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Hatch-Waxman Related Provisions of the Medicare Prescription Drug Bills (H.R. 1 and S. 1): A Side-by-Side Comparison

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Abstract. Congress is currently debating changes to the Medicare program. H.R. 1, the Medicare Prescription Drug and Modernization Act, and S. 1, the Prescription Drug and Medicare Improvements Act, as passed by each respective body on June 27, 2003, contain provisions that would amend P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). This report provides a thematic side-by-side comparison of the proposed changes contained in H.R. 1 and S. 1 that would affect the Hatch-Waxman legislation.

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Summary

The Congress is currently debating changes to the Medicare program. H.R. 1, the Medicare Prescription Drug and Modernization Act, and S. 1, the Prescription Drug and Medicare Improvements Act, as passed by each respective body on June 27, 2003, contain provisions that would amend P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). The Hatch-Waxman Act made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. The two bills currently under consideration would address Hatch-Waxman related issues of drug patents listed in the Orange Book, patent challenges by generic firms, and the award of market exclusivity, among other things. This report provides a thematic side-by-side comparison of the proposed changes contained in H.R. 1 and S. 1 that would affect the Hatch-Waxman legislation. The paper will be updated as events warrant.

Contents

Hatch-Waxman Related Provisions of the Medicare Prescription Drug Bills (H.R. 1 and S. 1): A Side-by-Side Comparison

Introduction

The Congress is currently debating changes to the Medicare program.[1] H.R. 1, the Medicare Prescription Drug and Modernization Act, and S. 1, the Prescription Drug and Medicare Improvements Act, as passed by each respective body on June 27, 2003, contain provisions that would amend P.L. 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act).

The Hatch-Waxman Act made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs. However, over the 18 years since its passage, concerns have been expressed as to whether or not implementation of certain portions of the law has led to unintended consequences contrary to the original intent. Some argue that brand name companies and/or generic firms have exploited provisions of the Act to prevent the timely marketing of less costly pharmaceuticals. Other experts maintain that while a few isolated cases of "misinterpretation" of the law have arisen, these can be addressed through existing procedures and that legislative changes are not necessary.[2]

The two bills currently under consideration would address Hatch-Waxman related issues of drug patents listed in the Orange Book, patent challenges by generic firms, and the award of market exclusivity, among other things. The following is a thematic side-by-side comparison of the proposed changes contained in H.R. 1 and S. 1 that would affect the existing Hatch-Waxman legislation.

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[1] For a discussion of the relevant bills see CRS Report RL31992, *Medicare Prescription Drug Provision of S. 1, as Passed by the Senate, and H.R. 1, as Passed by the House*, by Jennifer O'Sullivan.

[2] For detailed background information on the law and its implementation see CRS Issue Brief IB10105, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents*, by Wendy H. Schacht and John R. Thomas; CRS Report RL31379, *The Hatch-Waxman Act: Selected Patent-Related Issues*, by Wendy H. Schacht and John R. Thomas; and CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984*, by Wendy H. Schacht and John R. Thomas.

Side-by-Side Comparison of H.R. 1 and S. 1: Hatch-Waxman Related Provisions

Provision	Current Law	H.R. 1	S. 1
Patents and generic pharmaceuticals	***P.L. 98-417***	***Title XI Subtitle A***	***Title VII***
	P.L. 98-417, commonly known as the "Hatch-Waxman Act," modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent infringement. Generic manufacturers may commence work on a generic version of an approved brand name drug during the life of the patent, so long as that work furthers compliance with Food and Drug Administration (FDA) regulations. Although the Hatch-Waxman 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 afforded by the Patent and Trademark Office.		

Provision	Current Law	H.R. 1	S. 1
	Under PL 98-417, each holder of an approved new drug application (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 "Orange Book." A generic firm must certify 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 "abbreviated new drug application" (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	Requires the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.	Requires the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.

Provision	Current Law	H.R. 1	S. 1
	under 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. If the patent owner brings a patent infringement charge against the ANDA applicant in a timely manner, 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.	Requires the ANDA applicant to notify the patent holder and the brand name company (if different) of a paragraph IV certification within 20 days. The FDA may approve the ANDA 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. Allows modifications to the default 30-month stay based on district court judgments. The ANDA applicant may not amend the certification to include a drug different from that approved by the FDA, but may amend the application if seeking approval for a different strength of the same drug.	Requires the ANDA applicant to notify the patent holder and the brand name company (if different) of a paragraph IV certification within 20 days. The FDA may approve the ANDA 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. Allows modifications to the default 30-month stay based on district court judgments. No comparable provision.
	Once the brand name company indicates an intent to bring a patent infringement suit against the generic company as a result of the paragraph	Permits only one automatic 30-month stay for those patents listed in the Orange Book at the time of the filing of a paragraph IV ANDA.	Permits only one automatic 30-month stay for those patents listed in the Orange Book at the time of the filing of a paragraph IV ANDA.

Provision	Current Law	H.R. 1	S. 1
	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.	The FDA may approve the ANDA 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. Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of notification. However, if sued, the generic firm may file a counter claim to require the patent holder make changes to the Orange Book listings. No damages are to be awarded in either case. If a declaratory judgment is pursued, the action is to be brought in the judicial district where the defendant (the NDA holder) has its principal place of business. In a declaratory judgment action, the NDA holder may obtain access to confidential information contained in the ANDA application. No comparable provision.	The FDA may approve the ANDA 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. If a patent owner does not file an infringement suit within 45 days of notification of a paragraph IV ANDA, the ANDA applicant may request a declaratory judgment regarding the validity of the patent. However, if sued, the generic firm may file a counter claim to require the patent holder make changes to the Orange Book listings. No damages are to be awarded in either case. No comparable provision. No comparable provision. If the NDA holder does not file all the required information in the Orange Book, the court may decide not to

Provision	Current Law	H.R. 1	S. 1
			award treble damages if the ANDA applicant is found to have infringed on the patent.
	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.	The 180-day exclusivity period is to begin on the date of the first commercial marketing of the generic drug by the first ANDA applicant(s). A first ANDA applicant(s) is required to forfeit the 180-day exclusivity under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification, failure to obtain tentative marketing approval from the FDA, a Federal Trade Commission (FTC) or Attorney General determination that an agreement with a patent holder violates antitrust laws, or the expiration of all patents. No other subsequent ANDA applicants would be permitted the 180-day exclusivity if all first ANDA applicants forfeit.	The 180-day exclusivity period is to begin on the date of the first commercial marketing of the generic drug by the first ANDA applicant(s). A first ANDA applicant(s) is required to forfeit the 180-day exclusivity under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification, failure to obtain tentative marketing approval from the FDA, a Federal Trade Commission or Attorney General determination that an agreement with a patent holder violates antitrust laws, or the expiration of all patents. No other subsequent ANDA applicants would be permitted the 180-day exclusivity if all first ANDA applicants forfeit.

Provision	Current Law	H.R. 1	S. 1
Notification of agreements affecting the sale or marketing of generic drugs		***Title XI Subtitle B***	***Title IX***
	No provisions	Agreements between brand name companies and generic firms regarding the sale or manufacture of a generic drug that is equivalent to the pharmaceutical marketed by the patent owner must be submitted to the Federal Trade Commission and the Assistant Attorney General for review within 10 days of completion. Parties that fail to file such agreements are subject to civil penalties. The FTC may engage in rule making to carry out these provisions. The effective date is 30 days after enactment.	Agreements between brand name companies and generic firms regarding the sale or manufacture of a generic drug that is equivalent to the pharmaceutical marketed by the patent owner must be submitted to the Federal Trade Commission and the Assistant Attorney General for review within 10 days of completion. Parties that fail to file such agreements are subject to civil penalties. The FTC may engage in rule making to carry out these provisions. The effective date is 30 days after enactment.