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CRS Report for Congress

The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents

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Prepared for Members and Committees of Congress



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Summary

Congressional interest in the cost of prescription drugs, 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 pharmaceuticals in the marketplace. One of the most prominent legislative actions in this area is P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). This law makes several significant changes to the patent laws as they apply to pharmaceutical products in an attempt to balance the need for innovative new drugs and the availability of less expensive generic products. The Hatch-Waxman Act establishes several practices that make it easier for generic drugs to reach the market while permitting brand name companies to recover a portion of their intellectual property rights lost during the pharmaceutical approval process.

Many experts agree that the Hatch-Waxman 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, on-balance, the 1984 Act has not deterred the search for, and the development of, new drugs.

However, over the 20 years since passage of the Hatch-Waxman Act, Members of Congress and others expressed concerns as to whether implementation of certain portions of the law had led to unintended consequences. Some argued that brand name companies and/or generic firms exploited provisions of the act to prevent the timely introduction of lower cost drugs and changes were necessary to prevent such actions. Other experts claimed that the few isolated cases of "misinterpretation" of the law could be addressed through existing procedures.

As a result of the debate over the cost of prescription drugs, the 108th Congress passed P.L. 108-173, the Medicare Prescription Drug and Modernization Act of 2003. Title XI of the legislation amends the Hatch-Waxman Act and makes changes to the process of patent challenges by generic firms designed to decrease the time needed to bring generic pharmaceuticals to the marketplace. The provisions are intended to encourage more generic options to innovator drugs and to help ease some of the uncertainty surrounding the marketing of generic products.

However, several issues may remain of interest to Congress as Title XI of P.L. 108-173 is implemented. Certain concerns may be raised as a consequence of the changes in law; others may arise from the original legislation. Still additional issues may result from legal challenges and decisions of the court interpreting the law.

This paper will be updated if events warrant such action.

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The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents

Introduction

Congressional interest in the cost of prescription drugs, 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 pharmaceuticals in the marketplace. One of the most prominent legislative actions in this area is P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act).[1] This law made several significant changes to the patent laws as they applied to pharmaceutical products in an attempt to balance the need for innovative new drugs and the availability of less expensive generic products. The Hatch-Waxman Act established several practices Intended to make it easier for generic drugs to reach the market while permitting brand name companies to recover a portion of their intellectual property rights lost during the pharmaceutical approval process.

The changes legislated in the Hatch-Waxman Act include methods for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing consent from the Food and Drug Administration (FDA); a statutory exemption from patent infringement for activities associated with regulatory marketing approval; 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 Hatch-Waxman 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 Hatch-Waxman 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 company making a generic product 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.

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[1] 21 U.S.C. sec. 355 and following.

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 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 policy and industry experts agree that the Hatch-Waxman 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.

However, over the 20 years since passage of the Hatch-Waxman Act, Members of Congress and others expressed concerns to whether or not implementation of certain portions of the law had led to unintended consequences that affected attainment of the legislation's original goals. Some critics argued that brand name companies and/or generic firms exploited provisions of the act to prevent the timely introduction of lower cost drugs and changes were necessary to prevent such actions.

Other experts claimed that no pattern of abuse of the law existed and that the few isolated cases of "misinterpretation" of the act could be addressed through existing procedures. To support this position, proponents of maintaining the original Act pointed to a study by the Federal Trade Commission which found that 94% of the 8,259 generic applications filed with the FDA raised no patent-related issues.[2] Of the generic challenges to brand name pharmaceuticals, only 47 patents were the subject of court decisions.

In the 108th Congress, Members advocating change prevailed. As a result of the debate over the cost of prescription drugs, P.L. 108-173, the Medicare Prescription

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[2] U.S. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration*, July 2002.

Drug and Modernization Act of 2003 became law on December 8, 2003 . Title XI of the legislation amends the Hatch-Waxman Act and makes changes to the process of patent challenges by generic firms. Several of the changes reflect recent alterations in FDA rules regarding patent listings and generic drugs. Both congressional and executive branch actions are discussed later in this report.

General Provisions of the Original Law[3]

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 typically require that pharmaceutical manufacturers show their products are safe and effective in order to bring these drugs to the marketplace.[4]. USPTO issuance of a patent and FDA marketing consent are distinct events that depend upon different criteria.

The Hatch-Waxman Act modified the 1952 Patent Act[5] by creating a statutory exemption from certain claims of patent infringement in the pharmaceutical sector. Generic manufacturers may commence work on a generic version of an approved brand name 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 action is intended to allow judicial resolution of the validity, enforceability and infringement of patent rights afforded by the U.S. Patent and Trademark Office.

Under PL 98-417, each holder of an approved new drug application (NDA) is required to list patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA maintains this list of patents in its

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[3] For a detailed discussion of the law and its implementation see *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by Wendy H. Schacht and John R. Thomas, CRS Report RL30756.

[4] 21 U.S.C. sec. 355(b).

[5] P.L. 82-593; 35 U.S.C. sec. 1 and following.

publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

The Orange Book provides generic pharmaceutical manufacturers with an accessible list of approved drugs that are potentially eligible for an "Abbreviated New Drug Application" (ANDA) or a "paper NDA" (a 505(b)(2) application). An ANDA or paper NDA permits the generic manufacturer to rely upon the safety and efficacy data of the original manufacturer when applying to the FDA for approval of a generic drug.

A generic firm must certify to the FDA its intentions 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. An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements. An ANDA certified under paragraph III must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.

An ANDA applicant filing a paragraph IV certification must notify the proprietor of the patent. The patent holder may bring a patent infringement suit within 45 days of receiving such notification. If the patent owner timely brings a patent infringement charge against the ANDA applicant, then the FDA must suspend approval of the ANDA until: (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; 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.

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 such 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.

Under the original Hatch-Waxman Act, the first generic applicant to file a paragraph IV certification is awarded a 180-day market exclusivity period by the FDA. 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 decision holds that the patent which is the subject of the certification is invalid or not infringed. The interpretation of a "court decision" includes the decision of a U.S.

district court. A successful defense of a patent infringement suit is not necessary to obtain this exclusivity period.

Selected Patent-Related Issues[6]

The Hatch-Waxman Act requires a company submitting a new drug application to the Food and Drug Administration for approval list patent information associated with that pharmaceutical in the "Orange Book," an FDA publication. This document provides generic manufacturers with an accessible list of approved drugs that are potentially eligible for abbreviated new drug applications. Responsibility for maintaining the integrity of the Orange Book is an issue. The U.S. Patent and Trademark Office issues patents on pharmaceuticals based upon utility, novelty, and non-obviousness. The FDA provides market approval for drugs based on efficacy and safety. 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.

Under the original act, 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.

Orange Book listing issues typically were resolved once the patentee filed a patent infringement suit against the ANDA applicant. In other words, the 1984 Act expressly allows the patentee to sue the ANDA applicant for patent infringement. No other avenue for resolution of Orange Book listings was provided in the original 1984 Act.

The law also created a statutory exemption from certain claims of patent infringement associated with submitting a request to the FDA for marketing approval of a generic version of a patented pharmaceutical. Several incentives are provided to generic firms to challenge the validity of existing patents through a paragraph IV filing including the 180-day market exclusivity period for the first generic company to make, but not necessarily win, the challenge. 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. v. Shalala*, FDA guidelines were changed to eliminate the necessity for a "successful defense" by a generic

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[6] For a more detailed discussion of these issues see *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, by Wendy H. Schacht and John R. Thomas, CRS Report RL31379.

manufacturer against claims of patent infringement prior to receiving the 180-day market exclusivity.

Critics argued 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 maintained that settlements do not necessarily interfere with the timely marketing of generic drugs. Such settlements may be less expensive than court cases which typically take longer than 30 months to resolve and generate significant financial costs.

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. 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 circumstances surrounding pharmaceuticals, it may be unlikely 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 monetary loses from generic firms with significantly fewer capital resources.

Some critics also have raised concerns as to commencement of the 180-day market exclusivity period. The original Hatch-Waxman Act triggered the generic exclusivity in one of two ways: either when the generic manufacturer commences commercial marketing of its drug, or when a court decision finds the NDA holder's patent invalid or not infringed. With regard to the latter provision, the FDA interpreted the law as requiring a decision of the United States Court of Appeals for the Federal Circuit to commence the exclusivity period. According to the FDA, ANDA applicants that 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. The FDA thus hoped to eliminate what it perceived to be a difficult choice for generic applicants: either 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 wait until the appeal was decided, which almost certainly meant that the 180-day exclusivity period would have elapsed.

However, 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; that the FDA interpretation prolonged the period at which drug prices remained at inflated levels;

and that exclusivity periods were valuable commodities that could be traded to, among other parties, the NDA holder.

Federal Trade Commission Report

According to the Food and Drug Administration, between 1984 (when the Hatch-Waxman Act passed) and the end of 2000, 8,019 ANDAs were filed. In 7,536 of these abbreviated new drug applications (or 94% of the total) no patent-related issues were raised. The findings of the Federal Trade Commission, which studied ANDAs filed between January 1, 1992 and December 31, 2000 containing a paragraph IV certification challenging patents associated with the brand name drug, were published in a July 2002 report titled, *Generic Drug Entry Prior to Patent Expiration*. During this time period, 104 NDAs were the subject of paragraph IV certifications.

The FTC found that the patent owner sued the first generic applicant in 75 instances. Of the patent challenges brought to court and decided as of June 1, 2002, the patent was found to be invalid in 11 cases and the patents were found not to be infringed in 14 cases. Twenty suits resulted in a settlement between the brand name company and the generic firm. The analysis by the FTC indicated that the first 30-month stay expired before a district court decision was reached in 22 of the 75 cases that were litigated or are currently in the process of litigation between the brand name firm and the first generic applicant.

In approximately 85% of the 75 cases where the patent owner sued the first ANDA applicant, the brand name company also sued the second generic applicant. As of the date of the report, 40 drug products were the subject of court cases. In 29 of these suits, the generic applicant won while in 11 others the decision favored the brand name firm.

During the time period studied, in 8 instances additional patents were listed in the Orange Book after an initial ANDA filing. Six of these cases occurred since 1998. Approval by the FDA was delayed an additional 4 to 40 months. Four cases have been resolved in court to date and the patents were found to be either invalid or not infringed.

The FTC report indicates that FDA approval of ANDA applications without a paragraph IV certification took an average 25 months, 15 days. The time between a "complaint" and a district court decision on a patent infringement challenge took an average 25 months, 13 days. The time between a "complaint" and an appellate court decision was an average 37 months, 20 days. Most generic companies have waited for at least a district court decision prior to entering the market. Three-quarters of the patent cases resolved to date have favored the generic firm.

Since 1998, 31 generic products have received an 180-day market exclusivity provided by the FDA. Between 1992 and 1998, no 180-day market exclusivity was granted. The FTC found that 14 of the 20 settlements reached between the brand name companies and generic firms had the potential to "park" the first generic

applicant's use of market exclusivity and thereby delay entry of additional generic versions of the product.

Utilizing the results of this study, the FTC made the following recommendations (with accompanying rationale) for changes to existing law:

- Allow only one automatic 30-month stay per drug product per ANDA. Currently, according to the study, it appears that one stay associated with patents filed prior to the initial ANDA does not delay generic entry beyond the time needed for FDA approval of the filing. However, there appear to be problems associated with later-listed patents. The FTC identified questions as to whether or not later-listed patents actually meet the listing requirements to be included in the Orange Book, noting that the only way to challenge these listings is through a patent infringement suit.

- Enact legislation to require brand name companies and first-to-file generic firms to provide the FTC with copies of certain agreements between the parties. Antitrust scrutiny should be permitted to insure that such agreements do not delay the first generic's use of the 180-day market exclusivity rights.

The FTC study also recommended that the term "commercial marketing" be clarified to include instances where the first generic firm markets the brand name drug; the meaning of a "court decision" be codified to include any court decision on the same patent being litigated by the first generic filer; and any dismissal of a declaratory judgment action for lack of a case or controversy should be considered a "court decision" necessary to trigger the 180-day market exclusivity period.

FDA Rule Change

On June 12, 2003, the Food and Drug Administration announced new rules associated with the 30-month stay and the requirements for listing patents in the Orange Book. Originally published as a proposal in the October 24, 2002 Federal Register, the new regulations allow only one 30-month stay in the approval date of each ANDA or 505(b)(2) application. The agency will now prohibit the Orange Book listing of patents for drug packaging, drug metabolites, and intermediate forms of a drug. Process patents are not to be listed, although product-by-process patent information is required when the product claimed is novel. New drug application holders are obligated to provide additional patent-related information upon listing in the Orange Book and sign as to the veracity of the information under threat of criminal charges for false statements. These changes are similar to those suggested by the Federal Trade Commission and became effective on August 18, 2003. At that time, some experts argued that the FDA did not have the authority to alter application of the Hatch-Waxman Act through the regulatory process without related legislation. They predicted that the FDA actions would be challenged in court. However, the enactment of P.L. 108-173 may have provided the legislative basis necessary for some or all of the FDA actions.

P.L. 108-173, The Medicare Prescription Drug and Modernization Act of 2003

Title XI of P.L. 108-173, the Medicare Prescription Drug and Modernization Act of 2003, as signed into law by the President on December 8, 2003, makes several changes to the original Hatch-Waxman Act which are designed to decrease the time needed to bring generic pharmaceuticals to the marketplace. The new provisions are designed to "close some of the loopholes" critics argue the brand name companies are using to delay the introduction of generic products. The legislation permits only one automatic 30-month stay on FDA approval of drugs for which patents are listed in the Orange Book at the time of a paragraph IV ANDA or 505(b)(2) filing. The applicant may not amend the paragraph IV certification to include a drug different from that approved by the FDA, but may amend the application if seeking marketing consent for a different strength of the same drug. Modifications to the default 30-month stay are allowed based on district court judgments.

The applicant for an abbreviated new drug approval containing a paragraph IV certification must provide the brand name company and any patent owners with notice of such action within 20 days of filing with the FDA. Upon receipt of this notice, the brand name manufacturer has 45 days within which to file an infringement suit and thereby be eligible for the automatic 30-month stay.

In a situation where a patent holder does not file an infringement action within 45 days of notification of a paragraph IV ANDA, the ANDA applicant may request that a district court issue a declaratory judgment regarding the validity of the patent. In order to request a declaratory judgment, the generic manufacturer must have made available to the brand name company and the patent owners the confidential information contained in the ANDA application.

If sued, the generic firm may file a counter claim to require the patent holder make changes in the Orange Book listings. The generic firm may request that certain patents be delisted because they do not claim the drug to which they are attached. No monetary damages are to be awarded.

The Food and Drug Administration may approve the ANDA or 505(b)(2) filing containing a paragraph IV certification on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed.

The 180-day market exclusivity is to begin with the first commercial marketing of the generic drug (rather than being triggered by a "court decision" as under the original legislation). This exclusivity can be forfeited in certain situations including failure to market under specific time constraints, withdrawal of the application, amendment of the certification, failure to obtain approval from the FDA, expiration of all patents, or the determination by the Federal Trade Commission or the Assistant Attorney General that an agreement between the brand name and generic firms violates antitrust laws. Subsequent applicants would not be permitted the 180-day exclusivity.

Multiple generic firms may qualify for the 180-day market exclusivity if several ANDA applicants file a substantially complete application on the same day.

Agreements tendered between brand name companies and generic firms concerning the production, sale, or marketing of a pharmaceutical or a 180-day market exclusivity must be filed with the Federal Trade Commission and the Department of Justice within 10 days of the agreement.

Issues and Observations

Several issues may remain of interest to Congress as the Hatch-Waxman-related provisions of P.L. 108-173 are implemented. Individuals and groups involved with the availability of generic drugs may raise additional concerns as a consequence of changes in law; others may arise from the original legislation. Still additional issues may result from court cases that interpret the law These are discussed below.

Patents Not Listed in the Orange Book

Under the original Hatch-Waxman Act, brand name firms were encouraged to list all patents associated with an approved pharmaceutical in the Orange Book because only those patents listed were subject to an automatic 30-month stay. The listings offer generic firms easy access to information required for filing an abbreviated new drug application. Absent the compilation of relevant patents associated with the innovator drug provided by the brand name company, generic manufacturers would be forced to independently generate the data at considerable expense in terms of time and money. To balance the advantages afforded generic firms through Orange Book patent listings, innovator companies benefit from a defined, timed moratorium on FDA market approval of the pharmaceutical. Multiple 30-month stays were permitted by the original Act as patents issued later were subsequently added to the Orange Book.

The changes to the Hatch-Waxman Act in P.L. 108-173 limit brand name companies to only one 30-month stay on those patents listed in the Orange Book at the time of a paragraph IV filing. Thus, the incentive to list patents may be diminished if there is no perceived benefit for doing so. Whether or not patents are included in the Orange Book they continue to confer certain rights to the owner of the intellectual property. Generic firms may be subject to infringement suits on all patents. It is the responsibility of the generic firm to ensure that company products do not infringe on the intellectual property of others and may be subject to treble damages if found in willful violation of the patent holder's rights.

It should also be noted that the new FDA regulations limit the type of patents that may be listed in the Orange Book. Process patents are not permitted. However, if generic firms infringe upon process patents in making a generic product, they may still be liable for damages.

Declaratory Judgments

Title XI of P.L. 108-173 includes a new provision allowing an ANDA applicant, who files a paragraph IV certification alleging noninfringement, to bring a declaratory judgment against the brand-name drug company after the expiration of a 45-day period (assuming that the brand-name company has not already brought suit against the generic firm for patent infringement). A declaratory judgment action is like an ordinary patent lawsuit with the parties reversed. In a declaratory judgment suit, the generic firm serves as the plaintiff, requesting that the court rule that the brand-name company's patents are invalid or unenforceable, or that the generic product does not infringe those patents.

Under the new provisions of the Hatch-Waxman Act, the right of the ANDA applicant to file a declaratory judgment action for noninfringement is contingent upon the ANDA applicant providing the patent owner with an "offer of conditional access" to its ANDA. The ANDA applicant is not obliged to offer this conditional access. If such an offer is not made, however, then the ANDA applicant may not bring an action seeking a declaratory judgment of noninfringement.

Under P.L. 108-173, the offer of confidential access may "contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered . . . ."[7] Some observers have expressed concerns that generic drug companies will unilaterally impose such restrictions upon access to the contents of the ANDA that this provision will become unworkable. If an ANDA applicant limits which portions of the ANDA may be viewed, and also the persons entitled to access, a brand-name firm may have little basis on which to make a confident assessment of a patent infringement case. The FDA may be able to issue guidelines that would suggest broad disclosures under this provisions, but these guidelines would not bind ANDA applicants.

P.L. 108-173 also provides that the federal courts shall possess declaratory judgment jurisdiction only "to the extent consistent with the Constitution." That statute references the constitutional requirement that the federal courts hear cases only when there is an actual "case or controversy" between the litigating parties.[8] This requirement prevents the federal courts from issuing advisory opinions about hypothetical disputes, instead allowing only adversarial litigants involved in a live dispute to resort to the federal judiciary.

Applying this requirement to patent cases, the courts have held that in order to serve as a declaratory judgment plaintiff, a generic firm must have a reasonable fear of being sued by the patent holder. Ordinarily the patent holder must actually threaten the generic firm with an infringement suit, through a "cease and desist" letter or other mechanism, to satisfy this requirement. However, other factors — such as the enforcement of a patent against other defendants, a history of past disputes

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[7] 21 U.S.C. § 355(j)(5)(C)(i)(III).

[8] U.S. Constitution, Article III, § 2.

between the parties, and patentee statements that fall short of a formal charge of patent infringement — may in combination lead to the conclusion that an actual "case or controversy" exists.[9]

The requirement of an actual "case or controversy" potentially leads to some strategic behavior on the part of brand-name firms. Some observers believe that brand-name firms, as a matter of marketplace strategy, may choose neither to sue ANDA applicants nor to create such circumstances that they are subject to a declaratory judgment action.[10] Under these circumstances the brand-name firm may be able to delay filing a patent infringement suit against a generic firm until such time as the generic firm is on the verge of releasing its product onto the market. Arguably, this tactic would not promote the prompt resolution of patent disputes, one of the goals of the Hatch-Waxman Act, and may also discourage firms from taking the final steps needed to market generic drugs.

Brand Name Generics

Brand name companies can authorize another firm to make a generic version of their product, often one that is about to loose patent protection.[11] This authorized version may be brought to the market prior to or on the same day as a generic drug approved by the FDA and manufactured by a company that has won a paragraph IV challenge. Such arrangements allow the innovator firm to recover some of the sales income on a drug that will become widely available in generic form.

There are potential benefits and costs to the consumer of these actions. On the one hand, authorized generics may dissuade other firms from filing paragraph IV challenges to brand name patents if the often significant financial investments can not be recouped through the 180-day market exclusivity period. Thus, potentially invalid patents may delay the introduction of a generic version of certain pharmaceuticals. Conversely, even brand name authorized generics are less expensive than the innovator drug and often can be made available prior to patent expiration. In addition, through the introduction of an authorized generic, two lower cost products can be made available to the consumer. While research shows these actions may adversely affect the generic company, the brand name firm and the public benefit.[12]

The Federal Trade Commission appears to see the entry of authorized generics as an incentive to competitiveness and recently has signed off on several such

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[9] *See Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004).

[10] *See* "Declaratory Judgment is Looming Issue for Generics, Leary Says," *Drug Industry Daily* no. 42 (March 2, 2004).

[11] Leila Abboud, "Drug Makers Use New Tactic to Ding Generics," *The Wall Street Journal*, January 27, 2004, B1.

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

arrangements. Similarly, former FDA Commissioner Mark McClellen has stated that he tends to view authorized generics as pro-consumer.[13]

Antitrust Implications of Patent Settlements

Brand-name and generic firms engaged in litigation within the Hatch-Waxman statutory framework have sometimes concluded their litigation through settlement, rather than await a formal decision from a court. A few of these settlements have called for the brand-name company to pay the generic firm in exchange for the generic firm's agreement not to market the patented pharmaceutical. These arrangements have been termed "reverse payment" agreements because they are contrary to the usual situation in patent infringement settlements, where the plaintiff-patentee receives money from the accused patent infringer.[14]

"Reverse payment" settlements potentially had significant market consequences prior to the enactment of P.L. 108-173. Under the old law, such an arrangement could sometimes prevent all other generic firms from entering the market. The reason is that the first generic challenger was entitled to a 180-day exclusivity against other generic firms that could not be revoked or forfeited. If the first generic challenger chose not to market at all, then no generic versions of a drug could be approved by the FDA until such time as the patent expired.[15]

P.L. 108-173 includes two notable provisions that make "reverse payment" arrangement less likely to occur in the future. First, settlement agreements between brand-name and generic firms must, in many cases, be filed with the Federal Trade Commission and the Department of Justice. This provision allows the FTC and DOJ to review the settlements for anticompetitive effects. Second, P.L. 108-173 establishes various events that cause the first generic challenger to forfeit its 180-day exclusivity. Other generic firms will therefore be less easily shut out of the market in the future in the event that the first generic challenger opts not to market a particular drug.

Notably, certain "reverse payment" settlements reached under the old law have been subject to scrutiny under the antitrust laws. Enacted with the goal of preserving a competitive, open market, the antitrust laws make illegal a variety of practices that restrain trade and reduce consumer choices. Both the FTC and private plaintiffs have succeeded in persuading the federal courts that particular "reverse payment" settlements constitute antitrust violations. Different federal courts have reached conflicting rulings, however, on whether "reverse payment" settlements should

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[13] "GphA Opposes Authorized Generics, Calls Them Threat to the Industry," *Generic Line*, March 10, 2004 available at [http://global.factiva.com/en/arch/display.asp].

[14] Herbert Hovenkamp *et al.*, "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minnesota Law Review* (2003), 1719.

[15] *Ibid* at 1764, n.196.

automatically be considered to violate the antitrust laws,[16] or whether they should be subjected to a detailed, case-by-case review to determine whether the settlement was sufficiently anti-competitive to constitute an antitrust violation.[17] These rulings may have considerable impact upon the extent to which the antitrust laws will be used to monitor past conduct by different actors within the pharmaceutical industry. The U.S. Supreme Court may chose to resolve these conflicting views by issuing a ruling that would be binding upon the lower courts.[18]

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[16] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003) ("reverse payment" settlement constitutes a *per se* illegal restraint of trade under section 1 of the Sherman Act).

[17] *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (Fed. Cir. 2003) ("reverse payment" settlement **not** *per se* unlawful under section 1 of the Sherman Act).

[18] Neal R. Stoll & Shepard Goldfein, "Patent Protection or *Per Se* Violation?," 230 *New York Law Journal* (Nov. 18, 2003), 3.