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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 methods 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. This process—sometimes called Hatch-Waxman’s “[skinny-label](#)” provisions—allows a generic manufacturer to seek approval from the U.S. Food and Drug Administration (FDA) [only](#) for approved uses of the drug no longer protected by patents. This In Focus provides background and issues for Congress relating to skinny labels.

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 market entry of generic drugs, 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 the same as the referenced brand-name drug’s labeling.

Pharmaceutical Patents

Patents are granted by the [U.S. Patent and Trademark Office](#) to 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. Drug manufacturers [may patent](#) a drug’s

active ingredient, formulations, and methods of use (indications), among other things. A single 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 make what is called a [paragraph IV certification](#): a [claim](#) that the listed 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 some (but not all) 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. 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 identified by the NDA sponsor. 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 Use Codes

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, and may choose to file a paragraph IV certification or wait to file the ANDA.

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 will not [change](#) Orange Book patents or use codes unless the NDA holder agrees to update or correct them. 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 the 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 [express](#) her view that action from FDA or Congress is needed to fully “fix” the problem of overly broad use codes.

Skinny Labels and Induced Patent Infringement Liability

Because the brand-name drug is still protected by one or more patents, certain uses by patients and doctors of a skinny-label generic could be infringing (i.e., used for still-patented indications). If a generic manufacturer takes [active steps](#) to encourage the “carved out” patented uses, it may be held liable for [inducing](#) patent infringement. Courts

sometimes [disagree](#) on the line between permissible marketing of a skinny-label generic and encouraging patent infringement.

In the early 2020s, the [trend](#) of judicial decisions—particularly those of the U.S. Court of Appeals for the Federal Circuit—had run against generics using skinny labels, raising [concerns](#) from some stakeholders about whether the skinny-label pathway remained viable in light of litigation risks. For example, in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* (Fed. Cir. 2021), the Federal Circuit [affirmed](#) a jury verdict finding a generic manufacturer liable for inducement even though the manufacturer [carved out](#) the label portions identified by the brand’s use codes and did not directly tell doctors to prescribe the generic for patented uses. The majority in *GSK v. Teva* nonetheless [held](#) that a jury could reasonably find that Teva actively induced patent infringement based on the skinny [label](#) itself, as well as general statements about the drug in advertising and [press releases](#).

In its 2026 decision *Hikma Pharmaceuticals USA v. Amarin Pharma*, the Supreme Court “[reject\[ed\]](#)” *GSK v. Teva*’s approach and applied a more-demanding standard for pleading and proving induced infringement in a case involving skinny labels. The Court in *Hikma* emphasized that the Patent Act requires *active*, “[not passive](#),” inducement. Accordingly, plaintiffs must show “[affirmative](#)” actions or statements by the defendant that are “[designed](#)” to encourage infringement—“[mere omissions](#)” or “[vague statements](#)” that might cause another to infringe are not enough. Under this standard, the Court [held](#) that the skinny label itself and descriptions of the drug in press releases as a “generic equivalent” of the brand-name version were not affirmative acts that could support inducement liability. *Hikma* was [widely viewed](#) as reducing liability risks for generic drugmakers using skinny labels.

Considerations for Congress

Should Congress seek to clarify Hatch-Waxman’s skinny-label provisions, there are several possible issues it may consider. One issue concerns responsibility for monitoring and correcting patent information in the Orange Book. The FDA does not independently verify use codes, and generic manufacturers have limited means to challenge them. Yet, inaccurate use codes may interfere with generic drugmakers’ ability to effectively use section viii statements. This may lead to litigation and delay in generic approval 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, a bill introduced as S. 1128 in the 118th Congress would have created an independent cause of action to correct Orange Book patent information.

Another issue concerns the standards for inducement liability for skinny-label generics, which Congress could clarify or change by amending the Patent Act. For example, a bill introduced prior to the *Hikma* decision—the Skinny Labels, Big Savings Act (H.R. 6485 and S. 43 in the 119th Congress)—would create a statutory safe harbor from

patent infringement liability for generic and biosimilar manufacturers who comply with skinny-label requirements.

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