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CRS Report for Congress

Authorized Generic Pharmaceuticals: Effects on Innovation

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Summary

The practice of "authorized generics" has recently been the subject of considerable attention by the pharmaceutical industry, regulators, and members of Congress alike. An "authorized generic" (sometimes termed a "branded," "flanking," or "pseudo" generic) is a pharmaceutical that is marketed by or on behalf of a brand-name drug company, but is sold under a generic name. Although the availability of an additional competitor in the generic drug market would appear to be favorable to consumers, authorized generics have nonetheless proven controversial. Some observers believe that authorized generics potentially discourage independent generic firms both from challenging drug patents and from selling their own products.

These perceived disincentives result from the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984. Better known as the Hatch-Waxman Act, this legislation provides independent generic firms with a reward for challenging patents held by brand-name firms. That "bounty" consists of a 180-day generic drug exclusivity period awarded to the first patent challenger. During the 180-day period, the brand-name company and the first generic applicant are the only firms that receive authorization to sell that pharmaceutical. At the close of this period, other independent generic competitors may obtain marketing approval and enter the market, ordinarily resulting in lower prices for generic medicines.

Some commentators view the 180-day exclusivity period as a crucial incentive for generic firms to challenge patents held by brand-name firms. Under this view, the launch of an authorized generic during the 180-day exclusivity period makes the recovery of litigation expenses more difficult. In turn, the possibility that a brand-name firm will sell an authorized generic during the 180-day exclusivity period may decrease the incentives of generic firms to challenge patents in the first instance.

Other observers believe that authorized generics benefit consumers by increasing competition in the generic market. Because the authorized generic is manufactured by the brand-name firm and identical to its own product, consumers may be encouraged to switch to the lower-cost authorized generic alternative. Authorized generics may also facilitate the settlement of patent litigation between brand-name and independent generic firms. As an historical matter, certain of these settlement agreements have allowed authorized generics to enter the market, and therefore promoted competition, prior to the expiration of the relevant patent term.

Recent judicial opinions have upheld FDA practices allowing authorized generics. As a result of congressional interest, however, the Federal Trade Commission has agreed to release a report directed towards this issue. Although Congress may wish to take no action if the current allowance of authorized generics is deemed appropriate, other possibilities include subjecting them to the 180-day generic exclusivity period enjoyed by an independent generic firm, or simply disallowing them altogether.

This report will be updated as needed.

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Authorized Generic Pharmaceuticals: Effects on Innovation

Rising health care costs have for many years focused congressional attention upon the development and availability of prescription drugs. Recently, the presence of "authorized generic" pharmaceuticals in the drug marketplace has been the subject of congressional concern.[1] An "authorized generic" is a pharmaceutical that is marketed by or on behalf of a brand-named drug company, but is sold under a generic name. The brand-name firm may distribute the drug under its own auspices or via a license to a generic drug company. The price of this "authorized copy" is ordinarily lower than that of the brand-name drug.[2] Some sources refer to authorized generics as "branded,""flanking," or "pseudo" generics."[3]

Authorized generics may be pro-consumer in that they potentially increase competition and lower prices, particularly in the short-term. They have nonetheless proven controversial. Authorized generics ordinarily enter the market at about the time the brand-name drug company's patents are set to expire.[4] Some observers argue that such products may possibly discourage independent generic firms both from challenging drug patents and from selling their own generic products.[5] The potential diminution in independent generic incentives may in turn lead to less desire on the part of brand-name firms to market authorized generics themselves.

This report presents an analysis of the innovation and public health issues relating to authorized generic drugs. The report begins with a review of the procedures through which independent generic drug companies receive government permission to market their products and resolve patent disputes with brand-name firms. It then provides detailed background information pertaining to the concept of

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[1] *See* Thomas Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform," 93 *Virginia Law Review* (2007), 459; Saami Zain, "Sword or Shield? An Overview and Competitive Analysis of the Marketing of 'Authorized Generics'," 62 *Food & Drug Law Journal* (2007), 739.

[2] *See* Leila Abboud, "'Authorized Generics' Duel Grows," *Wall Street Journal* (March 25, 2004); Leila Abboud, "Drug Makers Use New Tactic to Ding Generic-Drug Firms," *Wall Street Journal* (January 27, 2004).

[3] *See* "Blockbuster Drugs with Expiring Patents Gain New Hope: Generic Drugs," *Drug Week* 352 (April 15, 2005).

[4] Stephen Barlas, "'Authorized' Generics May Pose Unauthorized Problems: Government Worries About Potential Brand-Name Blocking Technique," 30 *Pharmacy and Therapeutics* no.8 (2005), 435.

[5] *See* Michelle L. Kirsche, "Despite Challenges, Generics Dispensing is on the Rise," 27 *Drug Store News* no. 4 at 20 (March 21, 2005).

authorized generics and assesses their potential impact upon patent challenges and consumer welfare. The report closes with a summary of congressional issues and possible alternatives.

Marketing Approval and Patent Issues for Generic Drugs

The practice of authorized generics has arisen within a complex statutory framework established by the Drug Price Competition and Patent Term Restoration Act of 1984,[6] legislation more commonly known as the Hatch-Waxman Act.[7] Under parameters established by that statute, a manufacturer that wishes to sell a generic drug must both obtain marketing approval from the Food and Drug Administration (FDA) and account for any patent rights that pertain to that product. This report first addresses FDA marketing approval procedures for generic drugs, and then turns to possible patent implications.

FDA Approval Procedures

The FDA regulates the marketing of pharmaceuticals in the interest of public health.[8] Under this regime, the developer of a new drug must demonstrate that the product is safe and effective before it can be distributed to the public. This showing typically requires the drug's sponsor to conduct both preclinical and clinical investigations.[9] In deciding whether to issue marketing approval or not, the FDA evaluates the test data that the sponsor submits in a so-called New Drug Application (NDA).

Prior to the enactment of the Hatch-Waxman Act, the federal food and drug law contained no separate provisions addressing marketing approval for independent generic versions of drugs that had previously been approved by the FDA.[10] The result was that a would-be independent generic drug manufacturer had to file its own NDA in order to sell its product.[11] Some independent generic manufacturers could

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[6] P.L. 84-417, 98 Stat. 1585 (1984).

[7] *See, e.g.,* Laura J. Robinson, "Analysis of Recent Proposals to Reconfigure Hatch-Waxman," 11 *Journal of Intellectual Property Law* (2003), 47.

[8] CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV.

[9] *See* G. Lee Skillington and Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law and Business* (2003), 1.

[10] *See* Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389.

[11] *See* James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984," 34 *Catholic University Law*

(continued...)

rely on published scientific literature demonstrating the safety and efficacy of the drug by submitting a so-called paper NDA. Because these sorts of studies were not available for all drugs, however, not all independent generic firms could file a paper NDA.[12] Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval.[13] The result was that some independent generic manufacturers were forced to prove once more that a particular drug was safe and effective, even though their products were chemically identical to those of previously approved pharmaceuticals.

Some commentators believed that the approval of an independent generic drug was a needlessly costly, duplicative, and time-consuming process.[14] These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce independent generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[15]

In response to these concerns, Congress enacted the Hatch-Waxman Act, a statute that has been described as a "complex and multifaceted compromise between innovative and generic pharmaceutical companies."[16] Its provisions included the creation of two statutory pathways that expedited the marketing approval process for independent generic drugs. The first of these consist of Abbreviated New Drug Applications, or ANDAs. An ANDA allows an independent generic applicant to obtain marketing approval by demonstrating that the proposed product is bioequivalent to an approved pioneer drug, without providing evidence of safety and effectiveness from clinical data or from the scientific literature. The second are so-called § 505(b)(2) applications, which are sometimes still referred to as "paper NDAs." Like an NDA, a § 505(b)(2) application contains a full report of investigations of safety and effectiveness of the proposed product. In contrast to an NDA, however, a § 505(b)(2) application typically relies at least in part upon published literature providing pre-clinical or clinical data.

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[11] (...continued)
Review (1986), 433.

[12] *See* Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interest or Survival of the Fittest?," 57 *Food and Drug Law Journal* (2002), 247.

[13] *Id.*

[14] *See, e.g.,* Justina A. Molzon, "The Generic Drug Approval Process," 5 *Journal of Pharmacy and Law* (1996), 275 ("The Act streamlined the approval process by eliminating the need for [generic drug] sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.").

[15] *See* Jonathan M. Lave, "Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?," 64 *University of Pittsburgh Law Review* (2002), 201 ("Hatch-Waxman has also increased the generic drug share of prescription drug volume by almost 130% since its enactment in 1984. Indeed, nearly 100% of the top selling drugs with expired patents have generic versions available today versus only 35% in 1983.").

[16] Natalie M. Derzko, "A Local and Comparative Analysis of the Experimental Use Exception — Is Harmonization Appropriate?," 44 *IDEA: Journal of Law and Technology* (2003), 1.

The availability of ANDAs and § 505(b)(2) applications often allow an independent generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. They may also allow an independent generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.[17]

As part of the balance struck between brand-name and independent generic firms, Congress also provided patent proprietors with a means for restoring a portion of the patent term that had been lost while awaiting FDA approval. The maximum extension period is capped at a five-year extension period, or a total effective patent term after the extension of not more than 14 years.[18] The scope of rights during the period of extension is generally limited to the use approved for the product that subjected it to regulatory delay.[19] This period of patent term extension is intended to compensate brand-name firms for the generic drug industry's reliance upon the proprietary pre-clinical and clinical data they have generated, most often at considerable expense to themselves.[20]

Resolution of Patent Disputes

In addition to being the holder of an FDA-approved NDA, the brand-name pharmaceutical firm may own one or more patents directed towards that drug product.[21] The product described by an independent generic firm's ANDA or § 505(b)(2) application may possibly infringe those patents should that product be approved by the FDA and sold in the marketplace. The Hatch-Waxman Act therefore establishes special procedures for resolving patent disputes in connection with applications for marketing generic drugs.

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[17] *See, e.g.,* Sarah E. Eurek, "Hatch-Waxman Reform and Accelerated Entry of Generic Drugs: Is Faster Necessarily Better?," 2003 *Duke Law and Technology Review* (August 13, 2003), 18.

[18] 35 U.S.C. § 156(b) (2004).

[19] 35 U.S.C. § 156(b)(1) (2004).

[20] CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas. CRS Report RL32377, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, by Wendy H. Schacht and John R. Thomas.

[21] Patents, which are administered by the United States Patent and Trademark Office (USPTO), provide their owner with the ability to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention. 35 U.S.C. § 271(a) (2004). The term of the patent is ordinarily set at twenty years from the date the patent application was filed, 35 U.S.C. § 154 (2004), although pharmaceutical patents may be extended in order to compensate for a portion of the patent term that was lost during FDA marketing approval procedures. 35 U.S.C. § 156 (2004). Patent proprietors are permitted to file a civil suit in federal court in order to enjoin infringers and obtain monetary damages. 35 U.S.C. § 281 (2004). Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or unenforceable on a number of grounds. 35 U.S.C. § 282 (2004).

In particular, the Hatch-Waxman Act requires each holder of an approved NDA to identify patents it believes would be infringed if a generic drug were marketed before the expiration of these patents.[22] The FDA then lists these patents in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is more commonly known as the "Orange Book."[23] Would-be manufacturers of independent generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA or § 505(b)(2) applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market. Four possibilities exist:

> (1) that the brand-name firm has not filed any patent information with respect to that drug;
>
> (2) that the patent has already expired;
>
> (3) that the generic company agrees not to market until the date on which the patent will expire; or
>
> (4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.[24]

These certifications are respectively termed paragraph I, II, III, and IV certifications.[25] An ANDA or § 505(b)(2) application certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[26] An independent generic firm that files an ANDA or § 505(b)(2) application including a paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[27]

The filing of an ANDA or § 505(b)(2) application with a paragraph IV certification constitutes a "somewhat artificial" act of patent infringement under the Hatch-Waxman Act.[28] The act requires the independent generic applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification.[29] The patent owner may then commence patent infringement litigation against that applicant.

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[22] 21 U.S.C. § 355(c)(2) (2004).

[23] *See, e.g.,* Jacob S. Wharton, "'Orange Book' Listing of Patents Under the Hatch-Waxman Act," 47 *St. Louis University Law Journal* (2003), 1027.

[24] 21 U.S.C. § 355(j)(2)(A)(vii) (2004).

[25] *See* Douglas A. Robinson, "Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now In Exchange for Less Pharmaceutical Innovation Later?," 81 *Washington University Law Quarterly* (2003), 829.

[26] 21 U.S.C. § 355(j)(5)(B)(i) (2004).

[27] 21 U.S.C. § 355(j)(5)(B)(ii) (2004).

[28] Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 1047, 15 USPQ2d 1121 (1990).

[29] 21 U.S.C. § 355(j)(2)(B)(i) (2004).

If the NDA holder demonstrates that the independent generic firm's proposed product would violate its patents, then the court will ordinarily issue an injunction that prevents the generic drug company from marketing that product. That injunction will expire on the same date as the NDA holder's patents. Independent generic drug companies commonly amend their ANDAs or § 505(b)(2) applications in this event, replacing their paragraph IV certifications with paragraph III certifications.[30]

On the other hand, the courts may decide in favor of the independent generic firm. The court may conclude that the generic firm's proposed product does not infringe the asserted patents, or that the asserted patents are invalid or unenforceable.[31] In this circumstance, the independent generic firm may launch its product once the FDA has approved its ANDA or § 505(b)(2) application. In addition, the independent generic firm may benefit from a 180-day period of marketing exclusivity, a concept this report describes next.

Generic Marketing Exclusivity

The Hatch-Waxman Act provides prospective manufacturers of independent generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical. The reward consists of a 180-day generic drug exclusivity period awarded to the first ANDA applicant to file a paragraph IV certification. During this 180-day period, the FDA may not approve another ANDA containing a paragraph IV certification with respect to the same drug.[32] Notably, the 180-day generic drug exclusivity applies only to ANDA applicants, and not to those filing § 505(b)(2) applications.[33]

Commentators have long referred to this provision as creating "generic exclusivity" or "180-day exclusivity."[34] As originally enacted, the Hatch-Waxman Act allowed the brand-name firm and the first independent generic applicant to share

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[30] 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(i) (2006).

[31] Although patents enjoy a presumption of validity, 35 U.S.C. § 282 (2004), that presumption is not uncontestable. Accused infringers may demonstrate that the patent does not meet the standards established by the Patent Act, and as a result should not have been issued by the U.S. Patent and Trademark Office. *Id.* In addition, an accused infringer may demonstrate that the patent is unenforceable on a number of grounds, among that its owner has engaged in "misuse" of the patent. *Id.*

[32] 21 U.S.C. §355(j)(5)(B)(iv) (2004).

[33] U.S. Dept. of Health and Human Services., Food and Drug Admin., Center for Drug Evaluation and Research, *Guidance of Industry, Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, As Modified by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 5 n.14 (October 2004).

[34] *See, e.g.,* Valerie Junod, "Drug Marketing Exclusivity Under United States and European Union Law," 59 *Food and Drug Law Journal* (2004), 479; Gerry J. Elman, "FDA Approval of Generic Drugs: Instituting a First Successful Defense Requirement for Generic Exclusivity," 22 *Biotechnology Law Reporter* 97 (April 2003); Frederick Tong, "Widening the Bottleneck of Pharmaceutical Patent Exclusivity," 24 *Whittier Law Review* (2003), 775.

the market for the first 180 days of generic competition. At the close of this period, other independent generic competitors could receive FDA marketing approval. Because market prices often drop considerably following the entry of additional generic competition, the first independent generic applicant could potentially obtain more handsome profits than subsequent market entrants.[35]

Congressional enactment of the Medicare Modernization and Improvement Act of 2003[36] clarified that more than one patent challenger can enjoy "generic exclusivity," provided that certain conditions are met. Following the 2003 statute, all "first applicants" are potentially entitled to the 180-day generic exclusivity.[37] The statute defines the term "first applicant" to mean all applicants who, on the first day on which a substantially complete generic application with paragraph IV certification is filed, did themselves file a substantially complete generic application with a paragraph IV certification.[38] The statute therefore makes clear that multiple first applicants — that is to say, more than one generic that filed a paragraph IV generic application on the same day — may each enjoy "shared exclusivity."

The 180-day generic exclusivity period is intended to ameliorate collective action problems that may arise with regard to pharmaceutical patent challenges.[39] Stated less technically, an independent generic firm that challenges a patent must bear the expensive, up-front cost of litigation. If the independent generic firm is successful, however, the challenged patent is declared invalid with regard to the entire pharmaceutical industry. Any firm — not just the one who challenged the patent — could then introduce a competing product to the marketplace. Understandably, this forced sharing may undermine the incentives any one independent generic firm would possess to challenge a brand-name firm's patent. The award of 180 days of generic exclusivity is therefore intended to allow a successful patent challenger to capture an individual benefit for its effort, in turn encouraging such challenges in the first instance.[40]

The Concept of Authorized Generics

Authorized Generics Practice

As noted previously, an "authorized generic" is a pharmaceutical that is marketed by or on behalf of a brand-name drug company, but is sold under a generic

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[35] *See* Michael Bobelian, "1984 Act Led to a Boom in Prescription Drug Litigation," 231 *New York Law Journal* 1, col. 3 (May 24, 2004).

[36] P.L. 108-173, 117 Stat. 2066 (2003).

[37] 21 U.S.C. §355(j)(5)(B)(iv)(I) (2004).

[38] 21 U.S.C. §355(j)(5)(B)(iv)(II)(bb) (2004).

[39] Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

[40] *See generally* Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Technology Law Journal* (2004), 667.

name.[41] Authorized generics are thus similar to "private label" products, which are manufactured by one firm but sold under the brand of another. Although private label products are commonplace in food, cosmetic, and other markets, they have only recently attracted attention in the pharmaceutical industry.[42]

Current interest in authorized generics is largely due to a shift in corporate strategies that has been traced to the early 1990's. Until that time, many entrants in the pharmaceutical industry engaged exclusively either in selling brand-name, innovative drugs, or in selling generic drugs. Several other brand-name firms began to market authorized generics shortly before patents on their products were due to expire. Among such products were Nolvadex® (tamoxifen), authorized by the Stewart Pharmaceutical Division of ICI Americas (now AstraZeneca) and sold by Barr Laboratories; Dyazide® (triamterene/hydrochlorothiazide), marketed by SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline); and Ventolin® (albuterol), authorized by GlaxoSmithKline and sold by Dey LP.[43]

Many brand-name firms did not continue to sell authorized generics at that time, however, reportedly due to a lack of profitability.[44] One reason for the "resurgence" of authorized generics in the early 2000's is that physicians, pharmacists and patients more rapidly switch to generic drugs upon their introduction to the marketplace than a decade ago.[45] Because the rate of generic adoption is much greater now, brand-name firms reportedly are more willing to "genericize" their own brands in order to capture a share of that market.[46] The expanding generic adoption rate has also reportedly led to an industry trend where brand-name houses acquire generic firms.[47] This development too may encourage authorized generics practice in the future.

In line with current trends, a number of successful paragraph IV ANDA applicants have faced competition from authorized generics during the 180-day generic exclusivity period. These independent generic firms include Barr, for the

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[41] *See* Leila Abboud, "'Authorized Generics' Duel Grows," *Wall Street Journal* (March 25, 2004); Leila Abboud, "Drug Makers Use New Tactic to Ding Generic-Drug Firms," *Wall Street Journal* (January 27, 2004).

[42] *See* John Schmeltzer, "Upscale Generics Make Gains: 'Private Label' Items Battling Brand Names," *Montgomery County Herald* (May 19, 2006).

[43] "As brand-generic alliances grow, opponents cry foul," *Drug Store News* (August 23, 2004).

[44] Sanda Levy, "Why authorized generics are making a comeback," *Drug Topics: The Online Newspaper for Pharmacists*, available at [http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111159].

[45] *Id.*

[46] *Id.*

[47] *See* Andrew Humphries and Nick D'Amore, "Generic Deluge: As U.S. Regulators Receive a Record Number of Generic Drug Applications, Pharmaceutical Companies Continue to Align With or Combat Generic Competition," 24 *Med Ad News* no. 11 (November 1, 2005), 1.

product Allegra® (fexofenadine);[48] Eon, for the product Wellbutrin SR® (bupropion SR);[49] and Teva, for the product Glucophage®.[50] Some industry analysts believe that authorized generics will form an increasingly prominent feature of the U.S. pharmaceutical market in the future.[51] Other commentators believe that this time has already arrived: According to one account, since 2004 "authorized generic versions have appeared for nearly all drugs with expiring U.S. patents."[52]

Authorized Generics within the Hatch-Waxman Framework

Authorized generics practice has proven controversial due to the Hatch-Waxman Act's architecture and incentive structures. Some commentators have voiced concerns that the introduction of authorized generics, particularly during the 180-day market exclusivity granted to the independent generic firm that brought a paragraph IV challenge, thwarts the policy goal of encouraging the introduction of generic pharmaceuticals.[53] In particular, critics argue that the use of authorized generics may discourage firms from filing paragraph IV patent challenges if their litigation expenses cannot be recouped through the 180-day market exclusivity period.[54] As antitrust attorney David A. Balto explains:

> The bounty from challenging a patent is very important. Pharmaceutical patent litigation is a multimillion-dollar proposition. But for the potential reward of six-month exclusivity that represents the vast majority of potential profits from generic entry, many firms might forgo challenging patents.[55]

For example, the FDA ruled that the generic manufacturer Apotex was entitled to 180-day exclusivity for its version of the anti-depressant drug Paxil® in 2003. The brand-name drug company, GlaxoSmithKline, introduced an authorized generic version of Paxil®. Although Apotex anticipated sales of up to $575 million during the 180-day generic exclusivity period, its sales were reported to be between $150 million and $200 million.[56] In a 2004 filing with the FDA, attorneys for Apotex

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[48] *See* Beth Understahl, "Authorized Generics: Careful Balance Undone," 16 *Fordham Intellectual Property, Media, and Entertainment Law Journal* (Autumn 2005), 355.

[49] *Id.*

[50] *See* Tara Croft, "Building Teva," *Daily Deal* (October 25, 2004).

[51] *See* James Richie, "Prasco's market share Rx: authorized generic drugs: Firm helps pharmaceutical companies retain profits," *Cincinnati Business Courier* (February 6, 2006).

[52] Tony Pugh, "Drug companies battle generics with their own copies," *Duluth News-Tribune* (April 30, 2006).

[53] *See* Understahl, *supra* note 48.

[54] Tony Pugh, "Loophole may dampen generic-drug boom," *San Jose Mercury News* (May 3, 2006), A1.

[55] David A. Balto, "We'll Sell Generics Too: Innovator drug makers are gaming the regulatory system and harming competition," 39 *Legal Times* no. 12 (March 20, 2006).

[56] *See* Jenna Greene, "The Drug Industry Has Figured Out a Way to Best Generic Competition, and Pharmaceutical Patent Litigation Could Free-Fall," 183 *New Jersey Law*

(continued...)

asserted "that the authorized generic crippled Apotex's 180-day exclusivity — it reduced Apotex's entitlement to about two-thirds — to the tune of approximately $400 million."[57]

In addition, brand-name firms commonly introduce authorized generics on the eve of generic competition. Without an independent generic patent challenger in the first instance, brand-name firms may themselves make diminished, or delayed, use of the authorized generic strategy. As a result, the pro-competitive benefits of authorized generics may be postponed, or not realized at all, should independent generic rivals become less willing to challenge patents held by brand-name firms.[58]

On the other hand, authorized generics potentially offer several benefits both to drug companies and to consumers. Authorized generics are commonly less expensive than the brand-name drug. The introduction of an authorized generic therefore allows a lower-cost product to be made available to the consumer.[59] As the FDA opined in a statement issued in July 2004:

> Marketing of authorized generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market.[60]

In addition, once a generic version of a drug becomes available following patent expiration, brand-name firms may lose considerable market share. Indeed, many health management organizations and insurance companies reportedly promote the use of generic substitutes for brand-name medications once they become available.[61] Absent participation in the generic market, brand-name firms may not be able to take advantage of investments they previously made with respect to their manufacturing facilities. Authorized generics therefore allow brand-name firms to continue to

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[56] (...continued)
Journal (January 23, 2006), 217.

[57] *See* Pugh, *supra* note 54.

[58] *See* Narinder Banait, "Authorized Generics: Antitrust Issues and the Hatch-Waxman Act," Mondaq (November 4, 2005).

[59] Morton I. Kamien and Israel Zang, "Virtual Patent Extension by Cannibalization," *Southern Economic Journal*, July 1999.

[60] U.S. Food and Drug Administration, *FDA Supports Broader Access to Lower Priced Drugs*, FDA Talk Paper, July 2, 2004. A study prepared by IMS Consulting for the Pharmaceutical Research and Manufacturers of America reached a similar conclusion, determining that the average price discount to brand-name drugs during the 180-day exclusivity period is greater when an authorized generic has been marketed than when one has not. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (Spring 2006), available at [http://www.phrma.org/files/IMS%20Authorized%20Generics% 20Report_6-22-06.pdf].

[61] Kathleen Kerr, "Prescription Hurdles: Need Brand-Name Drug? Generic May Come First," *Newsday* (March 16, 2006), B13.

employ their manufacturing facilities at or near peak capacity even following patent expiration.[62]

Authorized generics may also support the research and development efforts of brand-name firms by providing them with additional revenue. Authorized generics may supply the brand-name firm with an additional income source, such as a royalty on sales made by its generic subsidiary or contracting partner.[63] These funds, or some portion of them, can potentially be employed in support of pharmaceutical innovation.

Authorized generics may also facilitate settlement of patent infringement suits between brand-name and independent generic firms. A judicial holding of patent invalidity may have a severe impact upon a brand-name firm in terms of its lost revenue. Many observers also believe that patent litigation is an uncertain venture.[64] By settling patent litigation, and allowing an ANDA applicant to produce an authorized generic, brand-name firms may potentially better manage risk. Such a technique provides a more stable revenue stream, both in support of the brand-name firm's research and development activities and for its investors. The generic company making an authorized generic can also benefit by not having to expend funds on litigation with an uncertain outcome or pursue an ANDA at the FDA, while expanding its product line, acquiring manufacturing experience, and gaining the first-mover advantage in the generic market.[65]

The use of authorized generics as a litigation settlement mechanism also impacts consumers, but in a manner that is both less certain and likely varies on a case-by-case basis. On one hand, particular settlement agreements may provide for the sale of authorized generics years before the disputed patent is set to expire. As a result, consumers may gain early access to a lower-cost alternative to the brand-name drug. On the other hand, had the generic firm refused to settle and ultimately prevailed in the litigation, then the market would have been open to full competition even earlier. The impact upon competition of a litigation settlement likely depends upon a number of complex factors, including the strength of the patent, the number of potential generic competitors, and the precise terms of the litigation settlement agreement.

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[62] Jon Hess and Elio Evangelista, *Authorized Generics: Lifecycle Management's Compromise in the Patent Wars* (Cutting Edge Information, August 23, 2005), 4.

[63] *Id.*

[64] *See* James Bessen and Michael J. Meurer, "Lessons for Patent Policy from Empirical Research on Patent Litigation," 9 *Lewis and Clark Law Review* 1 (2005).

[65] Christopher Worrell, *Authorized Generics*, presentation given at The 5th Generic Drugs Summit, September 27-29, 2004, and David Reiffen and Michael R. Ward, *"Branded Generics" as a Strategy to Limit Cannibalization of Pharmaceutical Markets*, May 2005, 2-4 available at [http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf]

Legality of Authorized Generics

The policy debate concerning authorized generics has been accompanied by legal challenges before the FDA and the courts concerning this practice. Opponents of authorized generics have contended that the Hatch-Waxman Act's generic exclusivity provisions should be understood as excluding authorized generics from the marketplace for the 180-day period.[66] The FDA has taken the opposite view, however, reasoning that the Hatch-Waxman Act does not require a brand-name pharmaceutical company to file any sort of application in order to market the drug as an authorized generic.[67] In turn, the 180-day period of generic exclusivity provided by the Hatch-Waxman Act only applies to ANDA or § 505(b)(2) applications with paragraph IV certifications. As a result, the 180-day generic exclusivity period does not bar authorized generics from entering the market.

Two notable judicial opinions have recently upheld the FDA's position favoring authorized generics. In the first of these opinions, *Teva Pharmaceutical Industries, Ltd. v. Crawford*,[68] the Court of Appeals for the D.C. Circuit found no reasonable reading of the Hatch-Waxman Act that would allow authorized generics to be barred by the 180-day generic exclusivity period. In that case, independent generic manufacturer Teva had previously entered into an arrangement with Purepac Pharmaceutical Co., the first paragraph IV ANDA applicant with respect to the drug gabapentin. Teva and Purepac had agreed to share the 180-day generic exclusivity period. During that period, however, Pfizer sold its own authorized generic version of gabapentin, which was priced substantially below the price of its brand-name drug.[69]

Teva responded by petitioning the FDA to prohibit the marketing of authorized generic versions of gabapentin during the 180-day generic exclusivity period. Alternatively, Teva asserted that Pfizer should be required to file a supplemental NDA (sNDA) before selling an authorized generic.[70] According to Teva, the impact of the latter proposed ruling would lead to the same outcome as the first: Pfizer would be compelled to respect the 180-day generic exclusivity period established by the Hatch-Waxman Act.

The FDA denied the petition, resulting in a Teva lawsuit against the FDA. The district court confirmed the FDA's views, concluding that "[n]othing in the statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with [an authorized] generic drug during the exclusivity

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[66] *See* Generic Pharmaceutical Association, *Comment in Support of Citizen Petition Docket No. 2004P-0075/CP1* (May 21, 2004), available at [http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf].

[67] *See* M. Howard Morse and Richard E. Coe, "Authorized Generics Are Good for You: Competition from drug pioneers shouldn't trouble the FTC," 29 *Legal Times* no. 15 (April 10, 2006).

[68] 410 F.3d 51 (D.C. Cir. 2005).

[69] *Id.* at 52.

[70] *Id.* at 52-53.

period."[71] Teva then appealed to the Court of Appeals for the D.C. Circuit, which affirmed.

Chief Judge Ginsburg began his opinion by observing that the Hatch-Waxman Act did not stipulate the manner in which the holder of an approved NDA must market its drug. Further, prior to the enactment of the Hatch-Waxman Act, nothing in the Food, Drug, and Cosmetic Act prevented the NDA holder from marketing an authorized generic. The D.C. Circuit thus saw the issue as whether it should "declare that a previously lawful practice became unlawful when the Congress passed a statute that said nothing about that practice."[72]

The Court of Appeals further rejected Teva's "functional" interpretation of the Hatch-Waxman Act. According to Teva, the practice of authorized generics had "developed only recently as a routine brand-name business strategy" and therefore had not been anticipated by Congress. Further, authorized generics practice severely diminished generic incentives to challenge pharmaceutical patents. According to Teva, then, "adhering to the 'literal' terms of the statute would lead to an absurd result, namely, that [the Hatch-Waxman Act] grants only a 'meaningless' exclusivity against subsequent ANDA filers rather than a 'commercially effective' exclusivity that runs against the NDA holder as well."[73]

The D.C. Circuit responded by reasoning that the balance between innovation and competition struck by the Hatch-Waxman Act was "quintessentially a matter for legislative judgment," such that "the court must attend closely to the terms in which the Congress expressed that judgment."[74] Here, Chief Judge Ginsburg reasoned, the statute was unambiguous. Although the Hatch-Waxman Act barred the approval of subsequent ANDAs for 180 days, the statutory language simply did not speak to marketing arrangements made by the holder of the approved NDA. The court of appeals further observed that, even in the event that an NDA holder authorized a generic, the 180-day exclusivity period continued to bar other firms from marketing a generic version of the drug. As a result, authorized generic practice hardly rendered the Hatch-Waxman Act's generic exclusivity provisions "meaningless."[75] In conclusion, because the Hatch-Waxman Act "clearly does not prohibit the holder of an approved NDA from marketing, during the 180-day exclusivity period, its own 'brand-generic' version of its drug," FDA practices concerning authorized generics were affirmed.[76]

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[71] Teva Pharm. Indus. v. FDA, 355 F.Supp.2d 111, 117 (D.D.C. 2004).

[72] 410 F.3d at 53.

[73] *Id.* at 54.

[74] *Id.*

[75] *Id.*

[76] *Id.* at 55.

A second judicial opinion, *Mylan Pharmaceuticals, Inc. v. U.S. Food and Drug Administration*,[77] also concluded that the Hatch-Waxman Act "does not grant the FDA the power to prohibit the marketing of authorized generics during the 180-day exclusivity period ...."[78] That case involved the pharmaceutical nitrofurantoin, which is used to treat urinary tract infections. When the FDA approved a paragraph IV ANDA filed by Mylan Pharmaceuticals, Inc, to sell nitrofurantoin, NDA holder Proctor & Gamble Pharmaceuticals, Inc., licensed a third party generic firm to sell an authorized generic version of the drug. Mylan reportedly lost sales of "tens of millions" of dollars due to this arrangement.[79]

Mylan challenged the FDA approval of authorized generics practice before the U.S. District Court for the Northern District of West Virginia. Mylan appealed the district court's dismissal of its case to the Court of Appeals for the Fourth Circuit, which affirmed. Citing the D.C. Circuit's decision in *Teva v. Crawford* with approval, the Fourth Circuit similarly concluded that the statute clearly defined the 180-day exclusivity period only with respect to other paragraph IV ANDAs, not to authorized generics.[80] The Fourth Circuit therefore concluded that "[a]lthough the introduction of an authorized generic may reduce the economic benefit of the 180 days of exclusivity awarded to the first paragraph IV ANDA applicant, § 355(j)(5)(B)(iv) gives no legal basis for the FDA to prohibit the encroachment of authorized generics on that exclusivity."[81] As a result, the district court's judgment was affirmed.

It is possible to criticize the statutory construction of both *Teva v. Crawford* and *Mylan v. FDA*. In particular, neither court of appeals stressed that the Hatch-Waxman Act describes the 180-day time frame as an "exclusivity period."[82] The term "exclusivity" might be viewed as a curious drafting choice in view of the ruling that generic firms must potentially compete alongside authorized generics during the 180-day period.

On the other hand, the notion of "shared exclusivity" that arose following the Medicare Modernization Act amendments may be viewed as codifying congressional intent that multiple generic applicants may enter the market during the 180-day marketing exclusivity period.[83] In addition, many prescription drugs are available in a number of different dosage forms and strengths. Under current Hatch-Waxman Act practice, each strength and dosage form is considered a separate drug product for

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[77] 454 F.3d 270 (4th Cir. 2006).

[78] *Id.* at 271.

[79] *Id.* at 273.

[80] *Id.* at 275.

[81] *Id.* at 276

[82] 21 U.S.C. § 355(j)(5)(B)(iv) (2004).

[83] *See supra* notes 36-38 and accompanying text.

which a distinct generic applicant can qualify for 180-day exclusivity.[84] As a result, the term "exclusivity" may be considered to have a particular meaning in the Hatch-Waxman Act — one that does not necessarily mean that independent generic firms will not face competition during the 180-day period even in the absence of authorized generics. Of course, these provisions may also impact the incentives that independent generic firms possess to challenge pharmaceutical patents.

In any event, *Teva v. Crawford* and *Mylan v. FDA* currently represent the law of the land. Absent further judicial developments or congressional activity, authorized generics will be judged as legitimate means for NDA holders to market their products under the Hatch-Waxman Act.[85]

The FTC Report

The Federal Trade Commission has become increasingly interested in authorized generics practice. Initially, the agency reportedly took the view "that authorized generic agreements are pro-consumer because they allow multiple generic entrants sooner."[86] Over the past several years, the FTC has either agreed to or has declined to challenge such arrangements.[87]

More recently, the FTC has expressed concerns about authorized generics practice. Jon Leibowitz, one of five FTC Commissioners, reportedly stated that "the introduction of an authorized generic will likely diminish incentives for generic firms to challenge patents and incur substantial development and litigation costs."[88] Although the commissioner was said to be skeptical that authorized generics practice violated the antitrust laws, he reportedly stated that he was "persuaded that authorized generics may have competitive implications that could upset the Waxman-Hatch balance."[89]

The FTC is currently considering the authorized generics issue at greater length. In response to a written request by three U.S. Senators, the FTC agreed to study "how competition between Paragraph IV generics and authorized generics during the 180-

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[84] *See* Apotex, Inc. v. FDA, 414 F. Supp. 2d 61, 64 (D.D.C. 2006).

[85] *See generally* Thomas P. Noud and Paul T. Meiklejohn, "The Developing Law of Pharmaceutical Patent Enforcement," 87 *Journal of the Patent and Trademark Office Society* (2005), 921.

[86] "Bristol/Teva 'Authorized' Generic Agreement Approved By FTC,' *The Pink Sheet*, May 31, 2004, 7.

[87] *See, e.g.*, FTC Press Release, "With Conditions, FTC Allows Cephalon's Purchase of CIMA, Protecting Competition for Breakthrough Cancer Drugs" (August 9, 2004), available at [http://www.ftc.gov/opa/2004/08/cimacephalon.htm]; Advisory Opinion In the Matter of Bristol-Myers Squibb Co., Docket No. C-4076 (May 24, 2004), available at [http://www.ftc.gov/os/caselist/c4076/040525advisoryc4076.pdf].

[88] "FTC Is Urged to Examine Authorized Generics," 27 *Chain Drug Review* no. 10 (June 6, 2005), at 257.

[89] Senators Request FTC Study on Authorized Generics," *World Generic Markets* (May 31, 2005).

day exclusivity period has affected short-run price competition and long-run prospects for entry by Paragraph IV generics."[90] The FTC will also address the impact of generic drug entry on the price of pharmaceuticals.[91] The report is expected to be released during the 2008 calendar year.

Issues in Innovation, Competition and Public Health

Because authorized generics are a relatively recent phenomenon, economic and scholarly evaluation of their effect upon innovation, competition and public health has been relatively limited. Even the handful of academic commentary reveals differences of views over their significance. This report next reviews two leading working papers that reached different conclusions about the impact of authorized generics practice upon social welfare.[92]

Authorized Generics and Consumer Welfare

One recent working paper, *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, was authored by Ernst R. Berndt, a member of the faculty of the MIT Sloan School of Management, and several individuals associated with the private firm Analysis Group, Inc.[93] The Berndt study concluded that "on balance authorized generics are unlikely to harm competition and can indeed benefit consumers."[94] The authors initially observed that authorized generics may potentially improve consumer welfare in several respects. In particular, by introducing price competition, the authorized generic could reduce the average price of the drug and

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[90] FTC Chairman Deborah Majoras quoted in "Authorized Generics Noose Tightens With 'Best Price' Proposal, FTC Study," *The Pink Sheet* (November 14, 2005), 20.

[91] *Id.*

[92] Two other notable published reports were sponsored by trade associations. The Pharmaceutical Research and Manufacturers of American (PhRMA), which represents brand-name firms, sponsored a report stating that authorized generics practice benefitted consumers. That report can be found at [http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf]. The Generic Pharmaceutical Association subsequently sponsored its own report, which "came up with drastically different results." *See* Generic Drug Industry Challenges PhRMA Authorized Generic Study," *FDA Week* (August 4, 2006). The report is available at [http://www.gphaonline.org/AM/Template.cfm?Section=Home&section=2006&template=/CM/ContentDisplay.cfm&ContentFileID=329]

[93] Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parcee, and Edward Tuttle, "Authorized Generic Drugs, Price Competition and Consumers' Welfare" (October 26, 2005), available at [http://www.aei.org/docLib/20051103_GenericsDraft.pdf]. The authors of the paper acknowledge the funding support of Johnson and Johnson, but further state that "The opinions expressed herein are those of the authors, and may not necessarily reflect those of the institutions with which they are affiliated, or of the research sponsor."

[94] *Id.* at 1.

result in greater marketplace penetration.[95] Because an authorized generic is identical to the brand-name drug, consumers who are loyal to the brand-name drug may also be encouraged to switch to the lower-cost authorized generic alternative.[96]

According to the Berndt study, because numerous factors determine the profitability of generic drugs, the additional variable of authorized generics should not substantially impact the decision of an independent generic firm to file a paragraph IV ANDA. These factors include the possibilities that the independent generic firm was not the first paragraph IV applicant, that the FDA may not approve its ANDA, and that other independent generic firms may sell the identical drug at a different dosage level during the 180-day exclusivity period.[97] Because independent generic firms have traditionally filed paragraph IV ANDAs despite these risks, the authors reason that "it is not clear that one additional factor, authorized generic entry, is sufficient to discourage many patent challenges."[98] The report further observed that, even with the entry of an authorized generic into the relevant market, the expected profits may still suffice to induce patent challenges.[99]

The Berndt study additionally reported empirical findings that, although the 180-day exclusivity period significantly increased short-run generic-to-brand price ratios, it had scant impact upon long-run generic-to-brand price ratios. Stated differently, once multiple generic products enter the market, the historical existence of an earlier 180-day generic exclusivity period had little effect upon drug pricing. The authors conclude that "high generic penetration and low generic-to-brand price ratios are achieved in the long run regardless of whether successful paragraph IV certifications occurred."[100]

The Berndt study further addressed the concern that authorized generics may potentially delay generic entry. According to the authors:

> It has been argued that authorized generics will deter paragraph IV certifications and potentially delay generic entry. Most drugs, however, do not face a paragraph IV certification (historically only about 20 percent have). If the anticipation of authorized generic entry decreases incentives for paragraph IV certifications for the drugs that do face paragraph IV certification, it will do so in those cases with the least likelihood of success. As a result, generic entry will not be delayed for most drugs (if any).[101]

To elaborate on this latter point, the report reasoned that authorized generics may also lead to the salutary effect of reducing wasteful litigation. According to the

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[95] *Id.* at 16.

[96] *Id.* at 13.

[97] *Id.* at 14.

[98] *Id.*

[99] *Id.*

[100] *Id.* at 17.

[101] *Id.* at 19.

authors, independent generics have prevailed in Hatch-Waxman Act litigation 42 percent of the time. As a result, the "paragraph IV certifications that may be deterred by the prospect of authorized generic entry would most likely have a lower likelihood of success than average."[102] Because such litigation is less likely to lead to improved consumer access to independent generic drugs, any potential discouragement of this litigation due to authorized generics practice is unlikely to impact competition and public health, the Berndt study explained.

Some of the contentions of the Berndt study may be subject to criticism. First, while it is true that the percentage of ANDAs with paragraph IV certifications is relatively low, that set of challenged patents are most likely the ones with sufficient sales to attract generic interest.[103] In turn, the challenged patents are likely to have a disproportionate impact upon public health. Second, although experience with authorized generics has thus far been limited, some commentators believe that this practice is growing.[104] If so, the marketplace presence of authorized generics may not amount merely to one risk among many, but rather a certainty.

Finally, although a successful patent challenge may not have much impact upon drug prices years after the patent was scheduled to expire anyway, such a challenge ordinarily allows generic competition to take place earlier than had the patent not been invalidated.[105] The judicial holding that a pharmaceutical patent is invalid has significant short- and medium-term consequences, including lower consumer expenditures on that medication but also the innovator's diminished ability to recoup research and development costs. Achieving the socially optimal balance between innovation and competition ultimately remains a difficult policy question that authorized generics practice renders even more complex.

Authorized Generics and Patent Challenges

A second recent working paper, *"Branded Generics" As a Strategy to Limit Cannibalization of Pharmaceutical Markets*,[106] was less sanguine about the marketplace impact of authorized generics practice than the Berndt study. As the authors, David Reiffin of the U.S. Commodity Future Trading Commission and

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[102] *Id.* at 15.

[103] *See* Kimberly A. Moore, "Worthless Patents," 20 *Berkeley Technology Law Journal* (2005), 1532 ("Whether a patent is likely to end up in litigation is indicative of the value of the patent to both the patent owner and competitors, since competitors are unlikely to infringe a patent of low value.").

[104] *See* George E. Jordan, "Trade officials will study so-called authorized generics," *Star-Ledger* (November 10, 2005), 59.

[105] *See* Stephanie Greene, "A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs," 30 *Journal of Corporate Law* (2005), 309.

[106] David Reiffin and Michael R. Ward, "'Branded Generics' As a Strategy to Limit Cannibalization of Pharmaceutical Markets" (May 2005), available at [http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf].

Michael R. Ward, a member of the economics faculty of the University of Texas at Arlington, concluded:

> Under current [FDA] regulations, the branded firm is not prohibited from producing [an authorized] generic drug during the exclusivity period. As in the analysis above, the introduction of a branded generic drug will reduce the successful litigant's profits significantly, creating a duopoly, rather than a monopoly during the 180 day period. Thus, branded generic entry in Paragraph IV cases can dramatically change the incentives of generic firms, perhaps eliminating the incentive to litigate the validity of patents in some cases.[107]

In reaching this conclusion, Reiffin and Ward explained that relatively few authorized generics had been introduced in the United States. Because the decision of an independent generic firm to submit a paragraph IV ANDA occurs prior to patent expiration, the authors asserted that "it seems reasonable to assume that the branded firm's action in the instances in which it took place was not anticipated by independent generic producers at the time they began the ANDA process."[108] Their report therefore develops an economic model representing "a stylized version of [pharmaceutical] industry characteristics and economic intuition."[109]

Although the Reiffin and Ward model is complex, its analysis is founded upon the notion that earlier entry by a firm into a generic market implies greater economic rents for that firm.[110] Generic firms essentially compete to obtain the largest rents by being the first market entrant, followed by diminished rewards for achieving "second place," further diminished rewards for "third place," and so on as additional firms commence sales. The authors' analysis reveals several salient points about authorized generics practice. Under their model, the anticipated entry of authorized generics should "crowd out" more than one independent generic firm.[111] Second, the "primary effect of branded generic strategy is to transfer rents from the consumer to the patent holder."[112] Finally, the effect of authorized generics upon generic drug

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[107] *Id.* at 28-29. Two other studies reached similar conclusions. One study, written by a member of the Department of Economics of the University of Calgary, concluded that authorized generic practice deterred market entry by independent generic firms within the Canadian pharmaceutical market. Aidan Hollis, "The Anti-Competitive Effects of Brand-Controlled 'Pseudo-Generics' in the Canadian Pharmaceutical Market," 29 *Canadian Public Policy* no. 1 (2003), 21. Another, authored by a member of the California Western School of Law faculty, concludes that "introduction of generics by brand name firms before patent expiration may be anticompetitive." Bryan A. Liang, "The Anticompetitive Nature of Brand Name Firm Introduction of Generics Before Patent Expiration," 41 *The Antitrust Bulletin* (Fall 1996), 599.

[108] *Id.* at 5.

[109] *Id.* at 15.

[110] *Id.* at 15.

[111] *Id.* at 18.

[112] *Id.* at 27.

prices is, according to Reiffin and Ward, less significant for larger markets than smaller ones.[113]

Some of the reasoning of the Reiffin and Ward study also is not immune to criticism. The authors are undoubtedly correct that past experience with authorized generics may not suggest the future impact of this practice, given the reported "resurgence" of authorized generic introductions in recent years.[114] Nonetheless, at least with respect to some medications, there has been no shortage of firms willing to compete in generic markets despite knowledge of potential competition. For example, on June 9, 2004, the FDA authorized fourteen firms to market Bayer's Cipro® (cirprofoxacin).[115] Similarly, on July 29, 2004, thirteen firms received FDA approval to market generic versions of Pfizer's Diflucan® (fluconazole).[116] Due to the possibility of "shared exclusivity" following enactment of the Medicare Modernization and Improvement Act of 2003,[117] the likelihood of multiple generic market entrants during the 180-day statutory period has in fact increased. Future experience will undoubtedly enrich economic understanding of the costs and benefits of authorized generic practice.

Concluding Observations

Although Congress made significant amendments to the Hatch-Waxman Act as recently as 2003,[118] authorized generics were not subject to discussion at that time. The rise of this practice, as well as the vigor of the debate surrounding it, suggests both the pace of change within the industry and the prominence of the pharmaceutical industry within the national public health system.

As discussion of authorized generics continues, Congress may wish to have a sense of its legislative options. Should Congress conclude that authorized generics are appropriate, then it may simply take no action. The opinions of the D.C. and Fourth Circuits suggest that, as currently drafted, the Hatch-Waxman Act does not allow the FDA to restrict the ability of brand-name firms to sell or approve of authorized generics.[119] Absent legislative input, the FDA may be unlikely to alter its interpretation of the Hatch-Waxman Act in this respect in the future.

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[113] *Id.* at 27.

[114] *See* Levy, *supra* note 44.

[115] *See* Dept. of Health and Human Services, U.S. FDA, Center for Drug Evaluation and Research, *Approvals — June 2004*, available at [http://www.fda.gov/cder/ogd/approvals/ap0604.htm].

[116] *See* Dept. of Health and Human Services, U.S. FDA, Center for Drug Evaluation and Research, *Approvals — July 2004*, available at [http://www.fda.gov/cder/ogd/approvals/ap0704.htm].

[117] *See supra* notes 36-38 and accompanying text.

[118] Medicare Modernization and Improvement Act, P.L. 108-173, 117 Stat. 2066 (2003).

[119] *See supra* notes 68-81 and accompanying text.

If Congress instead believes that authorized generics practice may instead disrupt the "bounty" system established by the Hatch-Waxman Act, one option is to require brand-name firms to file a supplemental NDA, or a similar application, with the FDA.[120] This filing would then place the brand-name firm in the same category as generic applicants who did not qualify as the first to file. In turn, the 180-day generic exclusivity period would then apply to the authorized generic. Alternatively, Congress could simply disallow authorized generics practice, at least during the 180-day generic exclusivity period.

Notably, whether the 180-day generic exclusivity period strikes an appropriate balance between encouraging patent challenges and ensuring prompt access to generic medications is itself a contested proposition within the pharmaceutical industry.[121] Discussion of the authorized generics issue may also prompt further reflection on the basic structure of incentives within the Hatch-Waxman Act.

Current interest in authorized generics reflects longstanding congressional concern for the appropriate balance between innovation and competition within the pharmaceutical industry. Although academic inquiry into authorized generics practice remains in its early phases, it is notable that knowledgeable commentators have reached disparate views of the benefits or detriments of this practice. Some observers stress that authorized generics benefit consumers by providing enhanced access to lower-cost alternatives to branded drugs, while others express concerns that authorized generics will defeat the incentives that independent generic firms possess to challenge pharmaceutical patents. The analysis to be provided in the forthcoming FTC report and other studies may shed additional light on the impact of authorized generics upon consumer welfare.[122]

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[120] This option is essentially the same as the one that Teva unsuccessfully argued before the Court of Appeals for the District of Columbia Circuit in the *Teva v. Crawford* case. *See supra* note 70 and accompanying text.

[121] Letter of Robert A. Armitage, Eli Lilly and Company, Re: Authorized Generic Study (June 5, 2006), available at [http://www.ftc.gov/os/comments/genericdrugstudy3/060605lilly.pdf].

[122] *See supra* notes 85-86 and accompanying text.