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IN FOCUS

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"Skinny Labels" for Generic Drugs Under Hatch-Waxman

New "brand-name" drugs are often protected from generic competition by patents. In general, a drug manufacturer intending to market a generic version of a brand-name drug must either wait for those patents to expire or challenge the validity or applicability of the patents in court.

While some drug patents cover the active ingredient itself, other patents cover different things related to the drug, such as a method of using the drug. When some methods of using a drug are still patented but other uses are not, the Hatch-Waxman Act of 1984 (P.L. 98-417) provides a special process to allow limited generic entry before patent expiration. This process—sometimes called Hatch-Waxman's "skinny-label" provisions—allows a generic manufacturer to seek approval from the U.S. Food & Drug Administration (FDA) only for approved uses of the drug no longer protected by patents. This In Focus provides background on the skinny-label provisions.

New and Generic Drug Approval

All new drugs must be approved by FDA before they can be marketed or sold in the United States. New drugs are generally approved by FDA through a new drug application (NDA). To obtain FDA approval, NDA sponsors typically conduct clinical trials to demonstrate a drug's safety and effectiveness—a costly and time-consuming process. NDA sponsors must also submit proposed labeling for the drug for FDA's approval, including the approved indications for use of the drug (e.g., the diseases or conditions that the drug is approved to treat). Although FDA approves new drugs for specific indications, physicians may still prescribe an approved drug "off label" to treat other indications that FDA has not reviewed for safety and effectiveness.

To encourage generic drug entry, Hatch-Waxman created a separate pathway for FDA approval through abbreviated new drug applications (ANDAs). ANDA filers need only show that their product is pharmaceutically equivalent and bioequivalent to an FDA-approved drug with the same active ingredient (such that the new drug can be expected to have the same therapeutic effect). As a result, generic drug manufacturers need not conduct their own clinical trials on safety and efficacy, and often sell the drug at lower prices. ANDA filers must also propose labeling for the generic drug, which generally must be identical to the referenced brand-name drug's labeling.

Pharmaceutical Patents

Patents, which are granted by the U.S. Patent and Trademark Office, protect new and useful inventions. Patent rights last for about 20 years. If the patent is valid, no one else may make, use, sell, or import the patented invention in the United States during that period without permission from the patent holder. Pharmaceutical manufacturers may patent a drug's active ingredient, drug formulations, methods of using a drug, devices to administer a drug, and methods of making a drug (among other things). A single brand-name drug may be protected by multiple patents that expire at different times.

Orange Book Patents and "Use Codes"

An NDA sponsor must submit to FDA information on any patent that either (1) claims the drug (i.e., an active ingredient, formulation, or composition patent) or (2) claims a method of using the drug for which FDA approval is sought.

For method-of-use patents, FDA regulations require the NDA sponsor to include a description of the patent and information on whether the patent claims one or more FDA-approved methods of using the drug. This description must be adequate to assist future ANDA filers in determining whether the patent covers a given approved use (i.e., a drug's indication). The description provided by the NDA sponsor on method-of-use patents is known as a *use code*. The NDA sponsor must also identify the sections of the proposed drug label that describe the method(s) of use claimed by the patent. If the drug is approved, FDA publishes the patent information and use codes (along with any updates) in a resource known as the "Orange Book." The Orange Book lists all FDA-approved nonbiologic drugs, along with therapeutic equivalence evaluations and information on drug patents and other exclusivities. For more information, see CRS In Focus IF12644, *Patent Listing in FDA's Orange Book*.

FDA views its authority over patent information in the Orange Book as "ministerial." That is, FDA does not independently verify the accuracy of use codes and other patent information; FDA merely publishes it in the Orange Book. NDA sponsors must declare that the patent information they submit is accurate and complete.

ANDAs and Patent Certification

Paragraph I-IV Certifications

Under Hatch-Waxman, ANDA filers must usually make a certification for each patent listed in the Orange Book for the drug at issue. For example, ANDA filers may certify that there are no patents listed for the drug or that all the listed patents are expired. In that case, FDA may approve the ANDA whenever its review is complete.

ANDA filers may also may make what is called a *paragraph IV certification*: a claim that the patent is either invalid, or would not be infringed (i.e., violated) by the ANDA filer making and selling the generic drug. Paragraph IV certifications often lead to patent litigation in federal

court. If the NDA sponsor timely files suit following a paragraph IV certification, FDA generally cannot approve the ANDA for 30 months while the litigation proceeds (known as the "*30-month stay*").

Section viii Statements and "Skinny Labels"

Hatch-Waxman provides an additional patent certification option for method-of-use patents. With a *section viii statement*, an ANDA filer certifies that the patent does not cover the uses of the drug for which the ANDA filer seeks approval. Section viii statements are typically used when only some approved methods of using the drug are still patented. Through a section viii statement, an ANDA filer may seek FDA approval only for the approved uses of the drug that are *not* patented. Unlike a paragraph IV certification, a section viii statement does not delay FDA's ability to approve the ANDA (i.e., the 30-month stay does not apply). Along with a section viii statement, the ANDA filer must submit proposed labeling that omits the parts of the brand-name drug's labeling that correspond to still-patented uses. For this reason, generics relying on section viii statements are said to "carve out" the patented uses. The result is a *skinny label* for the generic version.

Challenges to Orange Book Patent Information

The use codes and label portions identified by the NDA sponsor define what the ANDA filer must carve out when using a section viii statement. If the use codes are overly broad (i.e., they extend beyond what a patent actually claims) then an ANDA filer may be unable to use a section viii statement as a practical matter.

ANDA filers' ability to challenge the use codes and other patent information provided by NDA holders is limited. While FDA provides a regulatory process to dispute Orange Book patent information, FDA regulations provide that FDA will not change the information unless the NDA holder agrees to update or correct it. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA) (P.L. 108-173), Congress created a counterclaim allowing ANDA filers to seek a court order correcting or deleting Orange Book patent information. Because the counterclaim is not an independent cause of action, an ANDA filer cannot assert it unless they are sued first (e.g., after a paragraph IV certification).

In *Caraco Pharmaceutical Labs. v. Novo Nordisk* (U.S. 2021), the Supreme Court construed the scope of this counterclaim that MPDIMA created. The Court unanimously held that the counterclaim could be used by generics to correct inaccurate use codes (e.g., use codes that purport to cover methods not actually protected by patent).

Justice Sonia Sotomayor wrote separately in *Caraco* to note her view that the ruling did not fully "fix" the problem of overly broad use codes. As the MPDIMA counterclaim is not an independent cause of action, an ANDA filer cannot proactively challenge an inaccurate use code in court. Rather, they must first make a paragraph IV certification, potentially be sued, trigger the 30-month stay, and only then seek to correct use codes via the counterclaim. In Justice Sotomayor's view, the result is "delay and expense the statutory scheme does not envision."

Skinny Labels and Induced Patent Infringement Liability

Because the brand-name drug is still protected by one or more patents, patients and doctors may use a generic in an infringing manner (i.e., for still-patented uses) despite a skinny label. And if a generic manufacturer takes active steps to encourage the patented uses, they may be liable for inducing patent infringement.

In *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* (Fed. Cir. 2021), the U.S. Court of Appeals for the Federal Circuit addressed whether generic manufacturers may be liable even if they carve out the indications identified in the Orange Book's use codes and do not specifically tell doctors to use the generic for carved-out uses. In *GSK v. Teva*, the Federal Circuit affirmed a jury verdict finding the generic manufacturer liable, holding that a jury could find that Teva actively induced patent infringement based on generic's label (which included an infringing indication not identified by the use code), advertising, and press releases. Judge Prost dissented, arguing that allowing liability in the case "throw[s] a wrench into Congress's design" for the skinny-label provisions. Although the U.S. Solicitor General urged the U.S. Supreme Court to take the case, the Court declined to hear Teva's appeal in 2023.

Considerations for Congress

Following *Caraco* and *GSK v. Teva*, some stakeholders question whether Hatch-Waxman's skinny-label provisions remain effective in facilitating partial generic competition when only some uses of a drug are patented. Should Congress seek to clarify the Hatch-Waxman's skinny-label provisions, there are several possible issues it may consider.

One issue concerns responsibility for monitoring and correcting Orange Book patent information. The FDA does not independently verify listed patents or use codes, and generic manufacturers have limited means to challenge this information before filing an ANDA. Because inaccurate use codes may interfere with an ANDA filer's ability to effectively use section viii statements, generic manufacturers may decline to file an ANDA or use paragraph IV certifications instead. This may lead to unneeded litigation and delay in some cases. Congress may consider whether to impose more responsibilities on FDA to monitor Orange Book patent information, or to expand current procedures for challenging that information. For example, Congress could consider creating an independent cause of action to correct Orange Book patent information (such as that proposed by S. 1128 in the 118th Congress).

GSK v. Teva makes clear that a generic manufacturer may sometimes be liable for inducing patent infringement when marketing skinny label generics. The case has arguably increased risk and uncertainty for generic manufacturers when using the section viii pathway. Congress may thus consider whether to clarify when generic manufacturers using a skinny label should be liable for indirect patent infringement through a statutory safe harbor (such as that proposed by S. 5573 in the 118th Congress).

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