Counsel for the FDA), available at LEXIS, News Library Federal Document Clearing House Cong. Testimony File. On the other hand, before Hatch-Waxman, in the year 1983, only thirty-five percent of brand name drugs that had gone off patent had a generic counterpart available. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 37 (1998), available at <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf> (last visited Oct. 29, 2003).

²¹ Lauran Neergaard, *New Rules Promise Faster Generic Drugs*, June 12, 2003, available at LEXIS, News Library, AP File.

²² Congressional Budget Office, *supra* note 20, at 31. These figures were calculated as follows: The CBO assumed that all prescriptions would have been filled with the brand name drug if the generic was not available. The price difference between the innovator and generic version was multiplied by the number of generic prescriptions dispensed for that drug. This process was repeated for all drugs that had a generic version available and all of the savings to the consumer were added together. The data set used for this analysis was drugs sold in retail pharmacies. Since this only accounts for seventy percent of total drug sales, the actual savings are probably even higher.

²³ Jean P. Fisher, *As Patents Expire, Generic Drugs Will Get Boost*, Aug. 17, 2003, available at LEXIS, News Library, Scripps Howard News Service File.

²⁴ 21 U.S.C. § 355(j)(2)(A) (2000); 21 C.F.R. § 314.94(a) (2002).

²⁵ 35 U.S.C. § 271(e)(1) (2000).

²⁶ 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

1. *Abbreviated New Drug Application: ANDA.* Before the enactment of Hatch-Waxman, getting a generic approved by the FDA was difficult. The generic manufacturer had to perform the same safety and efficacy tests as the brand name company before its generic could get approved.²⁷ One of the benefits that Hatch-Waxman provides to generic manufacturers is the creation of a streamlined approach to FDA approval.²⁸ Under Hatch-Waxman, the generic manufacturer only must demonstrate to the FDA that its drug is the “bio-equivalent” of the brand name drug.²⁹ This procedure, called an abbreviated new drug application, or ANDA, is less costly and less time-consuming to the generic manufacturer.³⁰

2. *Exception to the General Rule of Patent Infringement.* The second way that Hatch-Waxman encourages generic manufacturers to bring their drugs to market is by creating an exception to the general rule against patent infringement. Before the enactment of Hatch-Waxman, a generic manufacturer could not begin making and testing a generic drug until after the brand name manufacturer’s patent expired. Title 35 of the United States Code dictates that “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent . . . infringes the patent.”³¹ Hatch-Waxman creates an exception to this general rule for generic drug manufacturers, which is codified at 35 U.S.C. § 271(e).³² This provision, commonly referred to as the Bolar Amendment, says: “It shall not be an act of infringement to make, use, offer to use, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture . . . of drugs. . . .”³³ This provision essentially allows generic drug manufacturers to infringe brand name manufacturers’ patents for purposes of obtaining FDA approval. No other industry enjoys this privilege to be exempt from blatant acts of patent infringement.³⁴ Allowing generic manufacturers to make and test their drugs before the expiration of the brand name patent creates more incentive for them to develop their generic drugs

²⁷ Congressional Budget Office, *supra* note 20, at 3.

²⁸ 21 U.S.C. § 355(j)(2)(A) (2000); 21 C.F.R. § 314.94(a) (2002).

²⁹ 21 U.S.C. § 355(j)(2)(A)(iv) (2000); 21 C.F.R. § 314.94(a)(7) (2002). Bioequivalence means that the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the innovator drug. *See also* Congressional Budget Office, *supra* note 20, at 3.

³⁰ 21 U.S.C. § 355(j)(2)(A) (2000); 21 C.F.R. § 314.94(a) (2002).

³¹ 35 U.S.C. § 271(a) (2000).

³² 35 U.S.C. § 271(e)(1) (2000). The Bolar Amendment overrode a 1984 Federal Circuit decision, *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984), in which the court held against the generic industry.

³³ *Id.*

³⁴ *Generic Drugs with a Focus on Assuring Greater Access to Affordable Pharmaceuticals: Hearing Before the Senate Comm. on Health, Education, Labor, and Pensions*, 107th Cong. (2002), available in 2002 WL 1067890 (F.D.C.H.) (statement of Senator Orrin Hatch).

and bring them to the FDA for approval. Prior to enactment of the Hatch-Waxman Amendments, bringing the generic to market took two to three years after the expiration of a brand name drug's patent.³⁵ Now, as a result of both Hatch-Waxman's abbreviated new drug application and the fact that a generic manufacturer can now test and manufacture its drug prior to the expiration of the brand name manufacturer's patent, that time period has been reduced to only three months.³⁶

3. *180-Day Marketing Exclusivity Benefit.* As a third incentive for generic manufacturers to bring their drugs to market, the Hatch-Waxman Amendments provide the generic company that is first to file its ANDA with the FDA 180 days of marketing exclusivity.³⁷ This is an enticing incentive to generic manufacturers because during this time of no other generic competition, the generic company first to file can sell its drug for a much higher price than it could if several other generic alternatives were on the market. This period of exclusivity begins when the first generic company begins selling its generic.³⁸

B. BENEFITS TO BRAND NAME PHARMACEUTICAL MANUFACTURERS

In addition to establishing mechanisms to assist generics onto the market, legislators recognized the need to encourage the continued development of new drugs by brand name manufacturers. Accordingly, they attempted to create balance within the Hatch-Waxman Amendments by providing benefits to pioneer companies and taking steps to preserve the patent rights that pharmaceutical companies have on their brand name drugs.

1. *Increases in Patent Term for Brand Name Manufacturers.* First, Hatch-Waxman provides brand name pharmaceutical manufacturers with the ability to restore some of the patent term lost during clinical testing and FDA approval.³⁹ The

³⁵ Congressional Budget Office, *supra* note 20, at 3.

³⁶ *Id.*

³⁷ 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

³⁸ Or the date of a court decision (either a district court or an appellate court). 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

If the application contains a certification in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—(i) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug or (ii) the date of a decision of a court in an action described in clause (iii) holding that the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Id.

³⁹ 35 U.S.C. § 156 (2000). See generally Congressional Budget Office, *supra* note 20, at 38

average length of patent term for brand name manufacturers rose by over two years after the Hatch-Waxman Amendments.⁴⁰ More specifically, the brand name manufacturer now gets back half of the time the drug spent in clinical testing⁴¹ and all of the time spent in FDA review.⁴² Further, if the FDA requires any supplemental clinical investigations, then it can grant up to three more years of patent term extensions, and drugs that contain a new chemical entity⁴³ can qualify for additional patent term benefits as well.⁴⁴

Another benefit that the Hatch-Waxman Amendments provide to pioneer companies is the ability to tack an additional six months onto their patent term in exchange for testing their drugs in the pediatric population.⁴⁵ During this six-month period, the FDA cannot approve a generic version of the drug.⁴⁶ This provision was intended to compensate for the lack of information on the effects of certain drugs in children and to contribute to the balance that Hatch-Waxman seeks to establish between brand name manufacturers and generic companies. This provision can provide a substantial benefit to brand name manufacturers because the six-month extension applies to every formulation, dosage form, and indication of the drug that contains the same active ingredient.⁴⁷

(discussing trends in patent term extensions under the Hatch-Waxman Act).

⁴⁰ Congressional Budget Office, *supra* note 20, at 39. According to the Patent and Trademark Office, the average patent term remaining to brand name manufacturers left after FDA approval rose from an average of nine years to an average of 11.5 years. (Of course, this increase in patent term is not a windfall for pharmaceutical manufacturers because the ANDA process for generic manufacturers established by Hatch-Waxman decreases the time of generic entry onto the market after patent expiration by approximately three years. So the benefits to generic manufacturers and pharmaceutical manufacturers are roughly offset in this respect).

⁴¹ Clinical trials are divided into three phases. Phase I tests the compound in fewer than 100 healthy volunteers to determine safe dosage levels and toxicity. Phase II tests the compound in 50-200 people who have the disease to determine both safety and efficacy. Phase III tests the drug in thousands of people to determine whether or not the results are statistically significant.

⁴² The average patent extension is two-three years. However, a patent term extension cannot exceed five years. In addition, the total patent term of a new drug can never exceed fourteen years. Congressional Budget Office, *supra* note 20, at 40; PhRMA, *supra* note 5, at 5-6 (quoting Sheila Shulman et al., *Patent Term Restoration: The Impact of the Hatch-Waxman Act on New Drugs and Biologics Approved 1984-1995*, 2 J. BIOLAW & BUS. 63, 66 (1999)). Notice that this maximum of fourteen years of exclusivity for a drug patent is still less than the term given to other non-drug inventions, which is usually closer to seventeen years (twenty years from filing date).

⁴³ PhRMA, *supra* note 5, at 5-6. A new chemical entity, or NCE, is the name for a drug that contains an active ingredient that the FDA has never before approved.

⁴⁴ *Id.* When the FDA approves an NCE, no generic application is accepted for five years.

⁴⁵ 21 U.S.C. § 355(a) (2000); Thomas Parker & Amy Manning, *Best Pharmaceuticals for Children Act is Now Law*, NAT'L L.J., Apr. 15, 2002, at C8.

⁴⁶ Parker & Manning, *supra* note 45, at C8. This is called the pediatric exclusivity provision.

⁴⁷ *Id.* For example, if a brand name manufacturer has a patent on an oral formulation, an intravenous formulation and a topical cream, all containing the same active ingredient, then an

Under Hatch-Waxman, another benefit accorded to brand name manufacturers is seven years of exclusivity and tax incentives if their drug qualifies for orphan drug status.⁴⁸ Orphan drug status is attributed to a medicine that treats a disease that less than 200,000 Americans suffer from.⁴⁹ This benefit is designed to encourage the research and development of new drugs in these less lucrative areas.⁵⁰ It also restores some of the balance to brand name manufacturers under Hatch-Waxman. According to the Congressional Budget Office, when all of these benefits are averaged,⁵¹ generic entry is postponed for 2.8 years.⁵²

2. *Thirty-Month Stay Provision.* Another major benefit that the Hatch-Waxman Amendments provide to brand name pharmaceutical companies is known as the thirty-month stay provision.⁵³ As part of the abbreviated new drug approval process, the generic manufacturer must certify one of four paragraphs concerning the brand name patented drug listed in the Orange Book. A paragraph I certification asserts that the listed drug is not patented; a paragraph II certification states that the listed drug has expired; a paragraph III certification indicates that the generic drug will not enter the market before the patent term of the listed drug expires; and a paragraph IV certification filed by the generic company indicates its belief that the brand name patent listed in the Orange Book is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug.⁵⁴

An ANDA submitted for approval to the FDA with a paragraph IV certification is the primary focus of this Article. This is the provision used to challenge a brand name drug manufacturer's patent. When a generic manufacturer files an ANDA with a paragraph IV certification, notice must be provided

additional six months of time will be added to the term of each patent.

⁴⁸ 21 U.S.C. § 360(c) (2000).

⁴⁹ William E. Holtz, *Reassessing Hatch-Waxman Incentives*, UPDATE MAG. (Federal Food and Drug Law Institute, Washington, D.C.), Mar. 2001, at 47-48.

⁵⁰ *Id.*

⁵¹ Meaning the term restored for the time spent in regulatory review, the term restored for the time spent in clinical testing, the time granted through the pediatric exclusivity benefit, and the time granted through the orphan drug status benefit.

⁵² Congressional Budget Office, *supra* note 20, at 42, 46. The study included all drugs approved from the time period between 1992 and 1995. Despite the patent term extensions and exclusivity provisions that Hatch-Waxman provides to brand name manufacturers, pharmaceutical companies are somewhat worse off. Their profits for bringing a new drug to market after Hatch-Waxman have declined by twelve percent. However, it is important to remember that these extensions in patent term provided by Hatch-Waxman play an important role in protecting the intellectual property rights of brand name manufacturers. Without them, the rise in generic market share since 1984 would have resulted in a much more dramatic reduction in the expected returns from marketing a brand name pharmaceutical. While pharmaceutical companies are slightly worse off under Hatch-Waxman than generic manufacturers, a balance still can be said to exist.

⁵³ 21 U.S.C. § 355(j)(5)(B)(iii) (2000); 21 C.F.R. § 314.107(b)(3) (2002).

⁵⁴ 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2000); 21 C.F.R. § 314.94(a)(12)(1)-(4) (2002).

to the brand name drug manufacturer.⁵⁵ Although preparation of an ANDA is not an act of infringement, the filing of a paragraph IV certification in connection with the ANDA is considered to be a technical act of infringement.⁵⁶ The brand name manufacturer then has the opportunity to bring an infringement action against the generic manufacturer within forty-five days; if he does this within the allotted time, then the FDA approval of the generic drug is automatically stayed for thirty months.⁵⁷

The thirty-month stay provision is a valuable benefit provided to pharmaceutical companies by Hatch-Waxman. The provision gives brand name manufacturers an opportunity to assert the validity of their patents and litigate their case before the approval of the generic. This is important because without strong, enforceable patent rights, pharmaceutical companies will not have the incentive to invent, which will decrease innovation and limit the development of new drugs. Hatch-Waxman gives generic manufacturers the right to make the generic version of the brand name drug and seek FDA approval before the expiration of the patent, and in return, it gives the pharmaceutical company a thirty-month stay in which to challenge the generic manufacturer. In this way, Hatch-Waxman seeks to establish a balance between generic manufacturers and brand name manufacturers.

The success of the Hatch-Waxman balance is evident by comparing the American system for protecting drugs with that of our European trading partners lacking an analogous system.⁵⁸ Some European countries, such as England and Germany, rely on free pricing and competition while others, such as Italy and France, rely on price fixing.⁵⁹ Neither European system is as successful as the United States' Hatch-Waxman regime.⁶⁰ Under Hatch-Waxman, the United States consistently discovers more innovative and successful drugs than any other country.⁶¹ In addition, last year the United States was projected to be responsible for approximately sixty-two percent of all breakthrough drugs.⁶²

⁵⁵ 21 U.S.C. § 355(j)(2)(B)(i) (2000); 21 C.F.R. § 314.95(c)(6) (2002).

⁵⁶ 35 U.S.C. § 271(e)(2) (2000).

⁵⁷ 21 U.S.C. § 355(j)(5)(B)(iii) (2000); 21 C.F.R. § 314.107(b)(3) (2002).

⁵⁸ See generally PhRMA, *supra* note 5, at 8 (discussing the benefits of Hatch-Waxman for the United States compared to the systems used in European countries).

⁵⁹ *Id.*

⁶⁰ *Id.* The countries that rely on the free market experience sharp declines following the expiration of the patent. The countries that fix prices are simply not competitive.

⁶¹ *Id.*

⁶² *Id.* This statistic was based on breakthrough drugs expected to enter the market last year.

II. ABUSE OF THE HATCH-WAXMAN AMENDMENTS

Despite the obvious successes of Hatch-Waxman in assisting generics onto the market while preserving the rights of brand name manufacturers, there has been criticism that some of its provisions have been abused.⁶³ Pharmaceutical corporations have devised several strategies to evade the spirit of Hatch-Waxman and prevent competition from generic drug companies. Generic manufacturers also participate in some of these abuses to prevent competition from other generic manufacturers.

A. ABUSE OF THE 180-DAY EXCLUSIVITY PROVISION: SWEETHEART DEALS

1. *Overview and Antitrust Law in the Pharmaceutical Industry.* The first type of these tactics is anticompetitive, collusive agreements between pharmaceutical companies and their generic competitors whereby the generic companies agree to delay introducing their generic version of a brand name drug into the market and the pharmaceutical companies pay them in return.⁶⁴ The pharmaceutical company pays much more than the generic company would have made from the sale of its generic, but not as much as the pharmaceutical company would lose from the competition.⁶⁵ Many of the settlements into which pharmaceutical companies and

⁶³ See generally Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers* 17 BERKELEY TECH L.J. 317 (2002) (noting some of the unintended side effects of Hatch-Waxman); Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch Waxman Act*, 10 GEO. MASON L. REV. 345 (2002) (discussing the interaction between complex patent infringement litigation and antitrust laws); Lara Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 J.L. & TECH. 227 (2000) (criticizing the various strategies that brand name manufacturers use to extend their patent term); Marcy Lobanoff, *Anti-competitive Agreements Cloaked as "Settlements" Thwart the Purposes of the Hatch Waxman Act*, 50 EMORY L.J. 1331 (2001) (discussing the rise in anticompetitive agreements between brand name and generic pharmaceutical companies); Elizabeth Powell-Bullock, *Gaming the Hatch Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21 (2002) (arguing that the current system is not effectively meeting the goals of Hatch-Waxman); David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000) (identifying problems surrounding the 180-day exclusivity provision); Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 J.L. & TECH. 389 (1999) (commenting that there has been abuse of the 180-day exclusivity provision and the thirty-month stay provision of Hatch-Waxman).

⁶⁴ *Generic Drugs: The Stalling Game*, CONSUMER REP., July 2001, at 36. These types of collusive agreements between brand name pharmaceutical companies and their generic competitors are often called sweetheart deals or horizontal agreements.

⁶⁵ *Id.* at 36.

their generic competitors enter either are or appear to be violative of the federal antitrust laws.⁶⁶

Antitrust law is a “body of law designed to protect trade and commerce from restraints, monopolies, price-fixing, and price discrimination.”⁶⁷ The objective of the antitrust law is the maintenance of competition.⁶⁸ On the other hand, both the law and public policy considerations encourage the settlement of lawsuits.⁶⁹ Antitrust concerns are often raised when competitors settle their disputes, especially when the patentee pays the alleged infringer to discontinue infringing use.⁷⁰ This is known as a reverse payment.⁷¹ Although public policy encourages the settlement of disputes, in reverse payment situations where money flows backwards, the settlement can have the appearance of violating the antitrust laws.⁷² If this agreement is reached to preserve the monopoly of one of the parties and the attendant monopoly rents, then this results in social losses and is per se illegal.⁷³ Indeed, this is precisely the behavior that the antitrust laws⁷⁴ were

⁶⁶ The principal federal antitrust laws are the Sherman Act (15 U.S.C. §§ 1-7) and the Clayton Act (15 U.S.C. §§ 12-27). The FTC derives its authority to act under section 5(a) of the FTC Act 15 U.S.C. § 45(a). See generally FTC, *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, at 9, available at <http://www.ftc.gov/ogc/brfovrw.htm> (Sept. 2002) (outlining the FTC's power and authority to investigate and litigate claims and enforce antitrust and other consumer protection laws).

⁶⁷ BLACK'S LAW DICTIONARY 92 (7th ed. 1999).

⁶⁸ *Id.*

⁶⁹ See U.S. Dept. of Justice & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995) at 28, available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> (“Settlements involving the cross-licensing of intellectual property rights can be an efficient means to avoid litigation and, in general, courts favor such settlements.”). The guidelines also advise, however, that “when such settlement involves horizontal competitors, the government will consider whether the effect of the settlement is to diminish competition between actual or potential competitors.” Balto, *supra* note 63, at 328 n.44.

⁷⁰ Daniel Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002). For a discussion of the economic incentives for generic drug firms signing patent settlement agreements and the resulting risk of monopoly, see generally Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, 14 ANTITRUST HEALTH CARE CHRON. 4 (Winter 2000/2001) and Balto, *supra* note 63, at 321.

⁷¹ Leary, *supra* note 70.

⁷² *Id.* See also Balto, *supra* note 63, at 335 (discussing the suggestion of anticompetitive intent in patent settlement agreements between innovators and challenging generic firms).

⁷³ Crane, *supra* note 70, at 748, 770. One case where emphasis was put on the “directional flow” of payments was *In re Cardizem CD*, 105 F. Supp. 2d 682 (E.D. Mich. 2000). In that case, the court said that any settlement between competitors that included reverse payments was “inherently suspicious.” *Id.* See also Complaint, Schering-Plough Corporation and Upsher-Smith Laboratories, FTC Dkt. No. 9297 (Mar. 30, 2001). The FTC has also found these types of settlements to be inherently suspicious. In its recent case against Schering-Plough, described later in the text, the major complaint of the FTC was that the settlement included a reverse payment. The FTC was unable to prove its case though, which suggests that adjudicators and decision makers are unwilling

designed to protect the consumer against. There would be considerably less concern if the cash flow traveled the other way, from infringer to patentee. Cash flow traveling from infringer to patentee is consistent with common licensing agreements. However, in settlement negotiations when the patent owner pays the company accused of infringement not to compete and either takes its product off the market or does not enter the market, it has the appearance of an antitrust violation.

But again, consensual transactions and settlements are encouraged by our legal system since they are designed to increase the social welfare and decrease waste.⁷⁵ The alternative is inefficient and expensive litigation, which ultimately will be passed on to the consumer.⁷⁶ The costs of litigation, as well as the costs of monopolies resulting from anticompetitive behavior, will both result in an increased cost to the consumer and decreased social wealth. When evaluating agreements between competitors, one must look not only at the directional flow of the payments, but also to the intent of the parties in the transaction.⁷⁷ If the

to look purely at directional flow as indicative of a per se violation of the antitrust laws. Many argue that *all* reverse payment pioneer-generic agreements are per se illegal naked market division agreements in restraint of trade. However, it is better to apply a rule of reason approach and evaluate all the factors involved. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 361 (2002).

⁷⁴ Sherman Act, 15 U.S.C. §§ 1-7 (2000); Clayton Act, 15 U.S.C. §§ 12-27 (2000); FTC Act, 15 U.S.C. § 45(a) (2000).

⁷⁵ Crane, *supra* note 70, at 749. *But see* Balto, *supra* note 63, at 337, quoting FTC Commissioner Sheila Anthony:

While settlements are generally favored, we cannot overlook other interests and concerns. Settlements can reduce costs and, through licensing or other similar means, even speed and engender competition. On the other hand, settlements between monopolists and would-be entrants are ripe for collusive dealing that leave the consumer and competition behind. In short, the public's interest must be represented at the settlement table. This is best left to a court.

⁷⁶ Crane, *supra* note 70, at 757-59. According to a 1999 study by the Intellectual Property Law Association, the median cost of litigation where the dollar amount at risk is \$10-\$100 million is approximately \$2,225,000. Anthony L. Miele, *Patent Strategy: The Manager's Guide to Profiting From Patent Portfolios*, 15 (2001). The costs of litigation also include the time and energy spent by the company on the litigation and away from the business. There are also indirect costs such as the fact that often companies must reveal their trade secrets during discovery. Some of these sort of social costs may be minimized by protective orders, but protective orders are difficult to enforce, so they are often not effective.

⁷⁷ Intent, of course, is often hard to ascertain. Looking at the intent or the "good faith" of the settling parties, however, is the prevailing standard. *See* United States v. Singer Mfg. Co. 374 U.S. 174 (1963) (examining the purpose of the parties as to whether their actions amounted to conspiracy under anti-trust laws). Since the subjective test of the parties' good faith is hard to determine, as suggested earlier, often all reverse payments are seen as being violative of the Sherman Act even though this is not necessarily the case. Another reason why this standard is ineffective is that a patentee's intentions are virtually always anticompetitive; that does not mean that the negotiated

intent is to diminish competition and preserve a patent monopoly, then the agreement is clearly a violation that needs to be remedied. However, if the intent is simply to settle the dispute and avoid excessive litigation costs, then the agreement is most likely legitimate and should stand.

There are great incentives for parties to settle patent infringement cases out of court. One reason is the uncertainty that is involved in patent litigation. In highly technical areas, courts commonly lack scientific expertise and struggle to understand the complex technology involved. Patent trials are also extremely expensive since experts are needed on both sides to explain the complicated and intricate technology to the court. Litigants may be motivated to settle for many reasons. These reasons must be thoughtfully reviewed when determining whether there has been an antitrust violation or whether the parties actually entered into a legitimate legal agreement.

Accordingly, a settlement should not be dismissed out of hand as a per se violation merely because it arose out of a patent dispute between competitors or because the payment traveled from patentee to the infringer.⁷⁸ It is easy to presume that an antitrust violation has occurred when considering agreements between brand name pharmaceutical companies and their generic competitors due to the abuse of the antitrust laws in the past in this area and the fierce competition between these two groups. However, all of the factors involved must be considered, and both social policies of pro-settlement and pro-competition must be accounted for when evaluating settlements between competitors.⁷⁹ Another social policy must be considered as well, and that is the policy favoring patent rights.⁸⁰ Our patent laws create a system of incentives that should not be ignored when evaluating whether a settlement is truly a violation of the antitrust laws. If patent owners choose to settle rather than risk their patent rights in litigation, then an argument can be made that they should be allowed to make that

settlement agreement was reached in bad faith. Perhaps the patentee simply did not want to risk losing his patent rights in court. The settlement also could be simply a mutual desire between the competition to avoid the associated costs of litigation. *See Crane, supra* note 70, at 778 (discussing approach of examining parties' intent).

⁷⁸ *Crane, supra* note 70, at 778-79 (explaining that firms may agree to a settlement where the patents of each are "anticompetitive" due to the nature of patents and the risk of losing rents).

⁷⁹ *Id.* It would also be beneficial to briefly analyze the merits of the case in making this determination. Who pays whom may depend on the strength of the relative cases, which could be indicative of the purpose behind the settlement.

⁸⁰ U.S. CONST. art. I, § 8, cl. 8. *See also* The Patent Act, 35 U.S.C. §§ 1-376 (2000). It is widely accepted that a patent system increases social wealth; however, some would argue that a patent system does not increase social wealth and only has the effect of creating artificial monopolies. *See Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 992-95, 202 U.S.P.Q. (BNA) 342 (9th Cir. 1979) (balancing conflicting bodies of law dealing with patents and problems of monopoly power).

decision.⁸¹ In the case involving settlements between pharmaceutical companies and their generic competitors, however, the 180-day exclusivity provision of Hatch-Waxman makes the anticompetitive effect of these settlements even more onerous. As will be explained in the following cases, certain types of settlement agreements between innovator companies and “first to file” generic companies could have the effect of preventing competition indefinitely.

2. *FTC Involvement and Case Law Analysis.* The FTC has been very involved in policing this type of anticompetitive behavior.⁸² The first action brought involved a collusive agreement between Abbott Laboratories and Geneva Pharmaceuticals.⁸³ The FTC alleged unreasonable restraint of trade⁸⁴ in violation of section 5 of the Federal Trade Commission Act.⁸⁵ Abbott manufactures and markets a pioneer brand name anti-hypertension drug named Hytrin.⁸⁶ At the time of this agreement, Abbott earned \$542 million per year, or \$45 million per month, from the sale of this patented drug.⁸⁷ Geneva Pharmaceuticals had obtained approval for a generic version of Hytrin and would have begun to sell the drug as soon as Abbott’s patent expired.⁸⁸ Geneva expected to earn between \$1 million and \$1.5 million a month from the sale of the generic version.⁸⁹ Abbott agreed to pay Geneva \$4.5 million per month (ten percent of what Abbott earns from sales of Hytrin per month) to *not* make and sell its competing generic version.⁹⁰ This amount was less than Abbott would stand to lose from generic competition but more than Geneva would make from the sale of its generic.

⁸¹ Others would say that the public has an interest in the determination of whether a patent is really valid. This would be an argument against the settlement of patent disputes. Another argument against allowing certain settlements in patent disputes specific to agreements reached between pharmaceutical companies and generic manufacturers is of course the fact that a settlement could have the effect of ‘putting a cork in the bottle’ and preventing generic competition for an indefinite period of time as will be shown and described in the following cases.

⁸² The FTC is very interested in protecting consumers from ever increasing drug prices which rise twelve percent to nineteen percent annually.

⁸³ *In re Abbott Lab. & Geneva Pharm.*, C-3945, 2000 FTC LEXIS 65, at *1 (FTC May 22, 2000) [hereinafter Abbott Complaint]. Abbott Laboratories is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Illinois. Geneva Pharmaceuticals, Inc. is an indirect wholly owned subsidiary of Novartis Corporation and is one of the leading generic drug manufacturers in the United States.

⁸⁴ *Id.*

⁸⁵ 15 U.S.C. § 45 (2000).

⁸⁶ Abbott Complaint, *supra* note 83, at *4.

⁸⁷ *Id.* at *6.

⁸⁸ *Id.* at *9.

⁸⁹ *Id.* at *10.

⁹⁰ *Id.*

Under Hatch-Waxman, the first generic company to apply for an ANDA is awarded 180 days of exclusivity, which starts when it begins selling the drug.⁹¹ No other generic company can enter the market until that 180-day exclusivity period ends. If that period never begins because of a collusive agreement between the generic manufacturer and the pharmaceutical company, then other generic drug manufacturers are prevented from entering the market with a generic form of Hytrin.⁹² The FTC ultimately brought this case to a successful resolution, resulting in a consent order where the two companies had to relinquish their anticompetitive agreement and agree not to enter into others like it in the future without prior approval from the FTC.

About this same time, the FTC also filed a complaint against Hoechst Marion Roussel, Inc. (Hoechst MRI), and Andrx Corporation alleging anticompetitive conduct in violation of the FTC Act.⁹³ Hoechst MRI manufactures the blockbuster drug Cardizem CD, which is a treatment for hypertension and angina.⁹⁴ Andrx submitted an ANDA with a paragraph IV certification to the FDA seeking approval of its generic version of Cardizem CD,⁹⁵ prompting Hoechst MRI's suit for infringement.⁹⁶ The parties decided to settle and pursuant to their settlement agreement, Hoechst MRI agreed to pay Andrx \$10 million per quarter to not bring their generic to the market.⁹⁷ Because Andrx was the first manufacturer to file an ANDA for a generic version of Cardizem CD, it obtained 180 days of exclusivity during which time no other generic could compete.⁹⁸ Because of this settlement agreement with Hoechst MRI, that period never began, so in effect, all generics were excluded from the market permanently. This anticompetitive agreement cost consumers \$750 million per year.⁹⁹ The FTC successfully resolved this case, resulting in a consent agreement similar to the one

⁹¹ Or the date of a court decision.

⁹² This is commonly known as blocking or parking market entry of the generic version.

⁹³ *In re Hoechst Marion Roussel, Inc. & Andrx Corp.*, No. 9293 (FTC filed Mar. 16, 2000). Hoechst Marion Roussel is owned by Aventis which is incorporated under the laws of the Republic of France.

⁹⁴ *Id.* at 2.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.* at 7.

⁹⁸ *Id.*

⁹⁹ *In re Hoechst Marion Roussel, Inc. & Andrx Corp.*, No. 9293 (FTC filed Apr. 2, 2001) (Consent Agreement) [hereinafter *Andrx Consent Agreement*]. Press Release, FTC Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp. (Apr. 2, 2001), available at <http://www.ftc.gov/opa/2001/04/hoechst.htm>.

attained in *Abbott*.¹⁰⁰ The parties must dissolve their agreement not to compete and refrain from entering into any similar agreements in the future.¹⁰¹

Despite its successes, the FTC is limited in what it can achieve in the complex area of analyzing the inherently difficult, technical, and intricate agreements that arise out of patent infringement litigations. The Schering-Plough and Upsher-Smith case, a recent high profile failure, has demonstrated that the FTC has been less successful in bringing administrative complaints in this area.¹⁰² Critics say this highly publicized failure was due to the FTC's lack of experience in cases involving complicated licensing agreements arising out of complex patent infringement cases.¹⁰³ However, the FTC has made a commitment to continue prosecuting these types of abuses of Hatch-Waxman, and as the FTC gains more experience, it will gain expertise.¹⁰⁴ In addition, the FTC could hire outside counsel specializing in patent infringement litigation to assist with the prosecution.¹⁰⁵

The administrative complaint against Schering-Plough and Upsher-Smith was brought on March 30, 2001, alleging conduct violative of section 5 of the Federal Trade Commission Act.¹⁰⁶ The complaint accuses the two companies of entering into an unlawful anticompetitive settlement agreement.¹⁰⁷ Schering-Plough owns the patent for the potassium chloride supplement marketed as K-Dur 20.¹⁰⁸

¹⁰⁰ Andrx Consent Agreement, *supra* note 99.

¹⁰¹ *Id.*

¹⁰² *In re Schering-Plough Corp. & Upsher-Smith Lab.*, FTC No. 9297 (June 27, 2002). This case is an initial decision in an administrative law proceeding. See generally 5 U.S.C. § 557 (2000) (describing initial decisions). This initial decision by an administrative law judge is subject to review by the agency (FTC) whose decision can then be reviewed by an appellate court.

¹⁰³ Stephen Nagin, *The Federal Trade Commission Tries its Hand at Patent Law with Disastrous Results*, PAT. STRATEGY & MGMT., Oct. 2002, at 5.

¹⁰⁴ *Access to Generic Drugs, Before the House Subcomm. on Health Comm. on Energy and Commerce*, 107th Cong. (2002), 2002 WL 100237966 (statement of Timothy J. Muris, Chairman, Federal Trade Commission) [hereinafter Statement of Timothy J. Muris]. See also *In re Biovail Corp.* FTC Complaint, available at www.ftc.gov/os/2002/04/biovailcomplaint.htm (stating that the FDA "has neither the expertise nor the resources to resolve complex patent coverage issues"). But see Tatiana Boncompagni, *Patently Political*, AM. LAW., Oct. 1, 2002, at 3 (stating that two FTC lawyers said that if the Schering-Plough/Upsher-Smith decision is upheld, the FTC will not have the resources to hire a flock of patent specialists and may stop pursuing these kinds of cases).

¹⁰⁵ That strategy would be similar to what the Department of Justice did in *Microsoft*. *United States v. Microsoft*, 253 F.3d 34 (D.C. Cir. 2001). Nagin, *supra* note 103, at 5.

¹⁰⁶ *In re Schering-Plough & Upsher-Smith*, No. 9297 at 2 (Mar. 30, 2001) [hereinafter Schering-Plough Complaint], 15 U.S.C. § 45 (2000).

¹⁰⁷ Schering-Plough Complaint, *supra* note 106, at 6.

¹⁰⁸ *Id.* Potassium chloride supplements, such as K-Dur 20, are given to patients who are on anti-hypertension medications to lower their blood pressure. Anti-hypertension medications have the tendency to deplete the potassium levels in the body to dangerously low levels, which could lead to heart disease. Potassium supplements are prescribed to increase potassium levels and prevent the

Upsher-Smith submitted an ANDA with a paragraph IV certification to the FDA seeking approval to manufacture a generic version of K-Dur 20 called Klor Con M20.¹⁰⁹ Since Upsher-Smith was first to file its ANDA, it received 180 days of exclusivity to market its generic version, which would have begun when the generic entered the market. As is usually the case when a generic manufacturer files an ANDA with a paragraph IV certification, Schering-Plough sued Upsher-Smith for patent infringement.¹¹⁰ On the night before the case was to go to trial, the parties settled.¹¹¹ Schering-Plough agreed to pay Upsher-Smith \$60 million and Upsher-Smith agreed to wait approximately three and a half years before marketing its generic drug¹¹² and agreed to grant licenses for five unrelated products to Schering-Plough.¹¹³

The FTC became involved with this case since this agreement appeared to be entered into solely to prevent or delay the entry of the generic version of K-Dur 20 onto the market.¹¹⁴ Evidence demonstrated that this was indeed the case because the licensed products were of little value to Schering-Plough.¹¹⁵ In fact, Schering-Plough never sold four of the five licensed products and has no plans to market those four products in the future.¹¹⁶ Also, the \$60 million bears no relation to the value of the licensed products.¹¹⁷ The FTC concluded that the effect of this agreement between Schering-Plough and Upsher-Smith unreasonably restrained commerce and therefore constituted an unfair method of competition in violation of section 5 of the FTC Act.¹¹⁸ The administrative law judge who heard the case filed an initial decision on June 27, 2002, dismissing all of the charges of anticompetitive conduct.¹¹⁹ The opinion said that although some of the evidence presented suggested the settlement agreement was anticompetitive, the FTC failed to meet its burden of proof.¹²⁰ More specifically,

cardiac problems that arise.

¹⁰⁹ *Id.* at 7.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² This would delay all generic entry of a generic potassium chloride supplement onto the market for almost four years (three years and three months from the agreement plus the 180 days of exclusivity that will begin once Upsher-Smith begins the marketing).

¹¹³ Schering-Plough Complaint, *supra* note 106, at 7.

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 6.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 9.

¹¹⁹ *In re* Schering-Plough Corp. and Upsher-Smith Labs., FTC initial decision by Administrative Law Judge, No. 9297 (June 27, 2002). This was only an initial decision and is therefore subject to appeal.

¹²⁰ Press Release, FTC, Administrative Law Judge Dismisses FTC Allegations of Anticompetitive

the judge held that the evidence submitted by the FTC was too weak to demonstrate that the \$60 million given by Schering-Plough to Upsher-Smith was not simply to settle the case or license the five products involved as Schering-Plough asserted.¹²¹ What appeared to be a clear-cut case was lost due to the FTC's lack of experience in prosecuting these types of cases.

B. ABUSE OF THE THIRTY-MONTH STAY PROVISION

One of the most often discussed forms of abuse, and the primary focus of this Article, is abuse of the thirty-month stay provision. As described above, under the United States patent law, making a patented invention before the expiration of the patent term constitutes infringement.¹²² One way Hatch-Waxman encourages generic manufacturers to bring their products to market is by creating an exception to this rule for generic drug manufacturers.¹²³ Under the Hatch-Waxman Act, a generic manufacturer is allowed to make the generic version of the drug and seek FDA approval before the expiration of the brand name manufacturer's patent. Generic manufacturers may do this because of the lengthy process of FDA approval, which could be up to three years. Thus, when the brand name drug's patent expires or is found to be invalid or not infringed, the generic is ready to be sold.

To balance this benefit given to generic manufacturers, Hatch-Waxman provides pharmaceutical companies with a thirty-month stay in the generic's approval if it brings an infringement action against the generic manufacturer.¹²⁴ The thirty-month stay of FDA approval is invoked when a pharmaceutical company files an infringement suit within forty-five days of receiving notice of the generic manufacturer's application with the paragraph IV certification.¹²⁵ Filing of the lawsuit stays the FDA's approval of the ANDA until the earliest of: (1) the date of the patent's expiration; (2) a determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of thirty months from the receipt of notice of the paragraph IV certification.¹²⁶

Conduct by Schering-Plough and Upsher-Smith (July 2, 2002), at <http://www.ftc.gov/opa/2002/07/schering.htm> (last visited Nov. 30, 2003).

¹²¹ *In re Schering-Plough Corp. and Upsher-Smith Labs.*, FTC initial decision by Administrative Law Judge, No. 9297 (June 27, 2002).

¹²² 35 U.S.C. § 271(a) (2000).

¹²³ 35 U.S.C. § 271(e)(1) (2000); *see also* Roche v. Bolar, 733 F.2d 858, 863, 221 U.S.P.Q. (BNA) 437, 441, *cert. denied*, 469 U.S. 856 (1984) (discussing testing of generic drugs before the patent expires).

¹²⁴ 21 U.S.C. § 355(j)(5)(B)(iii) (2000); 21 C.F.R. § 314.107(b)(3) (2002).

¹²⁵ *Id.*

¹²⁶ 21 U.S.C. § 355(2)(j)(5)(B)(iii) (2000); 21 C.F.R. § 314.50(i)(1)(i)(A) (2002). An FTC Study,

During this thirty-month stay while the litigation is ongoing, the brand name manufacturer may apply for other patents related to the drug and list them in the Orange Book too.¹²⁷ Before the generic manufacturer can get its drug approved, it must file an additional paragraph IV certification re-certifying that the newly listed patents are invalid or not infringed as well. Again, notice must be provided to the patent owner, and within forty-five days, the brand name manufacturer can sue and thus trigger another thirty-month stay. For every subsequent patent listed in the Orange Book, the generic company must submit another paragraph IV certification claiming that its drug does not infringe those patents either, and each time the pharmaceutical company then has the opportunity to bring an infringement action against the generic company triggering yet another thirty-month stay. Since the FDA does not police patents listed in the Orange Book,¹²⁸ and because no mechanism exists for “delisting” patents,¹²⁹ one can easily see the potential for mischief. Indeed, on a few highly publicized occasions, multiple frivolous patents were listed for the sole purpose of triggering additional thirty-month stays, and accordingly, this area of abuse is one of the most criticized aspects of Hatch-Waxman.¹³⁰

supra note 2, at 41-42.

¹²⁷ Once a pioneer company discovers a new drug and receives approval for its NDA, it does not mean that all research on the drug stops. Pharmaceutical companies often file patents related to drugs for which they already have NDAs. Once these patents issue, they may be listed in the Orange Book as well. Some typical examples of later listed patents include different formulations of the drug or extended release formulas. These types of later listed patents are entirely legitimate. In fact, it is desirable that pioneer manufacturers continue research on their existing drugs to improve them and increase their safety and efficacy.

¹²⁸ The FDA has said repeatedly that it has neither the expertise nor the resources to police the Orange Book. Instead, the FDA has only a limited “ministerial role” in listing patents. 59 Fed. Reg. 50338, 50343-50345 (Oct. 3, 1994). Actually, there is a very limited procedure in place for policing the Orange Book, but it is inadequate. 21 C.F.R. § 314.53(f) provides that if a generic manufacturer disputes the accuracy or relevance of patent information submitted to the FDA and listed in the Orange Book, it may notify the agency in writing stating its grounds for disagreement. However, the only thing the FDA does to act on such a complaint is to contact the brand name manufacturer/patent holder and ask it whether the listed patent is appropriate. If the brand name manufacturer responds that the information is appropriately listed and accurate, then the complaint is dismissed.

¹²⁹ See 21 U.S.C. § 337(a) (2000) (stating that “[e]xcept as provided in subsection (b) [of this section, regarding suits by states], all proceedings for the enforcement . . . of this Act shall be by and in the name of the United States”). This means that there is no private right to sue another party to delist its patent from the Orange Book. See also *Mylan*, 268 F.3d at 1330 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999)) (“It is well settled . . . that the FDCA creates no private right of action.”).

¹³⁰ See generally *Mylan*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx*, 276 F.3d 1368 (Fed. Cir. 2002) (illustrating abuse of the thirty-month stay by listing frivolous patents). Again, it is important to keep in mind that these are isolated cases. Most later listed patents are entirely legitimate.

To be listed in the Orange Book, patents must satisfy two criteria: (1) the patent must claim the approved drug product or method of using the approved drug product, and (2) the patent must be one with respect to which a claim of patent infringement could be reasonably asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.¹³¹ Since there is no policing of the Orange Book,¹³² and since many drugs generate over a million dollars per day, brand name manufacturers occasionally attempt to list inappropriate or frivolous patents in an effort to trigger multiple thirty-month stays.

1. *Mylan v. Bristol Myers Squibb*.

a. *Background of the Case.* The most often cited example of thirty-month stay provision abuse involves Bristol Myers Squibb Company (BMS) and their anti-anxiety drug called BuSpar, which yields \$600 million per year or approximately \$2 million per day for the company.¹³³ BuSpar was set to go off patent on November 21, 2000.¹³⁴ Mylan, in the meantime, had submitted its ANDA for a generic version of BuSpar, with a paragraph III certification and received pre-approval from the FDA.¹³⁵ Further, Mylan manufactured tablets and even loaded all of its trucks in preparation for delivery beginning at 12:00 a.m. on November 22, 2000.¹³⁶ Twelve hours before BMS's patent exclusivity was to expire, BMS received a patent for a metabolite produced by the administration of BuSpar, and BMS attorneys rushed to list the patent in the Orange Book.¹³⁷ Once a related patent has been listed in the Orange Book, the generic company then must file another certification saying that its drug does not infringe this patent or the newly listed patent is invalid. Again, the pharmaceutical company then has the opportunity to challenge, and this automatically triggers an additional thirty-month stay. Mylan Laboratories had to unload its trucks and go home.¹³⁸ Mylan brought suit claiming that the patent that Bristol Myers Squibb listed did not "claim" BuSpar since it was for a metabolite that the body makes when it metabolizes the drug and demanded that BMS delist it.¹³⁹ The District Court found for Mylan and ordered that the nonstatutory, frivolous metabolite patent

¹³¹ 21 U.S.C. § 355(b)(1)(F) (2000); 21 C.F.R. § 314.53(b) (2002).

¹³² 21 U.S.C. § 355(b)(1) (2000); 21 C.F.R. § 314.53(b) (2002). *See also Andrx*, 276 F.3d at 1378 (finding that the FDA acknowledges that it has no mechanism for review of submitted patent information), *Abbreviated New Drug Application Regulation*, 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314).

¹³³ *Mylan Pharm., Inc. v. Thompson*, 139 F. Supp. 2d 1, 7 (D. D.C. 2001).

¹³⁴ *Mylan*, 268 F.3d at 1327.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Mylan*, 268 F.3d at 1328.

be delisted.¹⁴⁰ That decision was later reversed by the Federal Court of Appeals, which concluded that a judge could not order patents to be removed from the FDA's Orange Book.¹⁴¹ Indeed, there is no mechanism whereby patents can be removed from the Orange Book, and private parties may not attempt to enforce the Federal Food Drug and Cosmetics Act.¹⁴²

b. Extent of FTC Involvement. Recently, the FTC has shown interest in cases involving abuse of the thirty-month stay provision of Hatch-Waxman.¹⁴³ Although the FTC was not a party in this case, it filed an amicus brief with the court condemning the anti-competitive behavior of Bristol Myers Squibb and opposing its motion to dismiss.¹⁴⁴ In its brief, the FTC addressed BMS's assertion that since it was "petitioning the government," it was immune from allegations of antitrust violations under the Noerr Pennington doctrine.¹⁴⁵ This doctrine was intended to protect the right of individuals and companies to communicate with the government.¹⁴⁶ The court adopted the FTC's analysis and held that simply submitting a patent to the FDA to be listed in the Orange Book

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 1332. Interestingly, in December 2001, the attorneys general of twenty states filed an antitrust lawsuit against Bristol Myers Squibb for keeping a generic version of Buspar off the market as well. These cases were settled on January 7, 2003. Bristol Myers Squibb agreed to settle for \$535 million although it "admits no wrongdoing." PR News, *Bristol Myers Squibb to Settle Antitrust Litigation* (Jan. 7, 2003), available at <http://www.prnewswire.com/news>.

¹⁴² 21 U.S.C. § 337(a) (2000).

¹⁴³ *Barriers to Entry in the Pharmaceutical Market: Before the Senate Judiciary, 108th Cong.* (2003) (statement of Timothy J. Muris, Chairman, Federal Trade Commission). The FTC began pursuing the promotion of competition in the pharmaceutical industry through antitrust enforcement in cases involving collusive settlements between pioneer companies and their generic competitors which involve abuse of the 180-day exclusivity provision and have the tendency to "park" the entrance of the generic onto the market. These cases are known as first generation FTC litigation and include collusive settlements between Abbott and Geneva, between Hoechst Marion Roussel (now Aventis) and Andrx, between Biovail and Elan, and between Schering-Plough and Upsher-Smith. The type of FTC litigation involving the thirty-month stay provision is known as second generation FTC litigation, and the FTC has only recently become involved with this unilateral abuse of Hatch-Waxman. Aside from submitting a brief in the Buspirone litigation, the only other enforcement action that the FTC has taken against this type of abuse is a consent order against Biovail for its anticompetitive activities in delaying the entrance of generic Tiazac (Andrx) onto the market. *Id.* *Biovail* is addressed in the next section.

¹⁴⁴ Memorandum of Law of Amicus Curiae Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, *In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 363 (S.D. N.Y. 2002) (No. 1410) [hereinafter FTC Memorandum].

¹⁴⁵ *Id.* at 2; see also *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965) (discussing the Noerr Pennington doctrine).

¹⁴⁶ FTC Memorandum, *supra* note 144, at 5-12.

is not “petitioning the government” and rejected BMS’s claim of Noerr-Pennington immunity and its motion to dismiss.¹⁴⁷

2. *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*¹⁴⁸

a. *Background of the Case.* Another case involving abuse of the thirty-month stay provision of Hatch-Waxman involved a brand name hypertension drug made by Biovail Laboratories and marketed as Tiazac.¹⁴⁹ In June 1998, Andrx Pharmaceuticals, a generic company, submitted an ANDA for a generic version of Tiazac along with a paragraph IV certification that the listed drug patent was invalid and its generic version did not infringe it.¹⁵⁰ Biovail Laboratories sued for patent infringement within forty-five days, thus triggering a thirty-month stay until February 2001 (or until a court decides the infringement case).¹⁵¹

In May 1997, a third party, Arnold Lippa from DOV Pharmaceuticals, filed a patent claiming an extended release formula of Tiazac, which issued in December 2000.¹⁵² Biovail Laboratories acquired an exclusive license to this drug and in mid-January 2001, listed it in the Orange Book just six weeks before Andrx’s generic version of Tiazac was to go to market.¹⁵³ Since the newly listed Biovail patent was said to “claim Tiazac,” Andrx then had to resubmit its paragraph IV certification.¹⁵⁴ This gave Biovail the opportunity to file a second infringement suit and trigger yet another thirty-month stay. As in *Mylan*, the generic company sued to get the “sham patent” delisted. Again, the court determined that there was no mechanism to delist patents from the Orange Book,¹⁵⁵ and thus, the generic company was left without any recourse except to

¹⁴⁷ *Id.*

¹⁴⁸ 276 F.3d 1368, 61 U.S.P.Q.2d (BNA) 1414 (Fed. Cir. 2002).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 1372.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1372, 61 U.S.P.Q.2d (BNA) 1414, 1418 (Fed. Cir. 2002).

¹⁵⁴ Although Biovail signed a declaration asserting that the new extended release formula patent claimed Tiazac, it actually did not. In fact, it was a completely different formulation, but since Biovail listed it in the Orange Book as claiming Tiazac, Andrx must recertify. *Id.* at 1372-73.

¹⁵⁵ Interestingly, in dicta, the appellate court’s opinion suggested that perhaps there was a way to get a sham patent delisted from the Orange Book. The court said that it is possible that an ANDA applicant can sue the FDA directly under the Administrative Procedure Act (APA) codified at 5 U.S.C. §§ 702-706 to compel approval of the ANDA if they have been “aggrieved by agency action.” *Andrx*, 276 F.3d at 1374, 1379. Since Andrx only alluded to this defense and did not assert it, the court said that it could not consider it in that particular case. However, in another case, the FDA was sued directly, and that strategy was unsuccessful. The court found that what the agency did was not arbitrary and capricious but was a reasonable exercise of its statutory and regulatory powers. *See also* *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442 (D. Md. 2001) (dismissing case where plaintiffs sought a mandatory injunction ordering the delisting of a patent).

wait for the statutory period of thirty additional months to run before it could begin to sell its generic version of the drug.¹⁵⁶

b. Extent of FTC Involvement. The FTC decided to take action against Biovail's anticompetitive behavior. This case was the first enforcement action to remedy the effects of an improper Orange Book listing.¹⁵⁷ In its complaint, the FTC alleged that Biovail obtained the patent from DOV Pharmaceuticals for the express purpose of blocking Andrx's entry into the Tiazac market.¹⁵⁸ The FTC asserted that the timing of the parties' exclusive license agreement was indicative of this fact.¹⁵⁹ As indicated in the discussion above, just as the first thirty-month stay was set to expire, Biovail acquired this license and prevented the entry of generic Tiazac onto the market. In addition, the license for the extended release formula does not even claim the same formulation of Tiazac that Biovail had been marketing (otherwise Mr. Lippa would not have been able to obtain the patent). Arnold Lippa's patent could not simultaneously be valid and be listed as claiming Tiazac in the Orange Book.¹⁶⁰ Both the timing and the character of the later listed patent suggested to the FTC that this patent was listed solely for the anticompetitive purpose of blocking Andrx from bringing a generic version of Tiazac onto the market in violation of section 7 of the Clayton Act and section 5 of the FTC Act.¹⁶¹

The FTC succeeded in its action against Biovail, and in April 2002, it issued a consent order against Biovail Corporation settling all charges in this case.¹⁶² Biovail agreed to divest the right to the patent it acquired and place no restrictions

¹⁵⁶ *Andrx*, 276 F.3d at 1380.

¹⁵⁷ Statement of Timothy J. Muris, *supra* note 104. See also *In re Biovail Corp. FTC Complaint*, available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm> [hereinafter *Biovail Complaint*]. See also Press Release, FTC, Wrongful "Orange Book" Listing Raises Red Flag with FTC; Leads to Consent Order with Biovail Corp. Concerning its Drug Tiazac (Apr. 23, 2002), available at <http://www.ftc.gov/opa/2002/04/biovailtiazac.htm>.

¹⁵⁸ *Biovail Complaint*, *supra* note 157, at 4.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 5.

¹⁶¹ FTC, *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, at 9, available at <http://www.ftc.gov/ogc/brfovrwv.htm> (Sept. 2002). The FTC enforces various antitrust laws through its Bureau of Competition. The two most significant statutory provisions are section 5(a) of the FTC Act and section 7 of the Clayton Act. Section 5(a) of the FTC Act (15 U.S.C. § 45(a)) prohibits, *inter alia*, "unfair methods of competition." This includes any conduct that would violate the Sherman Antitrust Act. Section 7 of The Clayton Act (15 U.S.C. § 18) seeks to prevent and eliminate unlawful tying contracts, corporate mergers, and acquisitions and interlocking directorates that may tend substantially to lessen competition. The FTC uses both administrative and judicial remedies to enforce the law.

¹⁶² *In re Biovail Corp.*, No. 011-0094 (F.T.C. Apr. 23, 2002) FTC Consent Order, <http://www.ftc.gov/os/2002/04/biovaildecision.htm>.

on DOV's use of the returned patent.¹⁶³ In addition, Biovail was ordered to take no further actions to initiate another thirty-month stay and again prevent Andrx's generic Tiazac from getting final approval from the FDA.¹⁶⁴ Biovail also may not make any improper Orange Book listings in the future and must notify the FDA before acquiring a patent for one of its approved drugs and listing it in the Orange Book.¹⁶⁵ As the FTC Chairman pointed out in his recent comments to Congress, "These measures should . . . send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry."¹⁶⁶

C. OTHER TYPES OF ABUSE

Another way that pharmaceutical companies delay the entry of generics onto the market is through legislative stealth by persuading legislators to add on patent extensions for certain drugs to "must pass" appropriation legislation.¹⁶⁷ One example of this is the two-year patent extension for Daypro, an anti-inflammatory agent made by Searle, which was added to the end of the omnibus budget bill that was necessary to prevent a government shutdown.¹⁶⁸ More recently, the government has become alert to this scheme, and in 1997, it cut out the rider in an emergency flood legislation, which included a lengthy patent extension for a Hoffman La Roche pain reliever.¹⁶⁹

Another way that both generic and brand name pharmaceutical companies prevent competition is by disabling their competitors by purchasing the entire supply of active ingredient that competitors need to manufacture a competing product. For example, Mylan Laboratories conspired with three chemical suppliers to deprive other companies of the active ingredient for one particular drug.¹⁷⁰ Mylan Laboratories was involved in manufacturing a generic drug Lorazepam, which is used to treat hypertension and insomnia, and Chlorazepate, which is used to treat anxiety and nicotine withdrawal.¹⁷¹ Mylan entered into ten-

¹⁶³ *Id.* at *5.

¹⁶⁴ *Id.* at *9.

¹⁶⁵ *Id.* at *7-8.

¹⁶⁶ Statement of Timothy J. Muris, *supra* note 104, at 9.

¹⁶⁷ *Generic Drugs: The Stalling Game*, CONSUMER REP., July, 2001, at 36.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25 (D.C.C. 1999) (No. 1:98CV03114, 1:98CV03115). Mylan is a corporation organized, existing, and doing business by virtue of the laws of Pennsylvania. Mylan is one of the nation's largest generic manufacturers. At the time this action was brought, Mylan made and manufactured at least ninety-one generic drugs. Cambrex, Profarmaco and Gyma are manufacturers and suppliers of chemicals for pharmaceuticals including active pharmaceutical ingredients (API).

¹⁷¹ *Id.*

year exclusive licensing agreements with three companies that made the active ingredient necessary for the manufacture of the drugs.¹⁷² These ten-year exclusive licensing agreements prevented other generic drug companies from manufacturing these two drugs since they had limited ways of obtaining the active ingredient. Once the market was cornered, Mylan Pharmaceuticals was able to significantly raise the price of its generic drugs.¹⁷³ The price of Chlorazepate increased from \$11.36 per 500-tablet bottle to \$377 per bottle and the price of Lorazepam increased from \$7.50 per 500-tablet bottle to \$190 per bottle.¹⁷⁴ This cost consumers over \$120 million, but the FTC successfully prosecuted Mylan, which was forced to compensate consumers.¹⁷⁵

As mentioned above, Hatch-Waxman encourages pharmaceutical companies to test their brand name drugs in children by providing an additional six months of exclusivity onto expired patents if the drug is tested in children. Pharmaceutical companies abuse this incentive by testing every drug in children after its patent expires, regardless of whether children could ever benefit from the drug. For example, Bristol Myers Squibb recently prolonged its patent for an anti-anxiety drug by six months by testing it in children.¹⁷⁶ Most children, of course, have no need for an anti-anxiety medication.

Another abuse of Hatch-Waxman involves the citizen's petition.¹⁷⁷ This provision of Hatch-Waxman was intended to give ordinary citizens a voice in the FDA approval process by allowing anyone to raise concerns about the efficacy or safety of certain drugs. However, pharmaceutical companies have employed scare tactics and caused citizens to become alarmed or concerned about the safety or

¹⁷² *Id.* at 33-34.

¹⁷³ *Id.* at 34.

¹⁷⁴ *Id.*

¹⁷⁵ *FTC v. Mylan Labs.*, 99 F. Supp. 2d 1 (D.D.C. 1999) (No. 1:98CV03114, 1:98CV03115, available at <http://www.ftc.gov/os/2000/11/mylandordandstip.htm>). This case may have been decided differently if Mylan could have shown a pro-competitive justification for entering into these three exclusive license agreements such as being fearful that it would run out of the active pharmaceutical ingredient (API). However, Mylan could not demonstrate any good reason for these exclusive licenses, and thus, it looked as if it was just trying to eliminate any possibility of competition. Further evidence to this was the fact that Mylan also entered into another exclusive license with a fourth supplier, FSI. When an ANDA is filed with the FDA, the generic manufacturer must indicate all of the sources from which it will be obtaining its API. It is not allowed to obtain API from any other sources other than the ones that it indicates in its application. Mylan, in their ANDA for Lorazepam, indicated that its sources would be Cambrex, Profarmaco, and Gyma. The fact that Mylan entered into a license agreement with FSI, a supplier from whom it could not even buy API, indicates that the sole purpose for these ten-year exclusive licenses was to prevent the competition from obtaining the API.

¹⁷⁶ *Id.*

¹⁷⁷ 21 C.F.R. § 10.30 (2002).

efficacy of certain generic drugs, prompting letters to the FDA.¹⁷⁸ This causes further delays to the entry of generics onto the market.¹⁷⁹

The generic industry is also guilty of abusing Hatch-Waxman. Because the first generic manufacturer to file an ANDA with the FDA obtains 180 days of exclusivity and during this time can charge much higher prices for its generic drug, generic manufacturers have a significant incentive to be the first to file. Consequently, many baseless claims are brought to challenge brand name manufacturers' patents, which wastes judicial time and resources.¹⁸⁰ Generic companies also employ the tactic of filing seriously flawed ANDA applications with the FDA to ensure "first-filer" status and then amending the applications throughout the approval process while the companies are litigating their cases.¹⁸¹ This also wastes judicial resources and forces the brand name pharmaceutical manufacturer to litigate against a continuously morphing ANDA.¹⁸²

III. FTC STUDY AND RECOMMENDATIONS REGARDING THE THIRTY-MONTH STAY PROVISION

In response to reports of abuse and calls for reform, the FTC undertook a study during the summer of 2002 to determine how prevalent the abuse of the Hatch-Waxman Amendments is and to determine whether reform is necessary. Much of the study concerned abuse of the highly criticized thirty-month stay provision.¹⁸³ The FTC examined all instances between 1992 and 2000 where a generic manufacturer filed an application with the FDA seeking to enter the market with a generic version of a drug product prior to the expiration of the brand name manufacturer's patent (in other words, with a paragraph IV certification). During the time period of the study, there were 104 generic drug applications with paragraph IV certifications filed with the FDA. Out of these 104 applications, only in eight instances have additional thirty-month stays been generated as a result of later listed patents.¹⁸⁴ The FTC study revealed that abuse

¹⁷⁸ See *supra* note 167, at 36-37.

¹⁷⁹ *Id.*

¹⁸⁰ "Challenging" refers to submitting an ANDA with a paragraph IV certification asserting that the application does not infringe the brand name manufacturer's patent or the brand name manufacturer's patent is invalid.

¹⁸¹ Robert D. Bajefsky & Gregory Chopskie, *Biting the Hand that Feeds: Generic Drugs and Abuse of the Hatch-Waxman Law*, 17 LEGAL BACKGROUNDER 4 (2002).

¹⁸² *Id.*

¹⁸³ Other parts of the study explored abuse of the 180-day exclusivity provision by collusive agreements between generic manufacturers and pioneer companies or two generic companies and abuse of the FDA's citizen petition process as used by brand name manufacturers to oppose generic applications.

¹⁸⁴ An FTC Study, *supra* note 2, at 40.

of the thirty-month stay provision is actually not as rampant as critics of the provision suggest. In fact, the results demonstrate that multiple thirty-month stays were generated in less than eight percent of all the cases involving generic applications filed with paragraph IV certifications. Moreover, the delays in FDA approval caused by the additional thirty-month stays (beyond the first thirty-month stay) ranged from only four to forty months. In short, the abuse is simply not that prevalent.

Most of these later-issued patents (patents listed in the Orange Book after the filing of the ANDA), however, were found to be of questionable character.¹⁸⁵ The FDA only allows patents directly related to the NDA to be listed in the Orange Book, such as patents involving the drug substance, the drug product, or a method of using the drug.¹⁸⁶ Metabolites, intermediates, polymorphs, and other tangentially related patents are not allowed, but since there is no policing mechanism, many inappropriate patents do end up getting listed.¹⁸⁷

One of the most flagrant abuses of the thirty-month stay provision mentioned by the study involved the drug Paxil, manufactured by Glaxo SmithKline (GSK).¹⁸⁸ Apotex¹⁸⁹ filed an ANDA with a paragraph IV certification to have its generic version of Paxil approved.¹⁹⁰ Under Hatch-Waxman, Apotex was required to provide GSK with notice of the paragraph IV certification, giving GSK the opportunity to file an infringement suit and obtain a first thirty-month stay, which it did. While that infringement action was being litigated, GSK filed *nine* additional related patents and listed them in the Orange Book.¹⁹¹ Apotex had to resubmit its paragraph IV certifications on each of these later listed patents and provide notice each time to GSK. For every notification it received, GSK had another opportunity to bring a separate infringement action and trigger yet another thirty-month stay. GSK brought infringement actions against Apotex on several of these later listed patents and generated four additional thirty-month stays.¹⁹²

Other than this case and the BMS BuSpar case, flagrant abuse of the thirty-month stay provision has been minimal. Still, the FTC recommends that the thirty-month stay should be limited to one. It also recommends that the FDA

¹⁸⁵ *Id.* at 55.

¹⁸⁶ 21 U.S.C. § 355(b)(1) (2000).

¹⁸⁷ An FTC Study, *supra* note 2, at 54-55.

¹⁸⁸ Glaxo SmithKline is headquartered in the United Kingdom, but its operations are based in the United States. Paxil is used to treat various anxiety disorders. Paxil, *About Paxil: What Does Paxil Treat?*, at http://www.paxil.com/about/ab_trt.html (last visited Oct. 6, 2003).

¹⁸⁹ Apotex is a generic manufacturer based in Canada.

¹⁹⁰ An FTC Study, *supra* note 2, at 51.

¹⁹¹ *Id.*

¹⁹² *Id.*

clarify exactly what is to be listed in the Orange Book to prevent inappropriate patents such as metabolites and product packaging from being listed and generating additional thirty-month stays.¹⁹³

IV. DISCUSSION OF THE NEW FDA REGULATIONS, THE PROPOSED LEGISLATION (GAAP ACT), AND HOW THEY ALTER THE CAREFULLY CONSTRUCTED BALANCE ESTABLISHED BY HATCH-WAXMAN

A. NEW FDA REGULATIONS

The new FDA regulations are unlikely to accomplish their stated objective of assisting generics onto the market. The rules make the two major changes to Hatch-Waxman that were recommended by the FTC study. First, they clarify the types of patents that are to be listed in the Orange Book, and second, they limit pharmaceutical companies to only one thirty-month stay. However, the FTC recommendations were merely adopted verbatim without any thoughtful analysis of how the recommendations should be implemented and without any consideration of the existing legal system in which they have to operate. Consequently, both changes will be ineffective, or their effectiveness will be limited to preventing only the most flagrant of abuses.

1. *Clarification of the Types of Patents that Should be Listed in the Orange Book.* In an effort to prevent the listing of frivolous, attenuated, and tangential patents in the Orange Book, the new rules clarify the type of patents that can be listed.¹⁹⁴ This was suggested by the FTC study to prevent some of the abuse that occurs. The regulation clearly outlines what types of patents are appropriate for Orange Book listing. The new regulation is as follows:

Patents for which information must be submitted (in the Orange Book): An applicant shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Such patents consist of patents that claim the drug substance (ingredient), patents that claim the drug product (formulation and composition), product by process patents, and patents that claim a method of use. Process patents, *patents claiming packaging, patents claiming metabolites,*

¹⁹³ *Id.* at ii and 55-56.

¹⁹⁴ New Drug Application—Final Version, *supra* note 11, at 36677.

and patents claiming intermediates are not covered by this section and information on these patents may not be submitted to the FDA.¹⁹⁵

The new rule clarifies what is inappropriate for listing; however, without also providing for any mechanism to delist or even police the Orange Book, this aspect of the new rule will be unenforceable and therefore meaningless. The FDA has repeatedly stated that it lacks the resources to police the Orange Book for improper listings, and courts have determined that there is no private right of action for parties to challenge Orange Book listings.¹⁹⁶ Therefore, the listing requirement clarification provision of the new regulation will be ineffective.

Even if the new Orange Book listing rule was enforceable, it would still be overbroad and therefore inappropriate. The new listing requirements could prevent many legitimate product packaging patents from getting listed in the Orange Book. Although some product packaging is only cosmetic and therefore unrelated to the claimed drug or does not “claim the drug,” other types of product packaging are an integral part of the drug. Patents claiming integrated drug delivery systems such as asthma inhalation devices, trans-dermal patches, and pre-filled syringes should be listable even if ordinary containers are not.¹⁹⁷

In addition, the new rules significantly expand the information that the brand name manufacturer must include in the patent declaration.¹⁹⁸ Among other things, the new rules include a claim-by-claim declaration requirement. Under the statute, *patents*, not claims, are listed in the Orange Book, and therefore, having to declare that each and every claim is legitimately listed in the Orange Book is inappropriate, would be unduly burdensome, and would prevent legitimate patents from being listed.

2. *Changes to the Thirty-Month Stay Provision.* The second major change that the new FDA regulation establishes is a limit of the thirty-month stays to only one.¹⁹⁹ Again in its rulemaking, the FDA tried to adopt the recommendation from the FTC study, but this new rule will not succeed in accomplishing the purported goal of assisting generics to market.

¹⁹⁵ 21 C.F.R. § 314.53(b) (2002) (where italics indicate recent additions to the current rule).

¹⁹⁶ *Andrx*, 276 F.3d at 1373-74; *Mylan*, 268 F.3d at 1330-32. See also An FTC Study, *supra* note 2, at 44 (citing the recent decisions of *Andrx* and *Mylan*).

¹⁹⁷ Pharmaceutical Research and Manufacturers of America (PhRMA), Comments of the Pharmaceutical Research and Manufacturers of America 13 (2002) [hereinafter PhRMA Comments].

¹⁹⁸ 21 C.F.R. § 314.53(c)(2)(i) (2002). See also PhRMA Comments, *supra* note 197, at 17 (noting that the proposed rule would require submission of detailed information for each claim of a patent).

¹⁹⁹ 21 C.F.R. § 314 (2002). Curiously, the new rules completely ignore suggestions by the July 2002 FTC Study to alter or restrict the 180-day exclusivity provision which has been arguably subject to even more abuse than the thirty-month stay provision.

The FDA tries to limit the thirty-month stay provision by “re-interpreting” some of the language pertaining to that part of the statute. Specifically, the new rule re-interprets 21 U.S.C. § 355(b)(3)(C), which says that if an ANDA application is *amended to include* a paragraph IV certification, then *notice* to the NDA holder or patent owner is required. If an ANDA contained a paragraph IV certification when it was submitted to the FDA, then notice must be given to the NDA holder, which would trigger one thirty-month stay. Under the new rule, any amendment to that ANDA application to include additional paragraph IV certifications (to later listed patents) would not require notice to the NDA holder because the original application was not *amended to include* a paragraph IV certification; it had included one all along.

As described earlier, the *notice* requirement is what triggers the thirty-month stay, or more specifically, after receiving such notice, if the brand name manufacturer brings an infringement action, then the thirty-month stay is triggered. By reinterpreting the language of section 355(b)(3)(C) to only require notice for the first paragraph IV certification, the rule attempts to limit the thirty-month stays to only one.

This change to the thirty-month stay provision is not likely to survive a court challenge. First, canons of statutory construction dictate that the clear language or plain meaning of the statute should be used rather than the mental gymnastics that the FDA used in its reinterpretation of this provision. The FDA’s interpretation of the language was extremely strained and therefore inappropriate. Second, even the FDA itself has expressed that it lacks the statutory authority to limit the scope of the thirty-month stay.²⁰⁰ Third, all previous interpretations by both the FDA and courts have been that more than one thirty-month stay is permissible.²⁰¹ Also, an agency’s interpretation of a relevant provision that

²⁰⁰ Generic Pharmaceutical Association (GPhA), Comments on Patent Listing and 30-Month Stay Proposals Submitted by the Generic Pharmaceutical Association 32 (2002) [hereinafter GPhA Comments].

²⁰¹ See Memorandum of Federal Defendants in Opposition to Plaintiff’s Motion for Summary Judgment Declaring Additional Thirty-Month Stay Inapplicable or Eliminated at 5, *Andrx Pharms. v. Biovail Corp.*, 175 F. Supp. 2d 1362 (S.D. Fla.), *vacated by* 276 F.3d 1368, 61 U.S.P.Q.2d 1414 (Fla. 2002) (No. 01-6194-civ-Dimitroulas/Johnson). Therein, the FDA unequivocally stated that:

nothing in the Hatch Waxman Amendments indicates that Congress intended the thirty-month bar to apply only once. . . . To the contrary, Congress’ decision to link the statutory stay to each individual patent claiming the approved drug, and not just the first patent, is fully consistent with the balance it struck between encouraging competition and rewarding innovation. . . . In any event, the plain language of the statute makes clear that the thirty-month stay provision of 21 U.S.C. § 355(j)(5)(B)(iii) is triggered whenever an infringement action is brought within 45 days of receipt of the notice of a paragraph IV certification.

Id. These comments were submitted to the court by the Food and Drug Administration only six

conflicts with an earlier interpretation is “entitled to considerably less deference than a consistently held agency view.”²⁰²

In addition to being ineffective and unlikely to survive a court challenge, limiting the number of thirty-month stays available to brand name companies to only one stay per ANDA may actually be detrimental to the FDA’s asserted goal of assisting generics to market. The thirty-month stay provision is an important carrot to brand name pharmaceutical companies. If it is unavailable, as it would be in certain instances under the new rules, or limited to only one, then pharmaceutical companies would not have any incentive to submit to Hatch-Waxman’s expedited patent resolution procedures. A brand name company is only entitled to receive a thirty-month stay in the approval of the generic if it lists its patent in the Orange Book and brings an infringement action within forty-five days of the notification of a paragraph IV certification from the generic company. If this thirty-month stay carrot is not available to the brand name pharmaceutical company, then it has less incentive to list its patents in the Orange Book or bring a *timely* infringement suit.²⁰³ This becomes a problem for the generic company because the generic cannot go to market without risking a later infringement suit with substantial damages under 35 U.S.C. § 284.²⁰⁴

Generic drug prices are seventy percent lower than brand name drug prices, and thus, generic company profits are much lower than the profits that would be lost by the brand name manufacturer if infringement were to be found. Therefore, a finding of infringement could be devastating for the generic company. A finding of *willful* infringement could be catastrophic to generic manufacturers since treble damages could be awarded.²⁰⁵ Consequently, generic companies cannot risk going to market unless all infringement actions against them have been settled. Without the thirty-month stay incentive, a brand name pharmaceutical company may choose not to list its patents and use the Hatch-Waxman system or wait until the generic is being sold and then sue for infringement of its patent and obtain huge lost profit damages. Limiting the thirty-month

months before the new reinterpretation was proposed. *See also* GPhA Comments, *supra* note 200, at 32 (noting the FDA’s acknowledgment that Hatch-Waxman cannot be read to limit the number of thirty-month stays).

²⁰² GPhA Comments, *supra* note 200, at 33 (quoting *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)).

²⁰³ Although 21 U.S.C. § 355(d)(6) states that the FDA has the authority to withdraw approval for an NDA that does not get listed in the Orange Book by the brand name manufacturer, the FDA never actually follows this. In fact, the FDA does not police the Orange Book at all. Thus, without the possibility of obtaining additional thirty-month stays, there is no incentive for brand name manufacturers to list their patents in the Orange Book.

²⁰⁴ 35 U.S.C. § 284 (2000) (stating that the court may increase the damages up to three times the amount found or assessed).

²⁰⁵ *Id.*

stay incentive to only one would cause savvy pharmaceutical companies to quickly adopt a new strategy: sue on the first patent to obtain the one available thirty-month stay but delay listing or suing on remaining listed patents later on or until after the generic goes to market.²⁰⁶ There would be no incentive for them to bring the action any earlier. The only incentive is to obtain an additional thirty-month stay, which is no longer available under the new rule. This would cause great uncertainty to generic manufacturers and would create even further delays in the entry of generics onto the market than under the current Hatch-Waxman system.

As formulated, the regulatory changes could also lead to gaming of the system by generic companies. Generic companies could manipulate the proposed regulation to deprive patent holders of the opportunity to obtain even a single thirty-month stay when their patents are challenged. Under prior Hatch-Waxman law, when an ANDA was filed with a paragraph IV certification, the generic applicant was required to *notify* the brand name manufacturer (NDA holder). Under the new interpretation of the statutory language, if an ANDA application already contains one paragraph IV certification and later is “amended to include” another paragraph IV certification (to another listed patent for example), then no further notification to the NDA holder is required. Therefore, no additional or subsequent thirty-month stay could arise based on the certification because the thirty-month stay is only triggered when an NDA holder initiates an infringement action based on that paragraph IV certification.²⁰⁷ In this way, the rules attempt to limit the NDA holder to only one thirty-month stay.

The new rules, however, could eliminate the NDA holder from obtaining even one thirty-month stay. Consider the following scenario: An NDA holder has two legitimate patents listed in the Orange Book: a broad patent claiming a drug and a narrow formulation patent for that drug. Let us say further that the generic drug seeking approval would infringe the broad patent but not the narrow formulation patent. The generic manufacturer could then file its ANDA with its one paragraph IV certification against the narrow formulation patent (that the generic manufacturer does not infringe) and file a paragraph III certification against the broad drug patent (that the generic manufacturer does infringe). Of course, the brand name manufacturer cannot sue and trigger a thirty-month stay because the generic does not infringe the narrow formulation patent. Now, the generic manufacturer can *switch* its paragraph III certification to a paragraph IV certification and not have to notify the brand name manufacturer because it already filed the ANDA with a paragraph IV certification.²⁰⁸ Under the prior

²⁰⁶ PhRMA Comments, *supra* note 197, at 3.

²⁰⁷ *Id.*

²⁰⁸ *Id.* at 6.

Hatch-Waxman scheme,²⁰⁹ if the generic company made this switch, it would then have to provide notice of the new paragraph IV certification to the brand name manufacturer, and the brand name manufacturer would have the opportunity to bring an infringement suit and trigger the thirty-month stay. Under the new rules, no notice is required for the second paragraph IV certification, and therefore, not only is the thirty-month stay not triggered, but the brand name manufacturer also is not even provided with notice that its patent may be infringed. This gaming is made possible by the new rules.

Neither brand name manufacturers nor the generics industry support the changes made to the thirty-month stay provisions outlined in the new FDA regulations. The opposition from both sides of the issue and the apparent lack of foresight as to the possible consequences of these changes could indicate that these new rules were essentially just hasty, ill-conceived, eleventh hour political posturing by the Bush administration.²¹⁰ The thirty-month stay provision portion of the new rules either needs to be substantially modified or withdrawn.

Overall, the generic industry sees the recent regulatory changes as a “first step” to reforming Hatch-Waxman but also recognizes that the rules are not well thought out, will be ineffective, and could even be harmful to the generic industry. Generic manufacturers strongly urge legislative changes in addition to any rulemaking. Brand name manufacturers also see the rules as harmful to their industry, but they indicate that they prefer rulemaking to any legislative changes and are willing to work with the FDA in modifying the rules.

B. THE GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT (GAAP)

In addition to the new regulatory changes, legislative changes have been proposed to amend Hatch-Waxman.²¹¹ The Greater Access to Affordable Pharmaceuticals Act, approved by the Senate last year and reintroduced this year, proposed sweeping changes to the Hatch-Waxman Amendments.²¹² Although

²⁰⁹ Meaning the version before the finalization of the new regulations.

²¹⁰ The proposal was a surprise move by the Bush administration made two short weeks before mid-term elections. Some critics even go so far as to suggest that proposing these new FDA rules was an attempt to thwart the harsh legislation (GAAP S. 812 and S. 54) which has quite a bit of support in the Senate. See *FDA Proposal Could Increase Generics, but Critics Say They've Seen It Before! Critics Say it Undercuts Bipartisan Senate Bill*, DRUG UTILIZATION REV., Dec. 1, 2002, at 89 (pointing out that “critics say [the proposed FDA rule is] a pale imitation of the Senate Bill passed in July”).

²¹¹ These proposed legislative changes have received much more attention in the literature than the new regulatory proposal. Perhaps this is because the legislation has been around longer. The rules were proposed in October 2002.

²¹² The Greater Access to Affordable Pharmaceuticals Act, S. 812, 107th Cong. (2002); The Greater Access to Affordable Pharmaceuticals Act, S. 54, 108th Cong. (2003).

legislative changes would be more effective than rulemaking in closing some of the loopholes in the Hatch-Waxman Amendments and preventing some of the abuses, The Greater Access to Affordable Pharmaceuticals Act goes too far in assisting the entry of generics onto the market and will have a disastrous effect on the ability of pioneer companies to continue the development of new lifesaving drugs. GAAP proposes radical changes to the existing system. First, GAAP would require innovators to list all of the patents in the Orange Book that a generic manufacturer would have to consider when filing its ANDA and certify that the listing was complete.²¹³ If a drug is not listed, then the brand name manufacturer forfeits entirely its right to defend its patent against infringement by a generic manufacturer.²¹⁴ Additionally, the legislation establishes a private cause of action for generic companies to sue pioneer manufacturers over their Orange Book listings,²¹⁵ and the legislation would limit the thirty-month stay provision to only one.²¹⁶

1. *GAAP Orange Book Listing Provisions.* GAAP goes too far in tipping the scales toward generic manufacturers by giving generic drug companies standing to sue innovators to have patents delisted from the Orange Book.²¹⁷ Although abuse has occurred, the solution to the problem should not be to give generic manufacturers the right to sue innovators and force them to delist patents from the Orange Book. This would result in needless, costly, and time-consuming litigation for brand name manufacturers. As the FTC study demonstrated, except for a few high profile cases, most of the patents that get listed in the Orange Book are legitimate, but pioneer companies would be forced to defend themselves in court for every patent they try to list. The first generic manufacturer to file is awarded 180 days of exclusivity to market its drug, and thus, it is in its best

²¹³ S. 812, 107th Cong. § 103(a)(C)(iv) (2002); S. 54, 108th Cong. § 3(a)(C)(iv) (2003).

²¹⁴ S. 812, 107th Cong. § 103(a)(F)(i)(ii) (2002); S. 54, 108th Cong. § 3(a)(F)(i)(ii) (2003).

²¹⁵ S. 812, 107th Cong. § 103(a)(E)(i)(I)(II)(aa)(bb) (2002); S. 54, 108th Cong. § 3(a)(E)(i)(I)(II)(aa)(bb) (2003).

²¹⁶ This limitation of the thirty-month stay provision to one was actually a compromise. The initial legislation, proposed in 2000, eliminated the automatic thirty-month stay provision entirely, saying that innovators instead would have to apply to the court for a preliminary injunction if they felt that the generic was infringing their patent. In addition to the changes discussed in the above text, GAAP has an interesting provision regarding the 180 days of exclusivity granted to the first to file generic. Under GAAP, if the first generic to file does not use his 180 days within a certain period of time, he loses his period of exclusivity. Instead, those 180 days of exclusivity 'roll over' to the second to file generic. This provision of GAAP is called the "use it or lose it" provision. Unlike the other provisions of GAAP criticized above, this provision may achieve its objective of limiting some of the anticompetitive agreements that delay or prevent the entry of generics onto the market without having a negative effect on the brand name manufacturer's incentive to invent.

²¹⁷ S. 812, 107th Cong. § 103(a)(E)(i)(I)(II)(aa)(bb) (2002); S. 54, 108th Cong. § 3(a)(E)(i)(I)(II)(aa)(bb) (2003).

interest to challenge patents listed in the Orange Book. Pioneer companies will find themselves continuously defending their listings, and those resources would not be available for innovator companies to invest in drug discovery. In addition, courts may not understand the technical and complex rules regarding the appropriateness of Orange Book listings, and therefore, at least some of the time, NDA holders will be deprived of their intellectual property because under GAAP, if the patent is not listed in the Orange Book, then it can never be used to accuse a generic manufacturer of infringement.

The new FDA rule has a somewhat better approach to the problem. The rule clarifies the types of patents that should be listed in the Orange Book and establishes a more stringent declaration procedure for NDA holders regarding their listing. This solution is not ideal either, however, since it is not likely to be enforceable. A superior solution to both of these proposals would establish within the FDA a procedure to police the Orange Book. The FDA has more expertise than courts in making determinations of the appropriateness of Orange Book listings based on its greater experience with this technical and complex area of the law. By establishing a mechanism to supervise, review, and evaluate Orange Book listings within the FDA, the pioneer companies will be free to list patents in the Orange Book without fear of multiple lawsuits, and generics will be assured that frivolous patents will not be listed (and trigger additional thirty-month stays) because someone at the FDA is watching out for such mischief.

2. *GAAP Thirty-Month Stay Provision.* Like the new FDA regulations, GAAP tries to prevent abuse of the thirty-month stay provision by limiting NDA holders to only one thirty-month stay, but it takes things further than the FDA rules in that it also forces the timely resolution of disputes. Requiring all patents to be listed in the Orange Book (within thirty days of obtaining them) forces pharmaceutical companies to participate in the Hatch-Waxman process because under GAAP, if the brand name manufacturer does not list its patents in the Orange Book, it completely forfeits its right to enforce those unlisted patents.²¹⁸ Since NDA holders are forced to participate in the Hatch-Waxman system, the timely dispute resolution problem encountered with the FDA rules is eliminated. In this regard, the legislation is likely to be more effective in bringing generics to market. However, taking away a patent holder's legitimate intellectual property rights due to its failure to list its patent in the Orange Book within thirty days seems inherently wrong. Pharmaceutical industries invest tremendous resources into discovering new medicines and obtaining intellectual property rights, and accordingly, they depend on those intellectual property rights for their survival.

²¹⁸ S. 812, 107th Cong. § 103(a)(F)(i)(ii) (2002); S. 54, 108th Cong. § 3(a)(F)(i)(ii) (2003).

Legislation should not be passed with a provision that would cause legitimately obtained patent rights to be forfeited so easily.

In addition, GAAP creates yet another way that a pharmaceutical company could needlessly forfeit its intellectual property rights. If the pharmaceutical company does not sue the generic company that files an ANDA with a paragraph IV certification within forty-five days, under this bill, the brand name manufacturer loses its right to sue the generic manufacturer for infringement entirely.²¹⁹ In other words, this bill establishes an arbitrary deadline of forty-five days for a pharmaceutical company to bring an infringement action against the generic company to defend its legitimate patent rights. GAAP goes too far in this regard as well. Legislation that prevents brand name manufacturers from enforcing their valid and legitimate patent rights is inappropriate and absurd. Patent rights are established to give innovators incentive to invent. The legitimate right to defend one's legally obtained patent should not be taken away entirely if not acted upon within an arbitrary forty-five day deadline. This would have a crippling effect on the continued research and development by innovator companies.

Many critics who argue that Hatch-Waxman is in need of reform and support drastic legislative changes to the thirty-month stay provision completely ignore the fact that legitimate patent rights could be forfeited.²²⁰ Instead, these critics choose to focus on isolated incidences of abuse from a few bad actors and conclude that harsh measures are warranted to prevent continued occurrences of abuse. Other Hatch-Waxman critics go even further by supporting both harsh legislative changes *and* strengthened enforcement of the antitrust laws in the pharmaceutical industry.²²¹ This would lead to an even more unforgiving and hostile environment for America's pharmaceutical companies and would severely hamper their efforts to continue the development of new life-saving drugs. Others, although

²¹⁹ S. 812, 107th Cong. § 104(a)(C) (2002); S. 54, 108th Cong. § 4(a)(C) (2003). Under current law, if an infringement action is not brought within forty-five days, the brand name manufacturer loses its opportunity to obtain a thirty-month stay in which to litigate, but under GAAP, the brand name manufacturer loses its right to sue the generic manufacturer and defend its patent rights entirely.

²²⁰ See Rosenthal, *supra* note 63, at 334 (reasoning that Hatch-Waxman should be amended because it illegitimately extends the patent rights of pharmaceutical companies); see also Stanley, *supra* note 63, at 358 (concluding that the perception that patent litigation settlements cause delays of generic drugs to enter the market is grounds for amending the Hatch-Waxman Act).

²²¹ See Glasgow, *supra* note 63, at 257 (arguing that “[w]hile Congressional efforts to close loopholes in Hatch-Waxman may provide some mitigation, antitrust law must . . . step in”); Lobanoff, *supra*, at 1355 (reasoning that amending the Hatch-Waxman Act and implementing harsher enforcement actions will turn the “Act around and will accomplish the Act’s original cost-containment goal”); Powell-Bullock, *supra* note 63, at 46 (proposing that Hatch-Waxman should be reformed to “include setting higher standards for patent infringement suits” and “eliminating the thirty-month stay on generic competition”).

recognizing that isolated incidences of abuse exist in the pharmaceutical industry, support a more balanced approach that preserves the rights of intellectual property holders.²²²

Overall, legislatures face tremendous pressure to take drastic steps in assisting generics to market due to the increasing prices of pharmaceutical drugs. Despite these pressures to speed generic drug approval, legislatures and critics need to bear in mind the huge costs involved in developing new cures and recognize that the period of exclusivity granted by patent law is necessary for brand name manufacturers to recoup some of these expenditures. Studies show that only three out of every ten marketed brand name drugs produce revenues that match or exceed research and development costs. Profits from successful drugs need to recoup the \$800 million to \$1 billion spent to develop the drug and make up for the millions of dollars spent on the failures.²²³ In other words, pharmaceutical companies must rely on a limited number of highly successful products to finance continuing research on treatments. Drugs must be priced accordingly.²²⁴ In addition, studies show that pharmaceutical profits are only slightly above average for all industries.²²⁵ Legislatures must recognize that although pharmaceutical companies charging exorbitant prices for life-saving medicines may seem wrong, the costs of developing new life-saving drugs are also extremely high. Taking away intellectual property rights, as GAAP does, in an effort to assist more affordable generics onto the market will jeopardize the continued discovery of new life-saving medicines by our nation's pharmaceutical companies.

C. NON-REGULATORY AND NON-STATUTORY SOLUTIONS

Clearly the regulatory and legislative proposals to reconfigure Hatch-Waxman described above are unsuitable. The regulatory changes will be completely ineffective in increasing access to affordable generics, and the legislative proposal would be disastrous to the pharmaceutical industry. If anything is to be achieved by tinkering with the statutory and regulatory provisions of Hatch-Waxman, it must be through a much more thoughtful and balanced approach than the recent proposals exhibit. Perhaps the answer is for legislatures and policy makers to not tinker with the provisions of Hatch-Waxman at all. The FTC study shows that

²²² See Kristen E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 24, 2707 (2002) (suggesting that “[g]ranted patent term extensions and creating an expedited generic approval process” balances the interests of the Hatch-Waxman).

²²³ An FTC Study, *supra* note 2, at i.

²²⁴ PhRMA Publications, *Why do Prescription Drugs Cost so Much?* 19 (2001), available at <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf>.

²²⁵ *Id.*

the abuse is not that prevalent.²²⁶ Maybe the best solution then is to allow the FTC to continue or redouble its commitment to “vigorous enforcement of the antitrust laws with respect to generic drug competition.”²²⁷ Although it has been criticized as lacking expertise in these matters,²²⁸ the FTC has had some success in enforcing consent orders against some of the most flagrant offenders, and as it takes on more cases like this, it will continue to gain experience.²²⁹ This solution would avoid the dangerous prospect of dismantling a complex set of rules designed to maintain a balance between pharmaceutical companies and generic companies so that consumers ultimately can have both new innovative life-saving medicines and access to more affordable generic drugs.

V. CONCLUSION

Hatch-Waxman has been successful in assisting more affordable generics onto the market while at the same time maintaining the incentive for pharmaceutical companies to design and develop new life-saving drugs. Since its enactment, however, several areas of abuse have delayed the entry of more affordable generic versions of drugs onto the market, which is of great concern to many Americans. Perhaps Hatch-Waxman needs to be reformed to close the loopholes that lead to some of the more flagrant abuses, but GAAP goes much too far, and the Bush administration’s new FDA rule just gets it wrong. Due to the importance of the dual goals of increasing access to affordable generics and maintaining incentives for our nation’s pharmaceutical companies to continue new drug development, legislatures and policy makers either should avoid getting involved and leave resolving the problems to the FTC or proceed with extreme caution when altering

²²⁶ An FTC Study, *supra* note 2, at 48.

²²⁷ Statement of Timothy J. Muris, *supra* note 104, at 2. In addition to increasing its enforcement efforts, the FTC also should continue its role in providing the industry with guidance and conducting industry studies through its Bureau of Economics.

²²⁸ These matters involve patent and infringement issues that the FTC does not usually handle. See Nagin, *supra* note 103, at 5 (referring to a recent high profile loss described earlier by the FTC in its case against Schering-Plough and Upsher-Smith alleging an anticompetitive settlement that prevented the generic version of the anti-hypertension drug K-Dur 20 from entering the market). The FTC’s lack of experience with patent cases was cited as being the reason for the loss. However, as mentioned earlier, the FTC will gain experience as it becomes more involved in these types of cases. Moreover, the FTC can always consider appointing firms with more experience in patent law to assist in the prosecution.

²²⁹ So far, the FTC has been successful in resolving several cases in this area by consent order. Specifically, the FTC has resolved anticompetitive settlement agreements between Abbott Laboratories and Geneva, between Hoechst Marion Roussel (now Aventis) and Andrx, and between Biovail and Elan. As discussed above, the FTC was also successful in the action it brought against Biovail for violation of the thirty-month stay provision by an improper Orange Book listing.

the delicate balance that Hatch-Waxman establishes between pharmaceutical companies and their generic competitors.