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The "Hatch-Waxman" Act: Selected Patent- Related Issues

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Summary

Congressional interest in the cost of pharmaceuticals, particularly for the elderly, has focused attention on several areas where the federal government has programs and policies associated with the development and accessibility of drugs in the marketplace. One of the most prominent legislative initiatives in this area is the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act" and also commonly known as the "Hatch-Waxman Act") which made several significant changes to the patent laws as they apply to pharmaceutical products. The provisions contained in the 1984 Act were designed to balance the need for innovative new pharmaceuticals and the availability of less expensive generic drugs.

Over the 18 years since passage of the Hatch-Waxman Act, there have been concerns expressed as to whether or not implementation of certain portions of the law has led to unintended consequences that have affected this balance. Some argue that there has been a pattern of "abuse" associated with the provisions of the 1984 Act and that changes should be made to prevent such actions. Others claim that no such pattern exists and that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures and legislative changes are not necessary.

The Hatch-Waxman Act requires that when a company submits a new drug application to the Food and Drug Administration (FDA) for approval, patent information associated with that pharmaceutical be listed in an FDA publication commonly known as the "Orange Book." Responsibility for maintaining the integrity of the Orange Book is an issue. In some cases, certain generic pharmaceutical companies have taken the position that a specific listing is inappropriate. They maintain that subsidiary patents have been added to the Orange Book that do not relate to the patented drug's active ingredient but still delay generic competition. However, the patent system has long allowed improvement patents so long as a sufficient inventive advance exists.

The 1984 Act created a statutory exemption from certain claims of patent infringement associated with submitting a request to the FDA for marketing approval for a generic version of a patented pharmaceutical. Several incentives are provided to generic firms to challenge the validity of existing patents (through what is termed a "paragraph IV filing") including a 180-day market exclusivity period for the first generic company to make, but not necessarily win, the challenge. Once a paragraph IV filing has been made and the patent owner declares the intention to sue for patent infringement, the FDA is prohibited from considering the generic product for 30 months or until the patent is found invalid or not infringed. Critics argue that these provisions encourage the filing of "sham" paragraph IV certifications as generic companies attempt to obtain the first to file position and then work out a "settlement" with the brand name firm that delays introduction of a generic version of the drug. Others maintain that settlements do not necessarily interfere with the timely marketing of generic drugs and are less expensive than court cases that typically take longer than 30 months and are extremely costly.

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Introduction

Congressional interest in the cost of pharmaceuticals, particularly for the elderly, has focused attention on several areas where the federal government has programs and policies associated with the development and accessibility of drugs in the marketplace. One of the most prominent legislative initiatives in this area is the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act"and also commonly known as the "Hatch-Waxman Act"). The Hatch-Waxman Act is designed to use patent law and market exclusivity procedures to met dual goals of increased innovation in the pharmaceutical arena and expanded availability of less expensive drugs. The provisions of the 1984 Act are intended to achieve a balance between incentives to encourage on-going technological progress in the pharmaceutical industry and mechanisms to expedite the marketing of lower-cost generic products.

Over the 18 years since its passage, there have been concerns expressed as to whether or not implementation of certain provisions of the Hatch-Waxman Act has led to unintended consequences that have affected this balance. Some argue that there has been a pattern of "abuse" associated with the provisions of the 1984 Act and that changes should be made to prevent such actions. Others claim that no such pattern exists and that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures thereby negating the need for change.

This report explores several of the major patent-related issues that have been raised in relation to the application of the 1984 Act. Discussions have focused on the process established in the Hatch-Waxman Act by which brand name pharmaceutical companies protect their patents and the mechanisms by which generic firms may challenge these patents. Experience accumulated during implementation of the law has afforded a new perspective on whether or not the balance remains in place. There are numerous opportunities to observe and determine how the provisions of the law have been applied as well as how court cases and regulatory activities have shaped the legislation and affected its original goals and objectives. The information provided in this paper is intended to be used as a companion piece to an earlier CRS study entitled *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").*

Patents and the Hatch-Waxman Act

Patents are issued by the United States Patent and Trademark Office (USPTO), generally for a term of 20 years from the date of filing. The patent grants its owner the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. To be afforded patent rights, an invention must be judged to consist of patentable subject matter, possess utility, and be novel and nonobvious. The application must fully disclose and distinctly claim the invention for which protection is sought.

The grant of a patent does not provide the owner with an affirmative right to market the patented invention. Pharmaceutical products are also subject to marketing approval by the Food and Drug Administration. Federal laws generally require that pharmaceutical manufacturers show their products are safe and effective in order to bring these drugs to the marketplace (21 U.S.C. sec. 355(b)). USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria.

The Hatch-Waxman Act made several significant changes to the patent laws as they relate to pharmaceutical products.[1] These changes include provisions for extending the term of a pharmaceutical patent to reflect regulatory delays encountered in obtaining marketing approval by the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval for generic drugs; establishment of mechanisms to challenge the validity of a pharmaceutical patent; and a reward for disputing the validity, enforceability, or infringement of a patented and approved drug. The 1984 Act also provides the FDA with certain authorities to offer periods of marketing exclusivity for a pharmaceutical *independent* of the rights conferred by patents.

The provisions in the 1984 Act are specifically and uniquely applicable to pharmaceutical patents and different from traditional infringement procedures associated with other patented products and processes. A statutory exemption is created for certain claims of patent infringement based on acts reasonably related to seeking FDA approval to market a drug that has been patented by another firm. The generic company is permitted to use data paid for and compiled by the original manufacturer to establish the drug's safety and efficacy. This may allow a bioequivalent drug to reach the market as soon as the patent on the original pharmaceutical expires. Nowhere else in patent law does such a robust "experimental use" exemption exist.

In the absence of the research, development, and testing performed by the brand name pharmaceutical companies, generic drugs would not exist. The generic industry relies on the information generated and financed by the brand name

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[1]For a detailed discussion of the law and its implications see: Congressional Research Service, *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, RL30756, Updated December 18,2000.

companies. While there is controversy over the actual cost of developing a new pharmaceutical, the process remains very expensive and fraught with risk. In addition, almost all other products may be brought to market without government approval and thus enjoy the full 20 years of patent protection allowed by law. Pharmaceutical firms, however, must use a portion of the patent term to apply for FDA market approval thereby forfeiting certain rights afforded other goods.

Additional, special provisions for addressing pharmaceutical patents are contained in the 1984 Act, including specific procedures for challenging the enforceability, validity, or infringement of approved drug patents. To encourage patent challenges, the first generic applicant to file a challenge is provided with 180 days of market exclusivity by the FDA when the patent is found invalid, not infringed, or unenforceable or when the patent expires. To balance such arrangements that appear to favor generic manufacturers, the Hatch-Waxman Act provides that the patent term for pharmaceuticals may be extended for a *portion* of the time lost during the FDA approval process. To obtain such an extension, patents associated with approved drugs are to be listed in what is commonly called the "Orange Book."

Many experts agree that the 1984 Act has had a significant effect on the availability of generic substitutes for brand name drugs. Generics generally are rapidly available after patent expiration and at lower prices. Concurrently, given the increasing investment in research and development (R&D) and the gains in research intensity of the pharmaceutical industry, it appears that the 1984 Act has not deterred the search for and the development of new drugs.[2] However, some in Congress and in the public are questioning whether or not participants in the process are misusing the provisions such that the original goals can no longer be achieved. Concerns have been raised as to actions associated with pharmaceutical patents listed in the Orange Book, patent challenges by generic firms, and the award of market exclusivity, among other things. These issues are discussed below.

Orange Book Listings

The Hatch-Waxman Act requires that when a company submits a new drug application (NDA) to the Food and Drug Administration for approval, patent information associated with that pharmaceutical be listed in an FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The law directs NDA applicants to identify "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted."[3]

The Orange Book provides generic pharmaceutical manufacturers with an accessible list of approved drugs that are potentially eligible for "Abbreviated New

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[2] *Ibid*.

[3] 21 U.S.C. § 355(b)(1).

Drug Applications (ANDAs)[4] and "paper NDAs." The Orange Book also provides a forum for innovative pharmaceutical companies to list patents they claim to be relevant to those approved drugs. Each ANDA or paper NDA must address the patent status of the referenced brand name pharmaceutical. In addition to the health and safety information required, the generic applicant must submit a "certification" as to any patents listed in the Orange Book that correspond to the referenced brand name drug. If the "certification" concedes that a valid patent covers the proposed product, then FDA approval may take effect only upon the date that patent expires.

However, when an applicant's certification claims that a listed patent is invalid or not infringed, a so-called "paragraph IV" certification, notice must be sent to the patentee. In the event that a generic manufacturer offers a paragraph IV certification, alleging that a patent is invalid, unenforceable, or not infringed, the FDA may approve the drug unless the patent owner commences a patent infringement action within 45 days. If the patent owner does so, FDA approval cannot be granted until 30 months after the notice. Alternatively, the FDA may grant market rights when the court decides the patent is invalid or not infringed, on the date on which the patent expires, or if a court issues some other order lengthening or shortening the 30-month stay.[5]

Determination of the Validity of Orange Book Patents

Responsibility for maintaining the integrity of the Orange Book is an issue that has been discussed in the context of changes to the 1984 Act. The USPTO issues patents on pharmaceuticals based on utility, novelty, and non-obviousness. The FDA provides market approval for drugs based on efficacy and safety. In particular cases, certain generic pharmaceutical companies have taken the position that an Orange Book listing is inappropriate. In several instances, generic competitors have argued that despite a listing tied to an approved drug, in actuality, the drug does not embody or otherwise make use of that patented invention. If these assumptions are correct, the listed patent serves as a barrier to generic competition because it does not cover the approved drug.

The role of the FDA in adjudicating Orange Book listing disagreements is limited. If a generic pharmaceutical company disputes the accuracy of an Orange Book listing, that enterprise must present the grounds for disagreement to the FDA in writing. The FDA will then request that the NDA holder confirm the propriety of the listing. Unless the NDA holder withdraws or amends the listing, the FDA will not alter the patent information in the Orange Book.

Under the 1984 Act, Orange Book listing issues have typically been resolved once the patentee files a patent infringement suit against the ANDA applicant. In other words, the 1984 Act expressly allows the patentee to sue the ANDA applicant

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[4]Established by the 1984 Act, an Abbreviated New Drug Application permits the generic manufacturer to rely upon the safety and efficacy data of the original manufacturer.

[5]Edward Hore, "A Comparison of United States and Canadian Laws As They Affect Generic Pharmaceutical Market Entry," *Food & Drug Law Journal*, 2000, 373.

for patent infringement.[6] No other avenue for resolution of Orange Book listings is provided in the 1984 Act.

However, the decision in *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*,[7] presents an additional development concerning the Orange Book. This litigation resulted from the efforts of a would-be generic competitor to contest a patent listing in the Orange Book. As previously noted, some commentators believe that NDA holders are encouraged to list as many patents as possible with regard to an approved drug. This incentive results from the mandate in the 1984 Act that each ANDA must include an appropriate certification for every patent listed in the Orange Book.

The *Ben Venue* decision resulted from a novel litigation strategy employed by a generic pharmaceutical company. This cause of action may allow the propriety of Orange Book listings to be litigated before an ANDA application is filed. In *Ben Venue*, the patentee, Novartis Pharmaceutical Corporation, listed in the Orange Book a patent covering a chemical intermediate used in the manufacture of the approved pharmaceutical. A would-be generic competitor, Ben Venue Laboratories, then filed an ANDA application with a paragraph IV certification. Under the 1984 Act, Novartis then possessed the option of bringing a patent infringement charge against Ben Venue.

Employing an original procedural tactic, Ben Venue filed a declaratory judgment action in the United States District Court of the District of New Jersey 32 days after it filed an ANDA. According to Ben Venue, the challenged patent should not have been listed in the Orange Book because the chemical intermediate did not appear in the final drug product. Novartis argued that Ben Venue's lawsuit should be dismissed. Novartis pointed to the following language from the 1984 Act: "Until the expiration of forty-five days from the date the notice . . . is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent."[8] According to Novartis, because the generic competitor had not waited the stipulated 45 days, its lawsuit was premature and should be dismissed.

The New Jersey district court ultimately rejected Ben Venue's substantive arguments. However, the court also held that Ben Venue's suit was not barred by the 1984 Act. Judge Bassler reasoned that the Ben Venue suit was not "with respect to the patent" because it did not raise the issue of validity or infringement of the patent. Instead, the suit was limited to the issue of whether the patent should have been listed in the Orange Book. Observing that "there is no indication anywhere in the statute that Congress even considered Orange Book listings as a potential source of litigation,"[9] the court held that the 1984 Act did not bar the Ben Venue litigation as prematurely brought.

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[6] 35 U.S.C. § 271(e)(2).

[7] 10 F.Supp.2d 446 (D.N.J. 1998).

[8] 21 U.S.C.§ 355(j)(5)(B)(iii).

[9] 10 F.Supp.2d at 451.

The practical effect of *Ben Venue* is that potential generic competitors may be able to raise Orange Book listing issues outside the context of the 1984 Act.[10] A possible result could be a proliferation of satellite litigation that apparently was not contemplated by Congress when it enacted the 1984 Act. Although the *Ben Venue* decision issued from a district court, and therefore does not strictly bind other courts, its reasoning may prove persuasive to other tribunals.

Subsequent judicial decisions from the U.S. Court of Appeals for the Federal Circuit have further addressed *Ben Venue*-style delisting lawsuits. These Federal Circuit decisions have considered whether courts possess jurisdiction to delist patents from the Orange Book. This jurisdictional issue depends in part on how the generic manufacturer states the basis of its cause of action in the pleadings it files with the court.

In *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), an ANDA applicant contended that its cause of action arose under the patent laws. The ANDA applicant observed that listing in the Orange Book was a necessary element of the patent infringement charge brought by the NDA holder. Therefore, an argument the patent should be delisted was effectively a defense to patent infringement, reasoned the ANDA applicant. As a result, the ANDA applicant concluded that it could simply rely upon the patent laws as a basis for jurisdiction in the federal courts.

The Federal Circuit disagreed, however. According to the Federal Circuit, the 1984 Act did not provide a private cause of action for delisting patents from the Orange Book. Following *Mylan Pharmaceuticals, Inc. v. Thompson*, an ANDA applicant could not request that a patent be removed from the Orange Book merely as a defense to patent infringement.

However, in the 2002 decision in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*,[11] the Federal Circuit suggested another jurisdictional avenue for generic manufacturers seeking to delist patents under the Orange Book. There the Federal Circuit suggested that an Orange Book listing could be challenged under the Administrative Procedure Act, or APA.[12] The APA is a general statute that in part allows adversely affected individuals to seek judicial review of an agency action. Under the APA, an ANDA applicant could conceivably sue the FDA directly, asserting that the FDA's denial of an ANDA due to an Orange Book patent listing was "arbitrary, capricious or not in accordance with law."[13]

Because the ANDA applicant in *Andrx Pharmaceuticals, Inc. v. Biovail Corp*. had not specifically stated that its cause of action was founded upon the APA, the Federal Circuit rejected this basis for jurisdiction. As a result, the Federal Circuit

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[10]Gregory J. Glover, "Regulatory Concerns & Market Exclusivity," *Health Care M&A 2000*, Practicing Law Institute, 2000, 646.

[11]276 F.3d 1368 (Fed. Cir. 2002)

[12]5 U.S.C. §§ 702-706.

[13]5 U.S.C. § 706.

has not directly ruled on whether the FDA's denial of an ANDA due to an Orange Book patent listing could be considered actionable under the APA. In the words of the court, the Federal Circuit expressed "no opinion here as to whether the FDA's action in refusing to inquire into the correctness of a listing, which then caused the FDA to stay the approval of an ANDA, might represent action that is arbitrary, capricious or not in accordance in law."[14] It therefore remains an open issue whether the APA will ultimately provide an effective jurisdictional basis for patent delisting suits.

"Late" Listed or "Later" Listed Patents

Several additional issues have been raised in conjunction with the procedures of listing in the Orange Book. Some observers have alleged that certain NDA holders have added subsidiary patents to the Orange Book in order to delay generic competition.[15] According to this view, an NDA holder will obtain from the United States Patent and Trademark Office, and submit to the FDA, numerous improvement patents directed towards advances in the pharmacological formulation associated with the drug's active ingredient. For example, an NDA holder might list formulation patents that change a drug's mode of administration to patients; increase its shelf-life or stability; or allow more efficient delivery. These additional patents may provide the NDA holder with an added period of intellectual property protection, at least with respect to the patented improvement.

Adding new patents for a drug close to the expiration date of the original patent(s) is called "late listing" by generic companies and "later listing" by brand name firms. The law provides the opportunity to extend market exclusivity by including these new patents in the Orange Book.[16] Some experts argue that this has encouraged firms to list patents for products that are not considered marketable.[17] According to attorney Alfred B. Engelberg:

> A cursory inspection of the FDA Orange Book's patent and exclusivity listings will reveal that most approved products have more than one listed patent. Sometimes, there are five or six patents listed for a single product. Some of these patents claim unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter which can easily be circumvented while still producing an

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[14]276 F.3d at 1380 n.8.

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

[16]For a discussion of the Orange Book see: *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, *supra* note 1.

[17]*Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? supra* note 13.

equivalent generic version of an approved drug. These patents nonetheless prevent competition for at least thirty months.[18]

However, the patent system has long allowed improvement patents so long as a sufficient inventive advance exists between the basic and improvement inventions. By issuing such a patent, the USPTO has determined that the applicant has met the necessary specifications for obtaining a patent. As observed by attorney Gregory J. Glover, "drug product patents are not identical to formulation patents – there are patentable aspects of a drug product that differ from the product formulation."[19]

The Federal Trade Commission (FTC) has begun several inquiries into whether brand name drug companies have engaged in anticompetitive behavior as a result of subsequent patent listings. For example, in January 2002, the FTC joined a court case in which Bristol-Myers Squibb is accused of antitrust violations by listing an additional patent on BuSpar as the drug was scheduled to come off patent in November 2000. According to one source, the FTC is investigating whether "...patents claiming one form of active ingredient are properly listed when the approved product contains a different form of the active ingredient."[20] The FTC also has begun an inquiry into whether or not AstraZeneca improperly listed patents associated with Prilosec[21] and if GlaxoSmithKline did the same with Paxil.[22]

On January 14, 2002, the U.S. Supreme Court let stand a decision of the U.S. Court of Appeals for the Federal Circuit that Eli Lilly and Co. had "double-patented" Prozac. The patent was invalidated and the company was unable to extend through 2003 the exclusive rights it sought. In a separate action taken in February 2002, U.S. District Court Judge John Koeltl issued an opinion that Bristol-Myers Squibb did, in fact, improperly list the additional patent on the antidepressant BuSpar involved with the FTC case mentioned above. The Judge granted Mylan Laboratories' request for a summary judgment that Mylan's generic product does not infringe on the Bristol-Myers Squibb patent for BuSpar.[23] Competitors have since commenced sale of generic versions of the drug.

Patent Challenges

The Hatch-Waxman Act modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent infringement. As codified in § 271(e)(1),

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[18]*Ibid,* 415.

[19]*Regulatory Concerns & Market Exclusivity*, 641, *supra* note 8.

[20]Leo Lewis, "Glaxo Targeted in Patent Probe," *The Independent* (London), 20 January, 2002.

[21]Theresa Agovino, "Drug Patents Get Attention of Regulators," *Pittsburgh Post-Gazette*, 24 January, 2002.

[22]"FTC Investigating Patent Protections," *The Los Angeles Times*, 9 January, 2002.

[23]"Mylan Laboratories Granted Summary Judgment in Buspirone Case," *Business Wire*, 19 February, 2002.

this provision mandates that: "It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products." This provision effectively overturns the opinion of the Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*[24] As a result, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

Although the 1984 Act provides a safe harbor from patent infringement, it also requires would-be manufacturers of generic drugs to engage in a specialized certification procedure. The core feature of this process is that a request for FDA marketing approval is treated as an "artificial" act of patent infringement. This feature was intended to allow judicial resolution of the validity, enforceability and infringement of patent rights before generic competition enters the market.[25]

Under the Hatch-Waxman Act, each holder of an approved NDA must list pertinent patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA publishes this list of patents in its list of approved products, the above-mentioned Orange Book.[26]

An ANDA applicant must certify its intent with regard to each patent associated with the generic drug it seeks to market. Four possibilities exist under the 1984 Act:

(1) that patent information on the drug has not been filed;

(2) that the patent has already expired;

(3) 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.

These certifications are respectively termed paragraph I, II, III, and IV certifications.[27] An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[28] An ANDA certified under

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[24]733 F.2d 858 (Fed. Cir. 1984). See *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, *supra* note 1.

[25]See *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 402, *supra* note 13.

[26]21 U.S.C. § 355(b)(1), 355(j)(2)(A)(vi).

[27]Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," *Food and Drug Law Journal*, 1999, 189.

[28]21 U.S.C. §§ 355(j)(5)(A), (B)(I).

paragraph III must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.

If the ANDA applicant files a paragraph IV certification, it must notify the proprietor of the patent. The patent owner may bring a patent infringement suit within 45 days of receiving such notification.[29] If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the FDA must suspend approval of the ANDA until one of the following events occurs:

> (1) the date of the court's decision that the listed drug's patent is either invalid or not infringed;
>
> (2) the date the listed drug's patent expires, if the court finds the listed drug's patent infringed;[30] or
>
> (3) subject to modification by the court, the date that is 30 months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.[31]

30-Month Stay

Filing of a paragraph IV certification is considered an act of infringement for which the brand name company can sue. The ANDA applicant is required to notify the patent owner of the intent to request market approval. Once the brand name company indicates an intent to bring a patent infringement suit against the generic company as a result of the paragraph IV filing, the FDA is prohibited from approving the drug in question for 30 months or until that time that the patent is found to be invalid or not infringed. If, prior to the expiration of 30 months, the court holds that the patent is invalid or would not be infringed, then the FDA will approve the ANDA when that decision occurs. Conversely, if the court holds the patent is not invalid and would be infringed by the product proposed in the ANDA prior to the expiration of 30 months, then the FDA will not approve the ANDA until the patent expires.[32]

Complex pharmaceutical patent litigation does not always run its course in 30 months, however. Patent challenges typically take 4 years and $4 million to conclude.[33] In many cases the courts will provide no conclusive resolution of the validity, infringement and enforceability once 30 months have passed. The 1984 Act

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[29]21 U.S.C. § 355(c)(3)(C).

[30]35 U.S.C. §§ 271(e)(4)(A).

[31]21 U.S.C. §§ 355(j)(5)(B)(iii)(I)(III).

[32]Elizabeth A. Dickinson, "FDA's Role in Making Exclusivity Determinations," *Food and Drug Law Journal*, 1999, 198.

[33]Jill Wechsler, "Pressure Mounts to Revise Generic Drug Policies," *Pharmaceutical Technology*, February 2001.

generally allows the FDA to approve the ANDA application at the end of 30 months, even though litigation is ongoing.[34]

Such an automatic 30-month injunction differs from typical infringement cases not involving pharmaceuticals. Commonly, the company suing for infringement places a bond to cover their competitor's market losses should the patent be found invalid or not infringed. If the patent owner prevails, the infringer is required to pay for lost income and may be required to pay treble damages if the infringement was willful. The patent owner may also have the offending product taken off the market. However, given the situation with pharmaceuticals, it would be highly improbable that a drug, once available for sale and in individual medicine cabinets, would be removed. In addition, given the value of certain pharmaceuticals on the market, it may be impossible for the brand name firm to recoup its monetary loses from generic firms with significantly fewer capital resources.

However, some argue that if the patent is found to be invalid or not infringed, the brand name company already has received 30 months of exclusive marketing without penalty. This, Engelberg asserts, gives an incentive to brand name firms to list as many patents as possible in the Orange Book because each infringement action provides a 30-month stay on FDA approval.[35] Yet, experience suggests that the 30-month delay-of-approval provision may not be as significant as it was intended. Some commentary indicates that generic pharmaceutical companies have been reluctant to market approved generic drugs until the associated patent litigation has been definitively resolved. As observed by Elizabeth H. Dickinson, Associate Counsel for Drugs in the Office of the Chief Counsel, FDA, "[i]f litigation is pending and the agency approves an ANDA at the end of the thirty-month period, most generic drug companies seem unwilling to risk liability for damages by bringing a generic drug product onto the market before the patent litigation is resolved."[36]

180-Day Market Exclusivity

The 1984 Act provides prospective generic manufacturers with a reward for challenging a patent associated with an approved pharmaceutical. This reward consists of a 180-day generic drug market exclusivity period awarded by the FDA to the first generic applicant that files a paragraph IV certification. The 180-day market exclusivity period ordinarily begins on the earliest of two dates: (1) the day the drug is first commercially marketed; or (2) the day a court holds that the patent which is the subject of the certification is invalid or not infringed.

Implementation of this provision has led to concerns by some in the community. Originally, FDA regulations required that a generic firm filing an ANDA had to be sued for patent infringement and *win* in court in order to receive approval for market exclusivity. However, in response to a court decision in *Mova Pharmaceutical Corp.*

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[34]*Ibid.*

[35]*Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?, supra* note 13.

[36]*FDA's Role in Making Exclusivity Determinations, supra* note 30.

v. Shalala, FDA guidelines were changed to eliminate the necessity for a "successful defense" by a generic manufacturer against claims of patent infringement prior to receiving the 180-day market exclusivity. Critics argue that this emphasis on first to file, rather than on the successful defense of a patent infringement law suit has transformed the intent of the law. Originally, this provision was planned as an incentive for generic companies to challenge patents by offering an opportunity for the firm to recoup its litigation costs during the period of market exclusivity. Now the sole criteria for obtaining the 180-day exclusivity is obtaining the first-to-file position.

Some experts claim that the *Mova* interpretation of the law has led to the filing of "...substandard or 'sham' ANDAs as generic companies race to establish themselves as being the first to file."[37] The first filer may have an incentive to submit a paragraph IV certification without any intent to actually challenge the patent. Additional generics can not be brought to market until the expiration of the 180-day exclusivity period. Yet, if no court decision issues, and the generic firm does not begin to market its product, other generic versions of the pharmaceutical cannot be approved. This creates a situation where, according to Senator Orin Hatch, ". . .the blocking position the statute grants to first filers creates perverse incentives for patent settlement."[38] Similarly, Professor Rebecca Eisenberg argues:

> Because the 180-day exclusivity does not begin until the first challenger either prevails in court or brings a generic product to market, and because there is no requirement of diligence in pursuing either goal, the first [generic] challenger may find it more profitable to enter into a collusive settlement agreement with the patent owner that affirms the validity and infringement of the patent and defers generic competition until the patent expires.[39]

Arguments have been made that the 180-day market exclusivity provision has "...created a litigation cottage industry, in which generic drug companies search for soon-to-expire patents of popular proprietary drugs and challenge vulnerable patents in court."[40] It may be easier and less expensive to make an agreement with the patent owner rather than take the issue to court. According to Engelberg, "the vast majority of patent challenges have resulted in a settlement involving either a cash payment to the challenger in exchange for an agreement to forego the challenge or the grant of a deferred license..." that permits the generic to be brought to market at a later date.[41]

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[37]Feliza Mirasol, "Generic Drug Industry Faces Regulatory and Patent Issues," *Chemical Market Reporter*, 12 April, 1999.

[38]Senate Committee on the Judiciary, Hearings on C*ompetition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*, 24 May, 2001. Statement of Senator Orin Hatch.

[39]Rebecca S. Eisenberg, "The Shifting Functional Balance of Patents and Drug Regulation," *Health Affairs*, September/October 2001.

[40]Joseph A. Slobodzian, "Patent Challenges are Key to Generics, Litigation Becomes a Mainstay to Making the Business Work," *The National Law Journal*, 12 February, 2001.

[41]*Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, *supra* note 13.

In some instances, such paragraph IV filings have become a business strategy. For example, several commentators have noted that challenges are the basis for many of the activities of Barr Laboratories, a generic drug manufacturer.[42] The firm's chairman, Bruce Downy stated that the opportunities to challenge patents are unlimited and that they generate "business opportunities" for Barr.[43] Only in a few instances has Barr failed to reach a settlement with a brand name company. Thus, over 65% of the company's revenues over the past 4 years were the result of settlements of patent litigation suits brought under Hatch-Waxman according to one analyst.[44]

Companies involved in such settlements claim that the agreements are a result of patent disputes, not a means to block market access.[45] According to Clay O'Dell, director of public affairs at the Generic Pharmaceutical Association, settlements are not inherently bad for the consumer. "The courts often urge a settlement rather than dragging a suit out for years. Sometimes a quick settlement actually helps the generic get to market sooner."[46]

Not all settlements with generic firms have brought lower cost generic drugs.[47] The Federal Trade Commission has brought several suits against brand name pharmaceuticals and generic companies charging them with anticompetitive behavior resulting from out of court settlements of patent infringement challenges. For example, in the past several years, the FTC sued Hoescht Marion Roussel (now Adventis) and Andrx alleging that the former paid Andrx not to release a generic version of Cardizem-CD. In April 2001, a consent agreement was signed under which the firms are prohibited from "...entering into arrangements in the future that have the purpose or effect of delaying the entry of generic pharmaceuticals, absent certain potentially procompetitive conditions set forth in the order."[48] Abbott Laboratories and Geneva Pharmaceuticals were also sued by the FTC over Abbott's payments to Geneva not to bring Hytrin to the marketplace. This case also was settled by a consent order that barred further similar arrangements.

In April 2001, the FTC filed a complaint against Schering-Plough and two generic firms, Upsher-Smith Laboratories and American Home Products (AHP),[49] charging them with anticompetitive activities as a result of payments regarding entry of the generic form of K-Dur. The complaint concerning Schering-Plough and

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[42]*Patent Challenges are Key to Generics, Litigation Becomes a Mainstay to Making the Business Work, supra* note 38.

[43]Bethany McLean, "A Bitter Pill," *Fortune*, 13 August, 2001.

[44]*Ibid.*

[45]"Driving Up Drug Prices," *New York Times*, 26 July, 2000.

[46]Quoted in Ann B. Gordon, "Patent Settlements: Guidelines Could Clear up Questions" *Drug Topics*, November 2001.

[47]*A Bitter Pill, supra* note 41.

[48]Federal Trade Commission, "Consent Agreement Resolves Complaint Against Pharmaceutical Companies Hoechst Marion Roussel, Inc. and Andrx Corp," 2 April, 2001.

[49]As of March 11, 2002 American Home Products is now know as Wyeth.

American Home Products was resolved by a consent agreement signed in February 2002. AHP is prohibited from entering into agreements in which the brand name company pays the generic firm not to market its product for a period of time. According to the FTC, the case against Upsher-Smith currently is before an administrative law judge at the Commission.

The FTC is also "looking at" or investigating arrangements between Bristol Meyers-Squibb and American Bioscience regarding Taxol as well as Bayer Corporation and Barr Laboratories concerning Cipro.[50] There is also a lawsuit in the courts where private parties are contesting the arrangements between Bayer and Barr regarding Cipro.[51] Concerns in this area reflect "...tension between antitrust enforcement, which seeks to protect consumers, and patent law, which is intended to reward innovation by giving companies temporary monopolies on new technology."[52]

Commencement of the 180-Day Exclusivity Provision

Interpretation of the 1984 Act's provisions regarding the 180-day market exclusivity period has spawned some additional disagreement. Under the 1984 Act, the first applicant that submits a Paragraph IV certification may be granted a 180-day period of generic exclusivity. Some difference of views has arisen over when this 180-day period should commence. The relevant statute states:

> If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after –
>
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.[53]

The 1984 Act therefore triggers the 180-day generic exclusivity period in one of two ways: either (1) when the generic manufacturer commences commercial marketing of its drug, or (2) when a court decision finds the NDA holder's patent invalid or not infringed.

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[50]*Patent Settlements: Guidelines Could Clear up Questions, supra* note 44.

[51]Adrian Michaels and Patti Waldmeir, "Lawsuits Mount Against Bayer Patents," *Financial Times* (London), 26 October, 2001.

[52]John R. Wilke, "Shering-Plough to Face Antitrust Charge in U.S.," *The Wall Street Journal* (Europe), 3 April, 2001.

[53]21 U.S.C. § 355(j)(5)(B)(iv).

The differences of views arose over the latter, "court-decision trigger" to the 180-day exclusivity period. Some observers believed that under the 1984 Act, a decision of a district court could trigger the 180-day exclusivity period. However, the FDA interpreted the 1984 Act as requiring a decision of the United States Court of Appeals for the Federal Circuit to commence the 180-day exclusivity period.[54] The FDA explained that ANDA applicants which prevailed at the district court level might wish to delay marketing their generic drug until the patent infringement litigation was more conclusively resolved on appeal.[55] The FDA thus hoped to eliminate what it perceived to be a difficult choice for generic applicants: either (1) launch a generic drug while the litigation was still pending on appeal, thereby risking infringement liability if the district court's opinion was overturned by the Court of Appeals; or (2) wait until the appeal was decided, which almost certainly meant that the 180-day exclusivity period would have elapsed.[56]

In its January 4, 2000, decision in *Mylan Pharmaceuticals, Inc. v. Shalala*,[57] the United States District Court for the District Court of Columbia held that the FDA's interpretation of the phrase "a decision of the court" was erroneous. According to Judge Roberts, the correct interpretation of that phrase included decisions of a U.S. district court. Judge Roberts further reasoned that nothing prevented the first ANDA applicant from utilizing the 180-day period if it concluded that the risk of reversal by the Court of Appeals was low;[58] that the FDA interpretation prolonged the period at which drug prices remained at inflated levels;[59] and that exclusivity periods were valuable commodities that could be traded to, among other parties, the NDA holder.[60]

Additional Observations

The Hatch-Waxman Act was constructed to balance incentives for the investments necessary to develop new, innovative pharmaceuticals while encouraging the introduction of widely available, and less expensive, generic drugs. There appears to be little doubt that the 1984 Act has had a positive impact on the availability of pharmaceuticals in the United States.[61] Since passage of the law, the amount of investment by pharmaceutical companies in biomedical research and development has increased while the availability of lower cost generic drugs has expanded significantly since the passage of the 1984 Act. However, some assert that both the brand name and generic firms may be utilizing the provisions of the 1984 Act in ways that circumvent the original purpose.

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[54]21 C.F.R. § 314.107(e) (1999).

[55]*Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F.Supp.2d 30, 39 (D.D.C. 2000).

[56]*Ibid.*

[57]81 F.Supp.2d 30 (D.D.C. 2000).

[58]*Ibid.* at 42.

[59]*Ibid.* at 41.

[60]*Ibid.* at 41-42.

[61]*Patent Law and Its Application to the Pharmaceutical Industry, supra* note 1.

> To Big Pharma, the quest for tomorrow's miracle drug is being jeopardized by the rise of superlitigious generics, which haven't always acted in consumers' best interests. To the generics, Big Pharma is willfully abusing patent laws, pursuing product extensions that benefit the bottom line, not consumers, and driving up drug costs. Determining who's right is by no means easy.[62]

In exploring the issues raised in this report, it might be worthwhile to note that several additional laws have been enacted since the passage of the Hatch-Waxman Act that may influence the debate and alter the context in which the original provisions are assessed. Under P.L. 107-109 (and previously the 1997 FDA Modernization Act), the Food and Drug Administration is permitted to grant a 6-month extension of market exclusivity for a drug on which pediatric testing has been performed. The FDA is also permitted by P.L. 97-414 (the Orphan Drug Act) to provide 7 years of market exclusivity for "orphan drugs," those pharmaceuticals that are developed to address diseases that affect fewer than 200,000 individuals a year. The American Inventors Protection Act (P.L. 106-113) allows a day-for-day extension of the term of a patent for certain delays at the Patent and Trademark Office. As Senator Orin Hatch remarked in his opening statement during May 24, 2001 hearings, it may be a

> . . .worthwhile inquiry to examine the implications of the fact that the 1999 American Inventors Protection Act generally permits all patents to be restored up to 17 years of patent life if there is undue delay at the PTO but under the 1984 Hatch-Waxman law, patent term restoration in recognition of the lengthy FDA review of new drugs is capped at 14 years. Why should [US]PTO review time be treated differently than FDA review time?

Within this context, it may be important to note that the laws and regulations associated with patents and patent terms differ from the procedures circumscribing market exclusivity afforded by the FDA. Some experts are questioning the quality of the patents issued by the U.S. Patent and Trademark Office and are interested in what effect this might have on the implementation of the Hatch-Waxman Act and beyond. Patent quality may affect court decisions concerning the validity of patents under the 1984 Act, the patent infringement process instigated by a paragraph IV filing, and/or antitrust suits.[63]

Other considerations include existing international treaties, to which the U.S. is a signatory, that may influence activity in the patent arena. In general, all patent categories are to be treated equally. According to the Agreement on Trade-Related aspects of Intellectual Property Rights, or TRIPS agreement, World Trade Organization members concur that patents must be issued on inventions "in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[64] The term of patent protection available shall not end

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[62]*A Bitter Pill*, *supra* note 41.

[63]See forthcoming CRS report *Patent Administration: Current Issues and Possibilities for Reform*, by John R. Thomas.

[64]Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, (continued...)

before the expiration of a period of 20 years counted from the filing date and patent owners must be provided the opportunity for judicial review of any decision to revoke or forfeit a patent. The TRIPS agreement also requires that the enforcement of intellectual property rights must be fair, equitable, without unnecessary complications or costs, and absent unreasonable time limits or unwarranted delays. While there are limited exemptions to the provisions in the TRIPS agreement, the treaty may circumscribe those actions Congress may take without triggering the possibility of international disputes and trade sanctions.[65]

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[64](...continued)
Article 27(1).

[65]For more information on the TRIPS Agreement and other international treaties see: Congressional Research Service, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*, by John R. Thomas, RL31132, 31 August, 2001.