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Authorized Generics: Careful Balance Undone

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AUTHORIZED GENERICS: CAREFUL BALANCE UNDONE

by Beth Understahl*

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INTRODUCTION

In September 2005, Sanofi-Aventis, the makers of the allergy tablet Allegra, announced plans that it would launch a generic version of its drug in the marketplace.¹ Sanofi-Aventis had recently lost a court battle to Barr Pharmaceuticals in connection with Allegra patents, which marked the end of Allegra's exclusive claim on the market.² This move by Sanofi-Aventis to launch a generic Allegra can be seen as a new permutation of its battle with Barr Pharmaceuticals; however, instead of combating in court, Sanofi-Aventis has found a new mode of attack in the marketplace.

The battle between such pharmaceutical companies as Sanofi-Aventis and Barr Pharmaceuticals can be classically deemed a struggle for economic profit. Generally, the process of bringing a new drug to market takes about twelve years, and typically costs a pharmaceutical company around \$359 million.³ It has been estimated that only one in five thousand of a pharmaceutical company's compounds make it to the second round of testing while only one in five of those receive final approval.⁴ Pharmaceutical companies take huge gambles for the hard-earned right to sell new drugs to consumers and should rightly expect to

¹ See Sanofi-Aventis, Press Release, Sanofi-aventis group enters agreement with Prasco Laboratories to market generic versions of ALLEGRA® (fexofenadine HCl), (Sept. 13, 2005), available at http://en.sanofi-aventis.com/press/ppc_26088.asp?ComponentID=26088&SourcePageID=24929.

² See *In re Aventis Pharmaceuticals, Inc.*, 372 F. Supp. 2d 430 (D. N.J. 2005).

³ U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS, OTA-H-522, at 15 (Feb. 1993), available at http://www.wws.princeton.edu/ota/disk1/1993/9336_n.html [hereinafter CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT REPORT].

⁴ CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT REPORT, *supra* note 3, at 8.

recoup their investment and make a profit. Pharmaceutical companies arguably provide a public good in the form of useful products that benefit the public's welfare. While patent rights guarantee market exclusivity for a finite period to innovator pharmaceutical companies ("innovators"),⁵ one debated issue in the pharmaceutical industry revolves around the transition time between the innovators' market exclusivity and the generic drug manufacturers' ("generics") entry into the market.

Most innovators want to hold off any dilution of their market by generic drugs that compete with their brand-name product for as long as possible.⁶ The financial incentive to do so is clear. However, a battle over the billion dollar drug market⁷ inevitably ensues as the generics seek to gain access to the market to profit on the sale of new drugs.

One new and controversial tactic employed by innovators in this battle is the "authorized generic."⁸ An authorized generic is a brand-name drug which is licensed by an innovator to another company to be marketed as a generic drug.⁹ This tactic may seem counterintuitive because, as noted before, the innovators aim to keep generic competition off the market for as long as possible. However, this tactic is employed in very specific situations. Under certain circumstances, a single generic manufacturer is awarded the right to have exclusive entry in the generic market before other generics.¹⁰ The exclusive entry by a generic drug manufacturer

⁵ 35 U.S.C. § 271 (2000) (stating that a person who, without authority, makes, uses, offers to sell, or sells any patented invention during the term of the patent infringes the patent).

⁶ See CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT REPORT, *supra* note 3, at 19–21.

⁷ *Drug Pricing & Consumer Costs: Hearing Before the U.S. Senate Commerce Committee*, 107th Cong. 3 (Apr. 23, 2003) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Association), available at <http://commerce.senate.gov/hearings/042302jaegar.pdf> (stating that consumers spent \$121.8 billion on prescription drugs) [hereinafter *Jaeger Senate Hearing Statement*].

⁸ See *Andrx Pharmaceuticals, Inc., Citizen Petition*, 2004P–0563, at 4 (Dec. 23, 2004), available at <http://www.fda.gov/ohrms/dockets/dockets/04p0563/04p-0563-cp0000-01-vol1.pdf> [hereinafter *Andrx Petition*].

⁹ *Id.*

¹⁰ See 21 U.S.C.A. § 355(j)(5)(B)(iv)(I) (Supp. 2005); see *infra* Part I.B.

constitutes the first arrival of an innovator's competition in the market.

In this context, the innovator might find the practice of marketing authorized generics to be useful. The innovator might find it more profitable to simultaneously market its brand-name drug at a higher, brand-name price and also sell the drug under a generic label at a lower, generic price. Such a practice would both increase sales profits and undercut the market of the exclusive-entry generic manufacturer because of increased competition by the authorized generic on the market.

Fundamentally, this practice seems unfair to consumers because the exact same drug, manufactured by the same innovator, is offered for sale at two different prices, but only one of the drugs bears the brand-name label. Although the practice of authorizing generics may be a result of the warfare between innovators and generics, it also preys on the inaccurate beliefs of many consumers that generic drugs contain slightly different active ingredients or lower doses of the same ingredients than brand-name drugs.¹¹ Consumers may benefit from cheaper prices offered in the generic market for the first time for the drug, but the lack of disclosure is still problematic. If a consumer were aware that a generic drug was actually a brand-name drug sold at a lower price, he would most likely be unwilling to pay a premium for the brand-name drug with the "correct" label.

Complicating the mix even further are the rights of the generic companies. Once several companies are manufacturing and marketing a generic drug, each generic manufacturer, individually, might feel little impact from the addition of another generic on the market. However, the impact would be felt in the circumstance where a single generic manufacturer is awarded the right of exclusive entry in the generic market. The authorized generic would undercut the market of the exclusive-entry generic and may force the exclusive-entry generic to lower its price.

The battle between innovators and generics over market entry has taken various turns in the last decade,¹² but the use of

¹¹ Andrx Petition, *supra* note 8, at 2.

¹² See discussion *infra* Part I.C.

authorized generics has sharply increased in the last few years.¹³ In 2003, Congress enacted The Medicare Prescription Drug, Improvement, and Modernization Act¹⁴ (“Medicare Amendments”) to foster greater access to affordable health care. The legislation was enacted in part to restore a balance between the interests of innovators and generics, which had been upset because of the abuse of previous legislation by innovators.¹⁵ Specifically, the Medicare Amendments addressed a number of issues that had arisen in the interpretation of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments.¹⁶ For several years, a number of loopholes in the Hatch-Waxman Amendments were exploited by innovators who sought to keep a corner on the market for the drugs they had developed.¹⁷ The Medicare Amendments sought to restore a balance between the generics and innovators by addressing those loopholes.¹⁸ Currently, the new controversial tactic of authorized generics employed by innovators arguably defeats the purpose of the recent legislation. However, the Food and Drug Administration (“FDA”) and federal courts have found the use of authorized generics to be statutorily permissible.¹⁹

Part I of this Note explains the history of the Hatch-Waxman Amendments with a particular focus on the original intent of the law which sought to improve consumer access to affordable prescription drugs. Part II explains the Medicare Amendments, which sought to maintain the balance between the competing

¹³ Glenn Singer, *Industry’s Biggest Manufacturers Enter Generics Through Loophole; Consumers, Smaller Firms Could Suffer*, SUN-SENTINEL, Apr. 10, 2005, at 1E.

¹⁴ Pub. L. No. 108–173, 117 Stat. 2066 (2003).

¹⁵ Representative Henry A. Waxman, Hearing on Affordable Pharmaceuticals (May 8, 2002), http://www.house.gov/waxman/news_files/news_statements_afford_drugs_5_8_02.htm (describing the objective of the legislation as restoring the balance intended by the Hatch-Waxman Amendments by encouraging low-cost generic drugs and rewarding brand name drug companies) [hereinafter Waxman Statement Regarding Hearing on Affordable Pharmaceuticals].

¹⁶ Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

¹⁷ See discussion *infra* Part I.C.

¹⁸ See Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

¹⁹ See discussion *infra* Part III.

interests of generics and innovators and to achieve the goals embodied in the Hatch-Waxman Amendments. Part III explores the current controversial use of authorized generics by innovators to capture a share of the market and the state of the law regarding that tactic. Part IV of this Note evaluates the legal analysis which permits innovators to profit from authorized generics. Part V of this Note offers a possible resolution to the use of authorized generics. This Note argues that the use of authorized generics upsets the careful balance between innovators and generics, which is a central tenet of the Hatch-Waxman Amendments and the Medicare Amendments.²⁰ Finally, this Note suggests that a restriction on an innovator's use of authorized generics through drug labeling would accomplish greater access to affordable pharmaceuticals by fostering balance between innovators and generics.

I. History of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)

A. *The 1962 Amendment of the Federal Food, Drug, and Cosmetic Act*

The FDA is the regulatory body that controls nearly every aspect of the development and marketing of pharmaceuticals, including clinical testing, the safety and effectiveness of new drugs, as well as the contents of advertisements for drugs.²¹ Without FDA approval, no new drug can be marketed in the United States.²² In order to improve the safety and effectiveness of pharmaceuticals, Congress passed legislation in 1962 that dramatically altered the drug approval process.²³ The 1962

²⁰ See Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

²¹ See United States Food and Drug Administration, <http://www.fda.gov> (last visited Oct. 26, 2005).

²² See Food, Drug & Cosmetics Act, 21 U.S.C. § 355(a) (2000) (requiring FDA approval for new drugs).

²³ Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.).

Amendment of the Federal Food, Drug, and Cosmetic Act (“FDCA”) requires the FDA to positively determine that a drug is safe before it enters commercial distribution and to consider whether new drugs are effective for the purposes for which they are intended.²⁴

A manufacturer seeking to market a drug that has not previously been approved by the FDA is required by the FDCA to submit a New Drug Application (“NDA”) to the FDA.²⁵ NDAs are usually long and detailed. They must include, among other things, evidence regarding the drug’s safety and effectiveness and information about any patents held by the NDA that could reasonably be asserted to cover the drug in question.²⁶ Specifically, the application must contain the patent number and expiration date of any patent claiming the drug or a method of using the drug upon which the NDA holder could file a claim of patent infringement “if a person not licensed by the owner engag[es] in the manufacture, use, or sale of the drug.”²⁷ After the NDA is approved, the FDA is required to publish the submitted patent information in a report called “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is commonly referred to as the Orange Book.²⁸

Under the 1962 Amendment, both innovators and generics had to demonstrate the safety and effectiveness of their drug products through clinical trials.²⁹ Therefore, if a generic wanted to market a drug after the innovator’s patent had expired, the generic would have to repeat extensive clinical trials to prove the drug’s safety and effectiveness to the FDA.³⁰ A generic took the risk of having a

²⁴ *Id.* at 784.

²⁵ See 21 U.S.C.A. § 355(b) (1999), amended by 21 U.S.C.A. § 355(b)(1) (Supp. 2005).

²⁶ *Id.*

²⁷ See *id.* § 355(b)(1).

²⁸ See 21 U.S.C. § 355(j)(7)(A) (2000); see also Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at <http://www.fda.gov/cder/ob/default.htm> (last visited Oct. 26, 2005).

²⁹ Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 396–97 (1999).

³⁰ Joseph P. Reid, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 314 (1999).

patent infringement suit filed against it by an innovator if the generic began conducting these trials before the drug patent expired.³¹

B. The Drug Price Competition and Patent Term Restoration Act of 1984

In the early 1980s, both houses of Congress introduced bills to expedite generic drug approvals and to stimulate competition between innovators and generics.³² However, it was not until the 98th Congress (1983-1985), when Representative Henry Waxman, Senator Orrin Hatch, and members of the innovator and generic drug industries began negotiations, that the Hatch-Waxman legislation was enacted.³³ The Hatch-Waxman legislation “was predicated on the desire to enhance the growth of the generic drug industry while simultaneously extending patent protection for brand name drugs developed by the research-based industry.”³⁴ The Senate and House approved S. 2748 and H.R. 3605, respectively, in September 1984.³⁵ President Ronald Reagan signed the Hatch-Waxman Amendments into law on September 24, 1984.³⁶ In the Hatch-Waxman Amendments, Congress attempted to strike a balance between two competing policy interests: (i) encouraging the research and development of new drugs and (ii) enabling generics to bring low-cost copies of those drugs to market.³⁷

For innovators, the Hatch-Waxman Amendments provide a number of incentives, including: (i) patent term extensions to compensate for delays during regulatory review of the brand-name product;³⁸ (ii) mandatory notice by generics seeking to challenge

³¹ See 35 U.S.C. § 271 (2000).

³² See Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 WHITTIER L. REV. 775 (2003).

³³ See *id.* at 780–82.

³⁴ *Bill To Ease Way for Generics Is Introduced in the House*, CHAIN DRUG REV., June 4, 2001, at RX11.

³⁵ Engelberg, *supra* note 29, at 404.

³⁶ *Id.*

³⁷ See *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

³⁸ See 35 U.S.C. § 156 (2000).

patents covering the brand-name drug;³⁹ (iii) up to a thirty-month stay of generic approval during patent litigation;⁴⁰ and (iv) market exclusivity of three and five-year periods under special circumstances.⁴¹

The Hatch-Waxman Amendments favor the interests of generics by allowing for an efficient regulatory proposal known as an Abbreviated New Drug Application (“ANDA”).⁴² In an ANDA, a generic must demonstrate its drug’s “bioequivalence” with the previously approved brand-name product.⁴³ However, ANDA applicants may rely on the innovator’s previous studies and are no longer required to repeat the expensive and lengthy clinical trials that had been required by law.⁴⁴ To establish bioequivalence, the Hatch-Waxman Amendments require that a generic drug must have the same active ingredient, route of administration, dosage form, strength, and labeling requirements as the brand-name drug approved in an NDA.⁴⁵ Although these requirements are stringent, establishing bioequivalence poses less of a burden than satisfying the requirements to complete an NDA application because the ANDA applicant is able to rely on the FDA’s findings of safety and effectiveness for the brand-name drug.⁴⁶ As a result, generics are able to shorten the time period for approval and avoid much of the research and development costs that would be otherwise necessary to bring a new drug to market.

In the interest of innovators, however, the Hatch-Waxman Amendments continue to provide protection to the innovator whose patent rights have yet to expire. In order to secure FDA approval, the ANDA applicant must certify that its generic version of the approved drug will not interfere with any patents that the

³⁹ See 21 U.S.C.A. § 355(j)(2)(B)(i) (Supp. 2005).

⁴⁰ See *id.* § 355(j)(5)(B)(iii).

⁴¹ See 35 U.S.C.A. § 156 (awarding a five-year market exclusivity to companies innovating drugs containing a new chemical entity, and awarding companies making improvements to already improved drugs three years of exclusivity).

⁴² See 21 U.S.C.A. § 355(j) (1999), amended by U.S.C.A. § 355(j) (Supp. 2005).

⁴³ See 21 U.S.C. § 355(j)(4)(F) (2000).

⁴⁴ See 21 U.S.C.A. § 355(j) (1999), amended by U.S.C.A. § 355(j) (Supp. 2005); see also 21 C.F.R. § 314.94(a)(3) (2005).

⁴⁵ See 21 U.S.C. § 355(j)(2)(A)(iii), (j)(4)(D)(i)–(ii) (2000).

⁴⁶ See *id.* § 355(j)(2)(A)(i)–(iii).

NDA holder has listed.⁴⁷ That is, the ANDA applicant must certify one of the following for each patent listed in the Orange Book that claims the drug for which the ANDA applicant is seeking approval: (i) no such patent information has been submitted to the FDA; (ii) the patent has expired; (iii) the patent is set to expire on a certain date; or (iv) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA application is submitted.⁴⁸ These are commonly referred to as paragraph I, II, III and IV certifications. The first three certifications can be handled directly by the FDA, but the fourth certification requires a court's involvement because it necessitates a determination of whether the patent is valid or whether it will be infringed by the generic.⁴⁹

To balance the interests of innovators and generics, the Hatch-Waxman Amendments require that, after filing a paragraph IV certification, an ANDA applicant who wishes to challenge the patent during the patent term must give notice to the NDA-holder/patentee within twenty days of the filing.⁵⁰ The notice must include a statement detailing the factual and legal basis upon which the ANDA applicant's belief rests that the patent is invalid or will not be infringed.⁵¹ If the certification is under paragraph IV, "the approval shall be made effective immediately"⁵² unless the patent holder files an infringement action in the district court within forty-five days of receiving the notice.⁵³ If the patent holder files suit, "the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice,"⁵⁴ unless the district court rules on the infringement claim within the thirty-month period⁵⁵ or the patent expires. If the district court issues a ruling during the thirty-month stay period, the ANDA approval date is determined by the decision of the

⁴⁷ See *id.* § 355(j)(2)(A)(vii).

⁴⁸ See *id.* § 355(j)(2)(A)(vii)(I)–(IV).

⁴⁹ See 21 U.S.C.A. § 355(j)(5)(B)(i)–(iii) (Supp. 2005).

⁵⁰ See *id.* § 355(b)(3)(B)(i).

⁵¹ See *id.* § 355(j)(2)(B)(iv)(II).

⁵² See *id.* § 355(j)(5)(B)(iii).

⁵³ See *id.*

⁵⁴ See *id.*

⁵⁵ See *id.*

district court, or by the decision of the appellate court, if it is appealed.⁵⁶ During the forty-five day period in which the patent holder can file an infringement action, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue.⁵⁷ If no infringement action is filed during this forty-five day period, the FDA may immediately approve the ANDA.⁵⁸

For generics, the Hatch-Waxman Amendments give further incentives to the first ANDA applicant to file a paragraph IV certification. The generic who files an ANDA application first and successfully litigates an ensuing patent dispute is granted a 180-day period of marketing exclusivity.⁵⁹ During this period, the FDA may not approve a subsequent generic applicant's ANDA application for the same drug product.⁶⁰ The innovator's premium-priced, brand-name product is the only product competing with the generic that obtains the exclusive marketing period. Generics are therefore given an economic incentive to challenge the validity of listed patents.⁶¹ Under the original Hatch-Waxman Amendments, this six-month exclusivity period typically began on the date of the first commercial marketing of the drug by the first applicant.⁶² However, the original Hatch-Waxman Amendments also provided that the commencement of the exclusivity period could be triggered by "the date of a decision of a court . . . [which holds] the patent which is the subject of the certification [is] invalid or not infringed."⁶³

In order to deal with potential patent infringement concerns, the Hatch-Waxman Amendments provide that it is not an act of patent infringement to engage in acts necessary to prepare an

⁵⁶ See *id.* § 355(j)(5)(B)(iii)(I)(aa), (II)(aa)(AA).

⁵⁷ See *id.* § 355(j)(5)(B)(iii), (j)(5)(C).

⁵⁸ See *id.* § 355(j)(5)(B)(iii).

⁵⁹ See *id.* § 355(j)(5)(B)(iv)(I).

⁶⁰ See *id.* § 355(j)(5)(B)(iv); FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at 13 (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter FTC GENERIC DRUG STUDY].

⁶¹ See FTC GENERIC DRUG STUDY, *supra* note 60, at 57.

⁶² See 21 U.S.C.A. § 355(j)(5)(B)(iv) (Supp. 2005).

⁶³ See *id.* § 355(j)(5)(B)(iv); Pub. L. No. 108-173, 117 Stat. 2066, 2457-58 (2003).

ANDA application which would otherwise constitute infringing acts.⁶⁴ However, the Act also provides that, if an ANDA applicant attempts to obtain approval for a generic drug claimed by a valid and unexpired patent, the applicant infringes a patent by filing an ANDA.⁶⁵ In this context, no monetary damages would exist because the generic would not have yet sold any product because the thirty-month stay provision would have been triggered by the infringement suit.⁶⁶ Therefore, the innovator would not have suffered from the activities of the generic manufacturer. In exceptional cases, an ANDA applicant may be penalized for willfully infringing a patent.⁶⁷ In cases of willful infringement, the patentee is awarded reasonable attorney's fees.⁶⁸

C. Abuse of the Hatch-Waxman Amendments

In the years following enactment of the Hatch-Waxman legislation, the generic drug industry experienced significant growth.⁶⁹ The availability of generic drugs increased and the generic share in the overall prescription drug market grew from 19 percent in 1984 to 45 percent in 2001 and realized more than \$11 billion in annual sales.⁷⁰ A 1998 study by the Congressional Budget Office ("CBO"), comparing brand-name and generic prices for twenty-one different brand-name drugs facing generic competition between 1991 and 1993, found that the average retail price of a generic prescription drug in 1994 was less than half the

⁶⁴ See 35 U.S.C. § 271(e)(1) (2000).

⁶⁵ See *id.* § 271(e)(2)(A) (2000).

⁶⁶ See 21 U.S.C.A. § 355(j)(5)(B)(iii) (Supp. 2005).

⁶⁷ 35 U.S.C. § 285 (2000).

⁶⁸ *Id.*

⁶⁹ *Jaeger Senate Hearing Statement, supra* note 7, at 3; CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at ix (July 1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> [hereinafter CBO REPORT ON EFFECT OF GENERIC DRUGS IN PHARMACEUTICAL INDUSTRY].

⁷⁰ *Jaeger Senate Hearing Statement, supra* note 7, at 3 (stating that consumers spent \$11 billion on generic drugs and that 45 percent of prescription drugs sold were generic); CBO REPORT ON EFFECT OF GENERIC DRUGS IN PHARMACEUTICAL INDUSTRY, *supra* note 69, at ix (finding that 19 percent of prescription drugs sold were generic).

average retail price of a brand-name prescription drug.⁷¹ The CBO study estimated that “in 1994, purchasers saved a total of \$8 billion to \$10 billion on prescriptions at retail pharmacies by substituting generic drugs for their brand-name counterparts.”⁷²

According to the CBO study, generic competition was also good for innovation in the pharmaceutical industry. “Between 1983 and 1995, investment in [research and development] as a percentage of pharmaceutical sales by brand-name drug companies increased from 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion”⁷³ The effect of the Hatch-Waxman Amendments also benefited innovators by extending their average exclusive marketing period. The average period of time between the entrance of a brand-name drug into the market and the expiration of its patent increased from nine years in 1984 to eleven or twelve years during the years 1992 through 1995.⁷⁴

In spite of the legislation, the market is still dominated by brand-name pharmaceuticals. Although a generic drug may immediately capture about 60 percent of the market share within its first year of entry, the price for a generic drug is, on average, only 61 percent of the price for a brand-name drug during the first month of entry by the generic drug and drops to 37 percent within two years.⁷⁵ More significantly, by the year 2000, the average brand-name prescription was priced 340 percent higher than its generic equivalent (\$65.29 versus \$19.33).⁷⁶

The Hatch-Waxman Amendments increased generic drug entry in the market, but they were also vulnerable to abuse by brand-

⁷¹ CBO REPORT ON EFFECT OF GENERIC DRUGS IN PHARMACEUTICAL INDUSTRY, *supra* note 69, at 28–32.

⁷² *Id.* at xiii.

⁷³ *Id.* at xv.

⁷⁴ *See id.* at 38.

⁷⁵ *See* Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT’L J. OF TECH. MGMT. 98, 105–06 (2000).

⁷⁶ Kirking et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. OF THE AM. PHARM. ASS’N 578, 579 (2001).

name manufacturers.⁷⁷ The terms of the original Hatch-Waxman Amendments created incentives for anticompetitive behavior. There were three primary abuses: (i) late additions of patents unrelated to the basic functioning of the drug; (ii) frivolous patent infringement lawsuits; and (iii) collusive arrangements between brand-name and generic companies.⁷⁸

First, innovators abused the original Act by filing inconsequential patents prior to the expiration of their original patents in order to prevent competition from generics.⁷⁹ The practice of filing frivolous patents furthered the second abusive practice. By filing these lawsuits, innovators sought to trigger the thirty-month automatic stay provision on patents that would otherwise expire.⁸⁰ The thirty-month stay provision was intended to allow patent holders to sue potential infringers before they received FDA approval.⁸¹ However, innovators manipulated this provision by listing multiple, meritless patents with the intent of creating opportunities to trigger this automatic stay and to reap the economic benefit of the market exclusivity.⁸² Lastly, innovators began entering into competition-stifling agreements with generics who had been granted a 180-day period of market exclusivity over other generics.⁸³ Although the 180-day exclusivity provision was created as a reward to encourage generics to challenge weak patents,⁸⁴ it became a device used by innovators to keep all generics from receiving FDA approval.⁸⁵ Innovators would pay the first generic not to trigger the 180-day exclusivity period, thus indefinitely preventing all subsequent approval of ANDA applications.⁸⁶

⁷⁷ See FTC GENERIC DRUG STUDY, *supra* note 60, at 3–4 (stating that one of the purposes of the Hatch-Waxman Amendments was to enable earlier generic entry); Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

⁷⁸ Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ See FTC GENERIC DRUG STUDY, *supra* note 60, at 42.

⁸² *Id.* at 52–56.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.* at 62–63.

⁸⁶ *Id.*

II. THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT

In response to the abuses by innovator drug companies of the Hatch-Waxman Amendments' legal framework, the Senate voted on June 19, 2003, to include the Greater Access to Affordable Pharmaceuticals Amendment to the Senate Medicare bill.⁸⁷ On June 27, 2003, the House passed its own version of a Medicare prescription drug bill that also contained provisions for greater access to generic drugs.⁸⁸ Finally, on December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act ("Medicare Amendments").⁸⁹ The FDA subsequently revised its rules to be consistent with the new legislation.⁹⁰

Title XI of the Medicare Amendments, entitled "Access to Affordable Pharmaceuticals," implemented significant changes to the Hatch-Waxman Amendments.⁹¹ In addition to other concerns, the Medicare Amendments sought to address the various anticompetitive loopholes in the Hatch-Waxman Amendments. Some of the changes include: (i) new remedies for the generic applicant;⁹² (ii) new requirements for the events that trigger the generic applicant's 180-day exclusivity period;⁹³ and (iii) restrictions on brand-name drug manufacturers' thirty-month stay necessary to resolve infringement disputes involving patents listed in the Orange Book.⁹⁴

⁸⁷ Greater Access to Affordable Pharmaceuticals Act, S. 1225, 108th Cong. (1st Session 2003).

⁸⁸ CONGRESSIONAL RESEARCH SERVICE ISSUE BRIEF FOR CONGRESS, 108TH CONGRESS, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENT, at CRS-11 (updated Jan. 5, 2004), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/IB10105.pdf> [hereinafter CRS HATCH-WAXMAN ISSUE BRIEF FOR CONGRESS].

⁸⁹ 21 U.S.C.A. § 355 (1999), amended by 21 U.S.C.A. § 355 (Supp. 2005) (including the amendments made to the statute by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. (2003)).

⁹⁰ CRS HATCH-WAXMAN ISSUE BRIEF FOR CONGRESS, *supra* note 88, at CRS-6-7.

⁹¹ *Id.* at CRS-7-8.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

A. New Remedies for Generics

First, the Medicare Amendments provide that a generic may initiate a civil action against an NDA-holder in order to “obtain patent certainty.”⁹⁵ Specifically, if the patentee does not bring an infringement action within forty-five days after receiving paragraph IV notice, the ANDA applicant may bring a civil action “for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval”⁹⁶ The provision also requires that the ANDA applicant must offer the patentee confidential access to its application for infringement evaluation.⁹⁷ The new cause of action is primarily designed for the benefit of generics so that they may control the risk of potential litigation. Prior to the Medicare Amendments, an innovator could refuse to file an infringement suit within the forty-five day period following its notice of a paragraph IV certification, give up the thirty-month stay provision and wait to initiate patent litigation after the generic had received FDA approval and had begun to market and sell its product. The damages awarded in a patent infringement suit are much greater if a generic had marketed the drug.⁹⁸ Therefore, if an ANDA applicant received FDA approval after filing an unchallenged paragraph IV certification, the ANDA applicant could then either market its generic product under the threat of a potential lawsuit or abandon the product. Now, ANDA applicants may obtain certainty regarding potential patent challenges prior to entering the market.

The Medicare Amendments also allow the ANDA applicant to assert a counterclaim to de-list a patent in the Orange Book.⁹⁹ Although not an independent cause of action, an ANDA applicant is permitted to assert a counterclaim requiring the holder of the NDA to correct or delete the patent information on the ground that

⁹⁵ See 21 U.S.C.A. § 355(j)(5)(C) (Supp. 2005).

⁹⁶ *Id.* § 355(j)(5)(C)(i)(II).

⁹⁷ *Id.* § 355(j)(5)(C)(i)(III).

⁹⁸ See Laura B. Pincus, *The Computation of Damages in Patent Infringement Actions*, 5 HARV. J.L. & TECH, 95, 95–99 (1991) (noting that the fact of patent infringement establishes the fact of damages because the patentees right to exclude has been violated).

⁹⁹ See 21 U.S.C.A. § 355(c)(3)(D)(ii)(I) (Supp. 2005).

the patent does not claim either the drug for which the application was approved or an approved method of using the drug.¹⁰⁰ This provision was included in the legislation because a Federal Circuit case¹⁰¹ had found that the FDA's duty in listing patents in the Orange Book is purely ministerial and, therefore, the FDA is under no obligation to review the appropriateness of the listing.¹⁰² The FDA has no duty to review the patents submitted by the NDA holder or to assess whether the claims in these patents cover the approved drug.¹⁰³ In addition, the FDA does not determine if a claim of patent infringement could reasonably be asserted against the unauthorized sale of the drug.¹⁰⁴ The provision does not permit the generic to recover damages from a successful counterclaim.¹⁰⁵ De-listing counterclaims, however, could serve to facilitate an early resolution of ANDA patent infringement suits.¹⁰⁶

B. The 180-Day Exclusivity Period

Second, Congress addressed the statutory scheme surrounding the 180-day market exclusivity period awarded to the first ANDA filer to invalidate the protecting patent. Specifically, Congress replaced the traditional court decision "trigger" with a more complex set of provisions.¹⁰⁷ The original Hatch-Waxman Amendments provided that either the first commercial marketing by the ANDA filer or the date of a district court decision triggered the 180-day exclusivity period.¹⁰⁸ A district court decision trigger

¹⁰⁰ *Id.*

¹⁰¹ *Apotex, Inc. v. Thomson*, 347 F.3d 1335, 1347–49 (Fed. Cir. 2003).

¹⁰² *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the Senate Committee on the Judiciary*, 107th Cong. 14 (2001) (statement of Gary Buehler, Acting Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food, and Drug Administration).

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Sutherland, Asbill, & Brennan LLP, Legal Alert: Significant Changes for Prescription Drug Patent Holders, NDA Holders, and Generics (Jan. 30, 2004), at 3, available at http://www.sablaw.com/practice/practice_detail.aspx?sSubType=Z&iPractice_ID=26126003&sType=A&sPType=A [hereinafter Sutherland, Asbill & Brennan Legal Alert].

¹⁰⁶ *Id.*

¹⁰⁷ See 21 U.S.C.A. § 355(j)(5)(D) (Supp. 2005).

¹⁰⁸ See *id.* § 355(j)(5)(B)(iv); Pub. L. No. 108–173, 117 Stat. 2066, 2457–58 (2003).

forced ANDA applicants to decide whether to market the product under the threat of reversal by an appellate court or risk loss of the exclusivity period. Under the new legislation, a district court decision is not a triggering event, but the first commercial marketing trigger is maintained, subject to forfeiture.¹⁰⁹ These forfeiture events include: (i) the generic applicant's failure to market the drug within seventy-five days of approval or thirty months after submission of its ANDA, whichever is earlier (or within seventy-five days of a final decision of an appellate court, if later); (ii) ANDA application withdrawal or amendment or the withdrawal of a paragraph IV certification; (iii) failure to obtain tentative approval within thirty months of an ANDA filing; (iv) entry into an agreement that is found by the Federal Trade Commission ("FTC") or an appellate court to be in violation of the antitrust laws; and (v) expiration of all patents certified by the generic applicant.¹¹⁰ If any forfeiture event occurs, the first ANDA filer loses its 180-day exclusivity period.

Prior to the Medicare Amendments, manufacturers occasionally entered into anticompetitive agreements in an attempt to block market entry of competitive generic products.¹¹¹ In many of these agreements, a generic manufacturer entitled to the 180-day marketing exclusivity period would agree to delay launch so as not to trigger the exclusivity period.¹¹² Because competing generic applicants could not obtain FDA approval until the expiration of the exclusivity period, such agreements effectively closed the market to all generics.¹¹³ As a remedy, the Medicare Amendments require that all agreements between an ANDA filer (that has filed a paragraph IV certification) and a brand-name manufacturer or between two ANDA filers which concern the manufacturing, marketing or sale of either the brand-name or generic drug or the 180-day exclusivity period be filed with the FTC and the Department of Justice.¹¹⁴ Past decisions by the FTC indicate that

¹⁰⁹ 21 U.S.C.A. § 355(j)(5)(D) (Supp. 2005).

¹¹⁰ *Id.*

¹¹¹ *See supra* Part I.C.

¹¹² Tong, *supra* note 32, at 793.

¹¹³ *Id.* at 793–94.

¹¹⁴ Sutherland, Asbill & Brennan Legal Alert, *supra*, note 105, at 4.

agreements that include payments by the brand-name manufacturer in excess of litigation costs and those requiring a delay of market entry by the generic are those most likely to raise a red flag.¹¹⁵ Although these provisions are in place, the Medicare Amendments provide that these new forfeiture provisions are not retroactive and are effective only with respect to those applications filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003.¹¹⁶

C. Thirty-Month Stay Provision

Third, in response to abuses of the Hatch-Waxman framework arising from multiple automatic thirty-month stays, the Medicare Amendments may limit innovators to only one thirty-month stay per ANDA application.¹¹⁷ As previously mentioned, the FDA has no authority to evaluate patents listed in the Orange Book.¹¹⁸ Prior to the Medicare Amendments, each newly issued, newly listed patent would trigger an additional thirty-month stay, thereby further delaying FDA approval of any ANDA application.¹¹⁹ Under the Medicare Amendments, only patents listed in the Orange Book at the time the generic application is filed may provide the statutory basis for a thirty-month stay.¹²⁰ Therefore, patents issued and listed in the Orange Book subsequent to the ANDA filing are subject to the certification and notice provisions of the Hatch-Waxman Amendments but cannot trigger an additional thirty-month stay period.

¹¹⁵ W. Edward Bailey et al., *Recent Hatch-Waxman Reform: Balancing Innovation, Competition, and Affordability*, http://www.buildingipvalue.com/05_NA/107_110.htm (last accessed Oct. 18, 2005).

¹¹⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §1102(b), 117 Stat. 2066, 2460 (2003).

¹¹⁷ 21 U.S.C.A. § 355(j)(5)(B)(iii) (Supp. 2005).

¹¹⁸ See *supra* Part II.A.

¹¹⁹ Michael Padden & Thomas Jenkins, *Hatch-Waxman Changes*, NAT'L L.J., Feb. 23, 2004, at 13.

¹²⁰ *Id.*

III. AUTHORIZED GENERICS

A number of trends have emerged in the battle between innovators and generics to capitalize on the lucrative business of selling pharmaceuticals. One new and controversial tactic employed by innovators is the “authorized generic,” which is a licensing arrangement that allows a generic manufacturer to market a brand-name drug with a generic label. This results in increased competition for ANDA applicants. The drug industry has presented data that more than two dozen authorized generics have been launched since 2003.¹²¹ For example, in January 2004, Eon Labs (the ANDA applicant) began marketing a generic copy of Wellbutrin SR, after having secured a 180-day marketing exclusivity period.¹²² At the same time, GlaxoSmithKline (the NDA holder) released an authorized generic, which undercut the value of the exclusivity period that Eon Labs had been awarded after challenging GlaxoSmithKline’s patent.¹²³ According to industry experts, the six-month window during which other generics are excluded from the market provides immense profits to the ANDA holder.¹²⁴ Therefore, if an authorized generic were released during the exclusivity period, the generic that undertook the process of challenging the innovator’s “meritless” patent would not be rewarded with the same amount of profit because of the increased competition posed by the authorized generic.

In authorizing a generic to market its drug, the goal for innovators is to retain a portion of the market during the 180-day exclusivity period awarded to ANDA applicants subsequent to paragraph IV challenges. Under this type of arrangement, the authorized generic will usually replace the brand-name manufacturer’s label with its own.¹²⁵ Because the authorized generic is selling the brand-name drug rather than a generic version of the brand-name drug, its sale is not prohibited during the ANDA

¹²¹ Singer, *supra* note 13, at 1E.

¹²² *See id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Teva Pharmaceuticals USA, Inc., Citizen Petition, 2004P-0262/CP1, at 4 (June 9, 2004), available at <http://www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf> [hereinafter Teva Petition].

filer's exclusivity period.¹²⁶ As would be expected, such an arrangement most likely will include an agreement that the authorized generic share its profits with the innovator in consideration for the license.¹²⁷ By selling the innovator's already approved drug, the authorized generic sidesteps the Hatch-Waxman Amendments' statutory language, which only prohibits non-approved ANDA applicants from selling the drug during that period of exclusivity.¹²⁸

Because the authorization may give another generic company the opportunity to enter the market quickly even if it is not the first ANDA applicant entitled to the period of exclusivity, the ANDA filer who has obtained the 180-day exclusivity period is usually compelled to lower its prices because of the increased competition.¹²⁹ Generics argue that such arrangements decrease the profits and incentives of the first ANDA filer who assumed the risk of a patent infringement suit.¹³⁰ Therefore, allowing authorized generics to enter the market during that time serves as a penalty for the applicant who is successful in obtaining a 180-day exclusivity period.

A. *Opponents of Authorized Generics*

In 2004, several generics filed Citizen Petitions with the FDA to seek prohibition of the marketing and distribution of reduced-price authorized generic versions of brand-name products during an ANDA applicant's 180-day exclusivity period. In the first half of 2004, Mylan Pharmaceuticals, Inc. ("Mylan")¹³¹ and Teva Pharmaceuticals USA, Inc. ("Teva")¹³² submitted petitions to the

¹²⁶ *Id.*

¹²⁷ *See id.*

¹²⁸ *See id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Mylan Pharm., Inc., Citizen Petition, 2004P-0075/CP1, at 1 (Feb. 17, 2004), available at <http://www.fda.gov/ohrms/dockets/dailys/04/feb04/021804/04p-0075-cp00001-vol1.pdf> [hereinafter Mylan Petition].

¹³² Teva Petition, *supra* note 125, at 6.

FDA on the issue of authorized generics and Apotex Corporation (“Apotex”)¹³³ filed a comment in support of Mylan’s petition.

In its February 17, 2004, Citizen Petition, Mylan argued that authorized generics are “generic” drugs and therefore subject to the prohibitions on marketing generic drugs during the exclusivity period awarded to the first generic applicant.¹³⁴ Mylan further argued that the “emerging trend” of marketing authorized generics “will negatively affect the incentive given to generic manufacturers to challenge drug patents.”¹³⁵

In the petitions, the generics contend that allowing licensing agreements between authorized generics and innovators cripples the generic manufacturer’s ability to derive a higher profit margin during the exclusivity period, which is when generics usually recoup the litigation costs incurred in challenging patents.¹³⁶ Without the financial reward, generics argue they will have little incentive to challenge patents, especially patents protecting drugs with modest sales.¹³⁷ Further, they allege that authorized generics will eventually obstruct consumers’ access to lower-priced drugs in the long term.¹³⁸ At the same time, innovators dispute these claims by arguing that such licenses promote early introduction of multiple competitive products and allow consumers expedited access to lower-priced generics¹³⁹—goals that are aligned with the intent of Congress in passing the Hatch-Waxman Amendments and the Medicare Amendments.

¹³³ Apotex Corp., Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004P-0075/CP1, at 4 (March 24, 2004), available at <http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf> (filed in support of Mylan Petition) [hereinafter Apotex Comment].

¹³⁴ Mylan Petition, *supra* note 131, at 1.

¹³⁵ *Id.* at 2.

¹³⁶ See Teva Petition, *supra* note 125, at 6.

¹³⁷ *Id.*

¹³⁸ See Apotex Comment, *supra* note 133, at 4.

¹³⁹ FDA, FDA TALK PAPER: FDA SUPPORTS BROADER ACCESS TO LOWER PRICED DRUGS (July 2, 2004), <http://www.fda.gov/bbs/topics/answers/2004/ANS01296.html>.

B. Current State of Law Regarding Authorized Generics

The FDA rejected both Teva's and Mylan's Citizen Petitions in a July 2, 2004 ruling.¹⁴⁰ The FDA stated that it would not prohibit authorized generics from marketing an innovator's drug during the first ANDA applicant's exclusivity period.¹⁴¹ The FDA found that this decision would advance the goal of more rapid access to lower-priced prescription drugs because authorized generics increase early competition and allow consumers more rapid access to lower-priced drugs,¹⁴² particularly during the exclusive 180-day period when the prices for generic drugs are often higher than they are after other generic manufacturers are able to enter the market.¹⁴³ By emphasizing that the FDA does not generally review business dealings between drug manufacturers,¹⁴⁴ the FDA also clarified that its mission is to protect and promote the public health.¹⁴⁵ The FDA concluded that the marketing of authorized generics is a pro-competitive business practice, and that, therefore, it would not intervene as the petitioners had requested.¹⁴⁶

In the December 23, 2004 decision, in *Teva Pharmaceuticals, Industries, Ltd. v. FDA*,¹⁴⁷ the United States District Court for the District of Columbia also refused to intervene on behalf of a generic's action challenging the FDA's ruling.¹⁴⁸ The district court found that the FDA had given effect to the plain and unambiguous language of the provisions of the Hatch-Waxman Amendments.¹⁴⁹ The district court granted summary judgment to the FDA, holding that the FDA's decision was not arbitrary, capricious, or contrary

¹⁴⁰ Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, Department of Health & Human Services, to Stuart A. Williams, Chief Legal Officer, Mylan Pharmaceuticals Inc., and James N. Czaban, Heller Ehrman White & McAuliffe LLP (July 2, 2004) (denying Mylan and Teva Petitions), available at <http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0261-pdn0001.pdf> [hereinafter FDA Ruling].

¹⁴¹ *Id.* at 13.

¹⁴² *Id.* at 10.

¹⁴³ *Id.* at 12.

¹⁴⁴ *Id.* at 3.

¹⁴⁵ *See id.* at 5.

¹⁴⁶ *Id.* at 13.

¹⁴⁷ *Teva Pharm., Indus. v. FDA*, 355 F. Supp. 2d 111 (D.D.C. 2004).

¹⁴⁸ *See id.*

¹⁴⁹ *Id.* at 117–18.

to law.¹⁵⁰ Teva filed an appeal to the United States Court of Appeals, in the District of Columbia Circuit.¹⁵¹ However, on June 3, 2005, the circuit court affirmed the district court's decision.¹⁵²

IV. ANALYSIS OF THE FDA AND DISTRICT COURT'S DECISIONS

The FDA's July 2, 2004 ruling¹⁵³ and the court's decision in *Teva Pharmaceuticals, Industries, Ltd, v. FDA*¹⁵⁴ are out of sync with the spirit of the Hatch-Waxman Amendments and the Medicare Amendments. The history of the Hatch-Waxman Amendments clearly demonstrates that innovators will exploit loopholes in the statutory language to squeeze out as much market share as possible when faced with generic competition.¹⁵⁵ By taking a strict statutory approach in their decisions, the FDA and the court in *Teva* tip the balance in favor of innovator control in the pharmaceutical market. While this tipping may be a nod to Congress to again address loopholes in the Hatch-Waxman legislation, the FDA and the *Teva* court decisions perpetuate the cycle of abuse instead of curtailing it. The FDA and the *Teva* court decisions suggest that Congress intended to exclude authorized generics from the requirements and prohibitions imposed on other generics because authorized generics are not specifically addressed in the legislation. However, this approach is inflexible to the design of legislation that was meant to foster a healthy balance between generics and innovators.

The FDA makes three main arguments in support of its refusal to prohibit authorized generics from marketing during an ANDA applicant's exclusivity period: (i) the authorized generics are marketing a brand-name product, not a generic product;¹⁵⁶ (ii) the

¹⁵⁰ *Id.* at 117–19.

¹⁵¹ *Teva Pharm., Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

¹⁵² *Id.*

¹⁵³ FDA Ruling, *supra* note 140.

¹⁵⁴ 355 F. Supp. 2d 111 (D.D.C. 2004).

¹⁵⁵ *See supra* Part I.C.

¹⁵⁶ FDA Ruling, *supra* note 140, at 3–6.

FDA does not have the authority to regulate commercial marketing arrangements;¹⁵⁷ and (iii) authorized generics do not undermine the goal of the Hatch-Waxman legislation to bring more affordable pharmaceuticals to the market.¹⁵⁸ These arguments remain unpersuasive for the following reasons: (i) in a previous ruling, the FDA found that an authorized generic had marketed a generic product (rather than a brand-name product) for the purpose of triggering a 180-day exclusivity period;¹⁵⁹ (ii) the FDA has broad powers to promulgate regulations for the efficient enforcement of the FDCA;¹⁶⁰ and (iii) allowing innovators to license their drugs to an authorized generic undermines the incentive for generics to challenge meritless patents. This final factor is contrary to one of the major provisions of the Hatch-Waxman Amendments—to promote competition in the pharmaceutical market.

A. Definition of Authorized Generic

First, the FDA's ruling refused to equate authorized generics with generics that seek approval through an ANDA filing.¹⁶¹ This is inconsistent with a previous FDA ruling, dated February 6, 2001,¹⁶² and a federal district court decision.¹⁶³ No language or provision in the Hatch-Waxman legislation directly addresses the marketing of authorized generics during an ANDA applicant's exclusivity period. However, opponents of these licensing agreements argue that no other generic, authorized or not, should be permitted on the market during the 180-day exclusivity period.¹⁶⁴

¹⁵⁷ *Id.* at 6–7.

¹⁵⁸ *Id.* at 12–13.

¹⁵⁹ *Mylan Pharm., Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D. W. Va. 2001).

¹⁶⁰ 21 U.S.C. § 371(a) (2000).

¹⁶¹ See FDA Ruling, *supra* note 140.

¹⁶² See Letter from Janet Woodcock, Director of Center for Drug Evaluation and Research, Department of Health & Human Services, to Deborah A. Jaskot, Senior Director Regulatory Affairs, Teva Pharmaceuticals USA Inc. (February 6, 2001) (granting Teva Citizen Petition dated August 9, 2000), available at <http://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030501/pav0001.pdf>.

¹⁶³ *Mylan Pharm.*, 207 F. Supp. 2d 476.

¹⁶⁴ See generally Apotex Comment, *supra* note 133.

In support of that assertion, opponents cite a case, *Mylan Pharmaceuticals v. Thompson*,¹⁶⁵ where the United States District Court for the Northern District of West Virginia made determinations about authorized generics in another context and supported the February 6, 2001, FDA ruling.¹⁶⁶ Mylan began marketing a version of Pfizer's Procardia (nifedipine) product pursuant to an agreement with Pfizer to settle patent infringement litigation for the drug.¹⁶⁷ At the time (prior to the enactment of the Medicare Amendments), the earlier of a court decision finding the patent at issue not infringed or invalid, or the commercial marketing of the drug product by an eligible ANDA, triggered the 180-day exclusivity period.¹⁶⁸ The issue in the case was whether the exclusivity period had been triggered when Mylan began marketing Pfizer's drug as an authorized generic.¹⁶⁹ Mylan argued that the 180-day period had not been triggered because no such court ruling had been issued and Mylan was marketing a version of Pfizer's product, rather than Mylan's own nifedipine product, for which it had sought approval in the ANDA.¹⁷⁰ Nevertheless, the district court determined that the marketing of an NDA holder's product by the holder of an approved ANDA application who is eligible for 180-day exclusivity for that same drug product constitutes "commercial marketing" under the statute and triggers the 180-day exclusivity period.¹⁷¹ The district court agreed with the FDA's previous determination that

whether Mylan markets the produc[t] approved in its ANDA or [whether] the product approved is Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic nifedipine, permitting Mylan to market nifedipine without triggering the

¹⁶⁵ *Mylan Pharm.*, 207 F. Supp. 2d 476.

¹⁶⁶ *See id.*

¹⁶⁷ *Id.* at 481.

¹⁶⁸ *See* 21 U.S.C.A. § 355(j)(5)(B)(iv); Pub. L. No. 108-173, 117 Stat. 2066, 2457-58 (2003).

¹⁶⁹ *Mylan Pharm.*, 207 F. Supp. 2d at 481-82.

¹⁷⁰ *Id.* at 483.

¹⁷¹ *Id.* at 488.

beginning of exclusivity would be inconsistent with the intent of the statutory scheme.¹⁷²

Opponents of the FDA's July 2, 2004 decision, finding that authorized generics are not prohibited from marketing a brand-name drug during the 180-day exclusivity period, argue that the *Mylan* decision establishes a precedent for treating "brand generics as the legal and functional equivalents of ANDA generics for purposes of applying and enforcing the 180-day exclusivity period"¹⁷³ Therefore, opponents argue, an authorized generic violates the statute when it markets the brand-name drug during the 180-day exclusivity period of the first ANDA applicant. Even though the district court in *Mylan* specifically refers to the activities of an authorized generic as the "commercial marketing of generic nifedipine,"¹⁷⁴ the FDA's recent ruling insists that when an authorized generic markets the drug, it is still a brand-name drug although it is not identified as such.

The July 2, 2004 FDA ruling distinguishes the *Mylan* case and offers another interpretation of the language of the statute. In that ruling, the FDA argues that, in *Mylan*, the statutory interpretation is that the 180-day exclusivity period could be triggered by the "first commercial marketing" of "the drug" by an ANDA applicant eligible for the 180-day exclusivity.¹⁷⁵ However, the FDA found that this interpretation was narrowly confined to section 355(j)(5)(B)(iv)(I) of the Hatch-Waxman Amendments and did not establish a broad policy regarding authorized generics.¹⁷⁶ In other words, "the drug" could mean a generic version or a brand-name version in this context, as long as the manufacturer who marketed it was the eligible ANDA applicant. In addition, the marketing by the ANDA applicant of either of these drugs sufficed to trigger the 180-day exclusivity period.

According to the July 2, 2004 ruling, the *Mylan* case did not preclude an NDA holder from "market[ing] or otherwise

¹⁷² *Id.* (emphasis added).

¹⁷³ Teva Petition, *supra* note 125, at 3.

¹⁷⁴ *Mylan Pharm*, 207 F. Supp. 2d at 488.

¹⁷⁵ FDA Ruling, *supra* note 140, at 10.

¹⁷⁶ *Id.*

arrang[ing] for the distribution of authorized generic versions of its own product during a 180-day exclusivity period.”¹⁷⁷ The FDA found further support for this interpretation in its practice of “allowing NDA holders to make manufacturing changes, including labeling and imprint changes, that permit the marketing of authorized generic versions of their products during 180-day exclusivity periods.”¹⁷⁸ The FDA seems to liken licensing arrangements that permit an authorized generic to distribute an unidentified brand-name product at a generic price to situations where an innovator makes minor labeling changes and continues to distribute the brand-name product at a premium price.

Even though this new tactic may mirror innovators’ previous maneuvers, the FDA and the circuit court dismiss the spirit of the Hatch-Waxman legislation by refusing to construe a broader interpretation of the statute. The FDA’s recent ruling takes a conservative position by a strict construction of the statute. This ruling may possibly be in deference to the newness of the Medicare Amendments. In the period of time between the above-mentioned FDA rulings, Congress enacted the Medicare Amendments, which addressed various loopholes in the Hatch-Waxman Amendments that had been exploited by innovators.¹⁷⁹ However, the Medicare Amendments failed to address the marketing of authorized generics. In the Medicare Amendments, Congress addressed the practice by which innovators had been entering into competition-stifling agreements with generics who had been granted a 180-day period of market exclusivity.¹⁸⁰ Congress created forfeiture events to prevent the practice that sought to keep an ANDA applicant’s 180-day period from being triggered.¹⁸¹ Specifically, the first ANDA applicant can forfeit its 180-day exclusivity period by entering into an agreement with another ANDA applicant, the NDA-holder, or a patent owner which results in an unfair method of competition.¹⁸² Since the

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 11.

¹⁷⁹ *See supra* Part II.

¹⁸⁰ *See* 21 U.S.C.A. § 355(j)(5)(D)(i)(V) (Supp. 2005).

¹⁸¹ *See id.* § 355(j)(5)(D).

¹⁸² *Id.* § 355(j)(5)(D)(i)(V).

Medicare Amendments effectively prevented these competition-stifling agreements,¹⁸³ innovators have resorted to the present tactic of the use of the authorized generic. Thus, the purpose of the Hatch-Waxman legislation is circumvented and the balance is tipped in favor of the brand-name manufacturers.

Nevertheless, the new licensing arrangements with authorized generics are a hybrid of the agreements that had previously been negotiated between innovators and generics and that would now result in a forfeiture of the ANDA applicant's exclusivity period.¹⁸⁴ In each arrangement, an innovator attempts to capitalize on the market of a brand-name drug while frustrating a generic's attempt to market the drug. Although the current tactic is not used to stop the 180-day exclusivity period from triggering, the licensing arrangement creates an artificial generic during a period when no other generic is supposed to be on the market. Thus, the FDA disregards the plain meaning of the word "exclusive" in its refusal to prohibit these artificial generics from marketing a particular drug during an ANDA applicant's exclusivity period. The FDA's ruling is contrary to one of the central provisions of the Hatch-Waxman legislation because it allows innovators to undermine a generic's incentive to assume the risk of patent infringement suits.

B. Authority of the FDA

The FDA refuses to recognize its broad power under the FDCA to prohibit authorized generics from marketing during an ANDA applicant's exclusivity period. While the FDA was willing to make a determination in *Mylan*¹⁸⁵ about the arrangement between Mylan and Pfizer licensing Mylan to market an authorized generic version of Pfizer's Procardia,¹⁸⁶ the FDA has recently taken a hands-off approach to such licensing arrangements. In its July 2, 2004 rejection of Teva's and Mylan's Citizen Petitions, the FDA stated that it "oversees the changes that holders of approved ANDAs and NDAs make to their products to enable the marketing

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Mylan Pharm., Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D.W. Va. 2001).

¹⁸⁶ *See supra* Part IV.A.

arrangements they wish to pursue.”¹⁸⁷ In addition, the FDA stated that it “does not consider the underlying marketing objectives or the competitive implications of the changes being made, only their implications for the public health.”¹⁸⁸ Finally, the FDA stated that it has no duty under the statute to prohibit such marketing or to afford any right of protection for the ANDA applicant.¹⁸⁹

Instead, the FDA characterized its role in the pharmaceutical industry as the regulator of safety and efficacy.¹⁹⁰ Thus, the FDA focuses on the issue of the bioequivalence in the approval process of ANDAs.¹⁹¹ This approach also assumes that authorized generics need not be “approved” because the drug has already been approved by the NDA holder.¹⁹² Therefore, the authorized generic is characterized as a “manufacturing change,” and the FDA found that “NDA holders have long made such manufacturing changes as well.”¹⁹³ As long as there are no manufacturing changes that pose safety and effectiveness concerns, the FDA argues that the Hatch-Waxman Amendments do not prohibit an NDA holder’s use of alternative marketing practices for its own approved new drug.¹⁹⁴

By taking this approach, the FDA ignores its broad power under the FDCA “to promulgate regulations for the efficient enforcement of [the FDCA]”¹⁹⁵ This provision empowers the FDA to implement the FDCA as Congress intended. The FDA relied on this power in the *Mylan* proceeding to determine whether the authorized marketing of Pfizer’s nifedipine product triggered the 180-day exclusivity period.¹⁹⁶ In *Mylan*, the district court stated that

an agency[,] in administering a program created by Congress, must be allowed to formulate policy and make

¹⁸⁷ FDA Ruling, *supra* note 140, at 5.

¹⁸⁸ *Id.*

¹⁸⁹ *See id.* at 2, 4–6.

¹⁹⁰ *See id.* at 2, 4.

¹⁹¹ 21 U.S.C. § 355(j)(2)(A)(iv) (2000); CBO REPORT ON EFFECT OF GENERIC DRUGS IN PHARMACEUTICAL INDUSTRY, *supra* note 69, at xii, 2.

¹⁹² *See* FDA Ruling, *supra* note 140, at 6–7.

¹⁹³ FDA ruling, *supra* note 140, at 4–5.

¹⁹⁴ *See id.* at 2, 5; Andrx Petition, *supra* note 8, at 6.

¹⁹⁵ *See* 21 U.S.C. § 371(a) (2000).

¹⁹⁶ *See* *Mylan v. Thompson*, 207 F. Supp. 2d 476, 481–83 (N.D. W.Va. 2001).

rules to fill a ‘gap’ which has been left, implicitly or explicitly, by Congress. There is an express delegation of authority to an agency to fill by regulation a gap explicitly left open by Congress.¹⁹⁷

Even though Congress closed several loopholes in the Medicare Amendments that innovators were abusing, the FDA refuses to recognize that authorized generics are likely abusing a loophole that Congress failed to address.

C. Policy

The FDA’s failure to prohibit authorized generics from marketing during an ANDA applicant’s exclusivity period undermines the Hatch-Waxman Amendments’ goal of balancing incentives for generics so that they are encouraged to challenge innovators’ patents. Although the FDA asserts a policy argument in support of its refusal to delay the marketing of authorized generics, this argument takes a short-sighted and narrow view of the goals of the statute. The FDA argues that the legislative intent of the Hatch-Waxman Amendments is to benefit the consuming public “‘through the prompt availability of lower cost generic drugs’ and [] to allow the eligible ANDA applicant to reap the benefits of 180 days of marketing exclusivity” without competition from other ANDA applicants.¹⁹⁸ The FDA found that its interpretation is consistent with the principles of the Hatch-Waxman Amendments because the interpretation

does not unduly favor either first ANDA applicants or NDA holders; it merely permits NDA holders to pursue competitive marketing strategies In fact, a contrary interpretation arguably would unduly favor first ANDA applicants, to the detriment of the public interest that is

¹⁹⁷ *Id.* at 487.

¹⁹⁸ FDA Ruling, *supra* note 140, at 10 (quoting Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Deborah A. Jaskot, Senior Director, Regulatory Affairs, Teva Pharmaceuticals USC, Inc., in response to Nifedipine Petition, at 7–8 (Feb. 6, 2001)).

promoted through encouragement of competition and, thereby, of lower prices in the pharmaceutical market.¹⁹⁹

On the other hand, opponents argue that permitting authorized generics to market drugs during an ANDA applicant's exclusivity period interprets the statute in a way that excessively favors innovators.²⁰⁰ If an NDA holder licenses an authorized generic to market a brand-name drug at a reduced price during the exclusivity period, opponents argue that this could reasonably be expected to diminish the ANDA holder's economic benefit because there are three versions of the drug on the market: (i) the brand-name drug, (ii) the ANDA holder's generic, and (iii) the authorized generic.²⁰¹ There is an obvious competition between the NDA holder's "generic" version of the brand-name drug and an ANDA holder's generic drug. The NDA holder's "generic" drug would not exist without the licensing arrangement. Regardless, the FDA found that any "such adverse economic effect is insufficient to justify the action requested [], even if the FDA had authority to grant the request."²⁰² The FDA argues that competition during the 180-day exclusivity period actually furthers the objective of enhancing competition overall among drug products.²⁰³ Specifically, the FDA argued that the competition posed by authorized generics "can be anticipated to encourage ANDA applicants to offer their products at lower prices during the exclusivity period, thereby reducing the substantial 'mark-up' ANDA applicants can often apply during the period, before approval of subsequent ANDA applicants increases competition."²⁰⁴

One of the fundamental problems with the FDA's policy argument is that it trivializes the purpose of the 180-day exclusivity period. According to the provisions of the Hatch-Waxman Amendments, the encouragement of competition and, thereby, lower prices in the pharmaceutical market, is not a one-

¹⁹⁹ *Id.* at 11.

²⁰⁰ *Id.*

²⁰¹ *Id.* at 12.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.* Mylan contests that issue, arguing that no pricing data "currently supports the bald assertion that authorized generics lower prices at a consumer level." *Id.* at n.19.

step process.²⁰⁵ As innovators take financial risks in the research and development of new drugs, generics take financial risks in challenging innovators' patents. The Hatch-Waxman Amendments and the Medicare Amendments attempt to balance those risks with various incentives such as the 180-day exclusivity period for generics and patent extensions for innovators.²⁰⁶ However, the 180-day exclusivity period serves another purpose as well. Congress has recognized that innovators have filed multiple, meritless patents in an attempt to prolong patent life.²⁰⁷ At the same time, it has been determined that the FDA does not have a duty to police Orange Book listings to ensure that ineligible patents are not listed in the Orange Book.²⁰⁸ According to *Ben Venue Labs, Inc. v. Novartis Pharmaceutical Corp.*,²⁰⁹ the FDA "has stated that it lacks the resources and the expertise to review patents submitted with NDAs, and that it intends listing disputes to be settled privately."²¹⁰ Therefore, generics who challenge allegedly meritless patents are effectively policing innovators from unjustly maintaining high, monopoly prices on drugs. In support of the theory that lawsuits are the method to dismantle innovators' monopoly-hold on the market, a recent FTC study found that when generics do bring patent challenges, their allegations are meritorious—"generic applicants prevailed in nearly 75% of the patent litigation ultimately resolved by a court decision."²¹¹ Yet the FDA's failure to prohibit authorized generics from marketing during an ANDA applicant's exclusivity period undermines this process by tipping the balancing of the incentives in favor of innovators.

It could be argued that generics will continue to bring patent challenges regardless of whether or not authorized generics are around because the potential financial rewards are still present. Therefore, the legislative goal of increasing the availability of

²⁰⁵ See 21 U.S.C.A. § 355(j) (1999), amended by 21 U.S.C.A. § 355(j) (Supp. 2005).

²⁰⁶ See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074–76 (D.C. Cir. 1998).

²⁰⁷ See FTC GENERIC DRUG STUDY, *supra* note 60, at 52–56; Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

²⁰⁸ See *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002).

²⁰⁹ *Ben Venue Labs, Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446 (D.N.J. 1998).

²¹⁰ *Id.* at 456.

²¹¹ FTC GENERIC DRUG STUDY, *supra* note 60, at viii.

affordable pharmaceuticals may not truly be threatened by allowing innovators to use authorized generics. Although the long-term effects of this practice can only be speculated, it is clear that innovators have an added weapon in their arsenal that puts a damper on a generic's supposed victory after winning a patent challenge.

V. ANOTHER APPROACH—LABELING

A. Pending Citizen Petition with the FDA

The FDA has an opportunity to potentially level the playing field between innovators and generics in a ruling on a pending petition. In a Citizen Petition filed on December 23, 2004 with the FDA, Andrx Pharmaceuticals, Inc. (“Andrx”) seeks to prohibit the marketing of authorized generics on another theory.²¹² Andrx planned to market a generic form of methylphenidate hydrochloride, an attention deficit drug, while the NDA holder McNeil Consumer and Speciality Pharmaceuticals (“McNeil”) planned to license its attention deficit drug Concerta® to an authorized generic.²¹³ In a move to block the licensing agreement, Andrx proposed that authorized generics are misbranded under section 502(a) of the FDCA and, therefore, are false, misleading and anticompetitive.²¹⁴ Specifically, Andrx argued that a drug label “can convey a misleading representation by implication or by omission of material information, as well as by express statements.”²¹⁵ The FDCA provides in relevant part that “[a]mong representations in the labeling of a drug which render such drug misbranded is a false or misleading representation with respect to another drug or a device or a food or cosmetic.”²¹⁶ In essence, the argument is that consumers and healthcare professionals are misled as to the true manufacturer of authorized generics and are, therefore, not receiving truthful and accurate information about the

²¹² Andrx Petition, *supra* note 8.

²¹³ *Id.* at 1–2.

²¹⁴ *Id.* at 2–3.

²¹⁵ *Id.* at 6.

²¹⁶ 21 C.F.R. § 201.6(a) (2005).

drug product. This works to the detriment of consumers because they pay more for a brand-name drug—which they assume has a greater therapeutic effect—when the same drug is actually available at a lower price.

In further support its argument, Andrx argues that the FDA has previously prohibited the business practice of mislabeling brand-name drugs that mislead consumers.²¹⁷ Specifically, Andrx makes a “man in the plant” argument. In the 1970s, some brand-name pharmaceutical companies employed a practice of hiring smaller companies to manufacture their drugs for sale with the drug’s brand-name label.²¹⁸ To supervise this manufacture, the brand-name company would send a “man in the plant” to “supervise” the manufacturing process.²¹⁹ Companies then placed their brand on the label, claiming to have manufactured the drug, and charged the brand-name price.²²⁰ However, the FDA stopped this business practice, finding that the “man in the plant” supervision was only nominal.²²¹

Andrx argues that the practice of authorized generics is essentially similar, although it works in reverse.²²² Instead of placing a brand-name on a product manufactured by a generic, the practice allows innovators to put a generic label on a brand-name drug. Consumers are misled by this practice because they buy the brand-name version while the same drug made by the same company is available more cheaply.

In response to Andrx’s petition, McNeil submitted an opposition comment to the FDA on February 25, 2005.²²³ McNeil argued that Andrx failed to allege

²¹⁷ See Andrx Petition, *supra* note 8, at 7–8.

²¹⁸ See *FDA puts off decision of Andrx’ authorized generic’s citizen petition*, FDA WEEK, July 29, 2005.

²¹⁹ See *id.*

²²⁰ See *id.*

²²¹ See Andrx Petition, *supra* note 8, at 7.

²²² See *id.* at 7–8.

²²³ McNeil Consumer & Specialty Pharmaceuticals, Comment to FDA (Feb. 24, 2005), available at <http://www.fda.gov/ohrms/dockets/dockets/04p0563/04p-0563-c000001-01-vol1.pdf> (filed in opposition to Andrx’s Petition, 2004P-0563).

any legally relevant FDCA violation related to generic drug bioequivalence or adulteration, or any violation of FDA's careful and deliberate regulatory process with respect to the labeling of products approved under both the NDA and ANDA processes. Although Andrx's argument is based on the alleged omission of information from labeling, its arguments do not satisfy the FDCA's definition of misleading labeling found at Section 201(n), which focuses on the consequences of using the drug as recommended in the labeling at issue in the light of any omitted material fact.²²⁴

Essentially, McNeil argues that Andrx has failed to identify any safety or efficacy issue with the labeling of authorized generics and, therefore, has failed to prove that the label is misleading.²²⁵

Section 201(n) of the FDCA provides:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.²²⁶

In a June 24, 2005 letter,²²⁷ the FDA delayed its decision regarding the Petition, due to "other Agency priorities."²²⁸

²²⁴ *Id.* at 4.

²²⁵ *See id.* at 4–5.

²²⁶ 21 U.S.C. § 321(n) (2000).

²²⁷ Letter from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, to David L. Rosen, Foley & Lardner LLP (June 24, 2005), available at <http://www.fda.gov/ohrms/dockets/dockets/04p0563/04p-0563-let0001-vol1.pdf> (filed in response to Andrx's Petition, 2004P-0563).

B. The Labeling Resolution

The importance of accurate labeling of drugs is clear for various safety reasons. The prohibition of brand-name manufacturers' use of the man-in-the-plant approach suggests a clear concern with practices that mislead consumers or that fail to disclose to consumers the actual manufacturer of a drug. This assumes that there is merit in disclosing to consumers the manufacturer of a drug, even when issues of safety or efficacy are not implicated.

Section 201.1(a) of the FDCA provides in part: "A drug or drug product . . . in finished package form is misbranded under section 502(a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor."²²⁹ The FDCA goes on to define such a manufacturer as one who mixes, granulates, mills, molds, encapsulates and coats a drug product.²³⁰ In addition, the FDCA provides that the

appearance on a drug product label of a person's name without qualification is a representation that the named person is the sole manufacturer of the product. That representation is false and misleading, and the drug product is misbranded under section 502(a) of the act, if the person is not the manufacturer of the product in accordance with this section.²³¹

Further, the statute requires that if a distributor is named on the label, the name shall be qualified by one of several phrases that specifies the manufacturer of and the distributor of the item.²³²

To comply with the statute, the FDA should require that innovators accurately label authorized generics. Specifically, authorized generics should clearly identify the brand-name

²²⁸ *Id.*

²²⁹ 21 C.F.R. § 201.1(a) (2005).

²³⁰ *Id.* § 201.1(b).

²³¹ *Id.* § 201.1(h)(2).

²³² *Id.* § 201.1(h)(5). Such phrases include "Manufactured for _____," "Distributed by _____," "Manufactured by _____ for _____," "Manufactured for _____ by _____," "Distributor: _____," "Marketed by _____." *Id.*

connection. If innovators were required to label their products as such, this might undermine the controversial tactic they are employing. During an ANDA holder's exclusivity period, an innovator will continue to sell its brand-name product at a premium price. At the same time, the authorized generic will offer the product at a lower price and pay the innovator a portion of the proceeds. If an innovator were required to identify the brand-name connection on the authorized generic's label, consumer choice might be affected. If consumers were aware that the authorized generic's product is actually the same as the brand-name product, they would be less willing to pay the premium price for the brand-name drug. This may undercut the market of the brand-name drug sold by the innovator at the higher price. Thus, this simple disclosure requirement might discourage innovators from making such licensing arrangements in the first place.

Statutory language constrained the FDA and the federal courts from altogether banning an innovator's use of an authorized generic during an ANDA applicant's exclusivity period. Yet, the statutory language of the FDCA seems to clearly require authorized generics to bear reference to the brand-name connection in the labeling of their product.

CONCLUSION

The high cost of healthcare is an issue of the utmost concern. A recent study found that wholesale prices for popular brand-name drugs increased by an average of 7.1 percent in 2004, which was more than twice the general inflation rate.²³³ At the same time, the study found that wholesale prices for seventy-five commonly used generic drugs rose only 0.5 percent in 2004.²³⁴ As is clear from the Hatch-Waxman Amendments and the Medicare Amendments, Congress had a clear intent to foster early generic market entry of pharmaceutical products. One of the central means of fostering that goal was granting ANDAs the 180-day exclusivity period. In the congressional hearings that led to the Medicare Amendments,

²³³ William M. Welch, *Drug Prices Outstrip Inflation Study: Brand Names' Cost Up 7.1% Last Year*, USA TODAY, Apr. 12, 2005, at 1A.

²³⁴ *Id.*

Representative Henry Waxman stated that in the negotiations that culminated in the Hatch-Waxman Amendments there “was no one-for-one trading of provisions. Instead, we weighed all of the provisions to encourage innovation, taken as a whole, against all of the provisions to encourage generic competition, as a whole, and concluded that an appropriate balance had been struck.”²³⁵ In the Medicare Amendments, Congress attempted to restore the careful balance that had been undone by the actions of innovators. However, innovators have found another loophole in the statutory language. It took almost twenty years for Congress to consider the Hatch-Waxman Amendments for revision. However, this was necessary due to plain abuse of loopholes in the legislation. Representative Waxman stated that innovators resorted to “creative lawyering” and “have not honored the careful balance struck by those Amendments.”²³⁶ Innovators are clearly utilizing creative lawyering again. The history of the Hatch-Waxman Amendments should teach that loopholes will be exploited when there are great financial rewards. Therefore, the FDA should require innovators to identify the brand-name connection on their labels for their authorized generic drugs to undercut this loophole which is undermining the careful balance of the law.

²³⁵ Waxman Statement Regarding Hearing on Affordable Pharmaceuticals, *supra* note 15.

²³⁶ *Id.*