No. 10-844

In the Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD., ET AL., PETITIONERS

v.

NOVO NORDISK A/S, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

DONALD B. VERRILLI, JR.
Solicitor General
Counsel of Record
TONY WEST
Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
BETH S. BRINKMANN
Deputy Assistant Attorney General
BENJAMIN J. HORWICH
Assistant to the Solicitor General
DOUGLAS N. LETTER
DANIEL TENNY
Attorneys
Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

By filing an abbreviated new drug application (ANDA), a manufacturer may seek approval from the Food and Drug Administration (FDA) to market a generic version of a previously approved brand-name drug. The ANDA must address, *inter alia*, each patent that claims a method of using the drug. If the ANDA seeks approval for a use claimed by a patent, it must include a certification that the patent has expired, will expire, is invalid, or would not be infringed by the sale or use of the generic drug. Alternatively, the ANDA applicant may inform FDA that it seeks approval for a method of use that the patent does not claim. To determine whether an ANDA seeks approval for a patented use—and hence whether it includes the required certifications—FDA relies on information describing the relevant patent's scope submitted by the brand-name manufacturer under FDA regulations.

The brand-name manufacturer may sue the ANDA applicant for patent infringement if, *inter alia*, the ANDA seeks approval for a patented use before the relevant patent has expired. The ANDA applicant may respond with "a counterclaim seeking an order requiring the [brand-name manufacturer] to correct or delete the patent information [it previously] submitted * * * on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. 355(j)(5)(C)(ii)(I). The question presented is as follows:

Whether an ANDA applicant may assert a counterclaim under Section 355(j)(5)(C)(ii)(I) by alleging that the brand-name manufacturer's patent information does not accurately and precisely describe the method of use claimed by its patent.

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INTEREST OF THE UNITED STATES

This case presents the question whether an applicant seeking approval from the Food and Drug Administration (FDA) to manufacture a generic equivalent of a brand-name drug can challenge the accuracy and precision of certain patent information that is submitted to FDA by the brand-name manufacturer. Because patent information submitted by the brand-name manufacturer is integral to FDA's decision whether to approve generic drugs, but FDA lacks the resources and expertise necessary to determine whether that information is accurate and precise, the United States has an interest in an effective judicial mechanism for resolving such challenges. If left uncorrected, inaccurate or imprecise brand-name

patent information can delay FDA's approval of generic drugs, thereby depriving consumers of the benefits of competition between generic and brand-name manufacturers. At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. a. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, FDA regulates the manufacture, sale, and labeling of prescription drugs. To obtain FDA's approval to market a new drug, a manufacturer must submit a new drug application (NDA). 21 U.S.C. 355(b). The NDA must contain, *inter alia*, a statement of the drug's components, proposed labeling that describes the uses for which the new drug may be marketed, and scientific data and other information demonstrating that the drug is safe and effective as labeled. 21 U.S.C. 355(b)(1). A drug approved under the NDA process is often referred to as a "brand-name" drug.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments. To facilitate the entry of generic competitors, the Hatch-Waxman Amendments provide that, after a brand-name drug's NDA has been approved, and subject to certain periods of NDA exclusivity (see 21 U.S.C. 355(j)(5)(F)), any manufacturer may seek approval to market a generic version by filing an abbreviated new drug application (ANDA) with FDA. See 21 U.S.C. 355(j). The ANDA process does not require the generic manufacturer to provide independent clinical evidence of safety or efficacy. Instead, the ANDA must generally show, *inter alia*, that the generic drug has the

same active ingredient(s) as, and is bioequivalent to, a reference listed drug (RLD), *i.e.*, the brand-name drug to which the proposed generic will be compared. 21 U.S.C. 355(j)(2)(A)(ii) and (iv).

b. An ANDA must also explain how the generic drug can be marketed without infringing certain of the NDA holder's patents. See 21 U.S.C. 355(j)(2)(A)(vii)-(viii). To facilitate that process, NDA holders submit patent information to FDA, and FDA publishes certain information in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." See 21 U.S.C. 355(b)(1), (c)(2) and (j)(7). The patent information published in the Orange Book then serves as a frame of reference for the ANDA.

i. The Hatch-Waxman Amendments require an NDA applicant to submit "the patent number and the expiration date of 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 if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). FDA "publish[es] in the [Orange Book] the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant." 21 C.F.R. 314.53(e). FDA's implementing regulations require the applicant to submit certain additional patent information during the NDA approval process. See 21 C.F.R. 314.53. The current regulations trace to a significant 2003 rulemaking, which is discussed in detail below, pp. 7-10, *infra*.

The informational requirements applicable to method-of-use patents are of particular relevance here. Once a new drug is approved, the manufacturer must

submit "a description of each approved method of use or indication and related patent claim of the patent being submitted"; identify "the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted"; and provide a "description of the patented method of use as required for publication" in the Orange Book. 21 C.F.R. 314.53(c)(2)(ii)(P). "[F]or each use patent," FDA publishes "the approved indications or other conditions of use covered by a patent" (commonly called a "use code"). 21 C.F.R. 314.53(e).

ii. An ANDA must account for each patent listed in the Orange Book as associated with the RLD. That requirement is easily satisfied when the listed patent has expired or the ANDA applicant is willing to await approval until the patent expires. See 21 U.S.C. 355(j)(2)(A)(vii)(II)-(III). Otherwise, the ANDA applicant has two choices with respect to a patent claiming a method of using the drug.

In appropriate circumstances, the ANDA applicant may assert that, although the listed patent claims a method of using the RLD, the ANDA applicant does not seek approval of its drug for that use. 21 U.S.C. 355(j)(2)(A)(viii). This assertion is known as a "section viii statement." If an ANDA applicant makes a section viii statement, and the ANDA is otherwise approvable, FDA may approve the ANDA without requiring any further steps relating to the patent. In that circumstance, FDA will approve appropriate labeling for the generic drug that "carves out" information related to the patented use (as described in the use code) from the RLD's existing approved labeling, thus approving the generic drug only for unpatented uses. See 21 C.F.R. 314.94(a)(8)(iv), 314.127(a)(7). Approval with carve-out

labeling is permitted, however, only if the drug so labeled will remain safe and effective for the remaining non-patented methods of use. See *ibid.* FDA will not approve an ANDA with a section viii statement if there is any overlap between the methods of using the drug reflected in (1) the carved-out labeling proposed in the ANDA and (2) the use code in the Orange Book. See 68 Fed. Reg. 36,682-36,683 (2003). In performing that comparison, FDA does not independently assess the patent's scope, but instead relies on the NDA holder's description (*i.e.*, the use code) of the method(s) of use that its patent covers.

Alternatively, if a section viii statement is not feasible (because the patent's use code effectively precludes carve-out labeling) or undesirable (because the ANDA applicant wishes to market its drug before expiration of the patent without carving out the protected use), the ANDA applicant may certify that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the [ANDA applicant's] drug," 21 U.S.C. 355(j)(2)(A)(vii)(IV). This is known as a "paragraph IV certification." A paragraph IV certification cannot be premised on proposed carve-out labeling. Rather, the ANDA applicant must certify that the NDA holder's patent is invalid or will not be infringed even if the generic drug is labeled in the same manner as the RLD.

Rather than embroiling FDA in controversies over patent validity and infringement, Congress channeled disputes about paragraph IV certifications to the courts. Thus, an ANDA applicant that makes a paragraph IV certification must provide notice to the NDA holder, 21 U.S.C. 355(j)(2)(B), which may then file a patent-infringement suit in district court without waiting for some other potentially infringing act, see 35 U.S.C.

271(e)(2)(A). If the NDA holder sues within 45 days after receiving statutory notice, FDA generally may not approve the ANDA until the court finds the patent invalid or not infringed, or 30 months elapse from the NDA holder's receipt of statutory notice. See 21 U.S.C. 355(j)(5)(B)(iii). If the patent owner does not sue within 45 days, FDA may approve the application immediately, *ibid.*, though without prejudice to infringement claims the patent owner might assert when the ANDA applicant produces or markets the generic drug.

c. The Hatch-Waxman Amendments include additional provisions that further affect the length of time a brand-name manufacturer can market its drug free from generic competition. Because a brand-name manufacturer generally cannot exploit its patent until its drug is approved, the sometimes-lengthy NDA process effectively shortens the period during which the manufacturer enjoys patent protection. To address that issue, the Hatch-Waxman Amendments authorize the extension of patents on approved drugs to account for the period during which the NDA was under review at FDA. 35 U.S.C. 156(a). On the other hand, the Hatch-Waxman Amendments authorize would-be generic competitors to engage in specified preparatory activities that would otherwise constitute patent infringement, 35 U.S.C. 271(e)(1), so that generic competitors can be ready and able to market their drugs as soon as the brand-name manufacturer's patents expire. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 671-672 (1990) (discussing these changes).

2. a. The Hatch-Waxman Amendments have benefitted consumers by fostering substantial competition from generic drugs. When multiple generic competitors enter the market for a drug, the price for the drug (in

generic form) is typically 50% to 80% below the brand-name drug's price. FDA, *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (Mar. 1, 2010). According to Congressional Budget Office (CBO) estimates, consumers saved $8 to $10 billion in 1994 from generic drugs, and in 2007, Medicare alone (through its prescription drug benefit) saved $33 billion from generic drugs. CBO, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 13 (July 1998); CBO, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending* 7-8 (Sept. 2010).

Starting in the late 1990s, however, brand-name manufacturers began to exploit certain features of the original Hatch-Waxman scheme to prevent or delay FDA approval of generic competitors. See generally Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (*Generic Drug Entry*) (discussing manufacturers' anticompetitive behavior). In particular, some brand-name manufacturers submitted to FDA patent information that arguably was not appropriate for listing in the Orange Book. FDA was nevertheless obliged under the statute and regulations to publish that information, and the ensuing litigation prevented or delayed FDA's approval of ANDAs. See *id.* at 39-56; A-39 to A-45 (discussing Orange Book listing issues and describing several such episodes).[1]

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[1] Even if a patent cannot be listed in the Orange Book, the brand-name manufacturer may be able to assert a traditional claim of patent infringement once the generic drug is marketed. From the NDA holder's point of view, the significance of Orange Book listing is that, if the ANDA applicant makes a paragraph IV certification and the brand-name manufacturer timely commences an infringement action, FDA

In 2002, FDA initiated a rulemaking to ameliorate this situation. 67 Fed. Reg. 65,448. FDA explained that it interpreted the Hatch-Waxman Amendments to permit listing only of patents that claim the active ingredient or formulation of the approved drug, or an approved method of using the drug. FDA stated that "process patents [for making the drug], patents claiming packaging, patents claiming metabolites [*i.e.*, compounds produced in the body as a result of administering the drug], and patents claiming intermediates [*i.e.*, materials produced in processing the drug that are not present in the finished product] are not covered." *Id.* at 65,451. FDA acknowledged that its existing practice—which allowed an NDA applicant simply to declare that its patent "covers the formulation, composition and/or method of use of [the drug]"—may have proven "insufficient in practice to prevent NDA applicants * * * from attempting to list inappropriate patents." *Id.* at 65,453. FDA therefore proposed to "ask NDA applicants * * * to provide more patent information to help ensure that only appropriate patents are listed," and it "propos[ed] to require * * * NDA applicants to identify the specific pending or approved use claimed by a method of use patent." *Id.* at 65,453, 65,454.

FDA's 2003 final rule largely implemented that proposed approach. To "reduce confusion and help curb attempts to take advantage of th[e] process," FDA replaced the conclusory declarations that its prior approach had allowed with structured forms and a "rule

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approval of the ANDA is significantly delayed pending resolution of that suit. See pp. 5-6, *supra*. An Orange Book listing thus can provide the NDA holder the rough practical equivalent of an automatic preliminary injunction during the first 30 months of any infringement litigation.

[that] clarifies patent submission and listing requirements." 68 Fed. Reg. at 36,676; see *id.* at 36,707-36,712 (forms). To "ensure that only patents meeting the statutory requirements will be submitted for listing," *id.* at 36,683, the forms and rule direct the NDA holder to classify the submitted patent as claiming either a "drug substance (active ingredient)," a "drug product (composition/formulation)," or a "method of use" of the drug, *id.* at 36,711.

The forms and rule addressed method-of-use patents in further detail because mischaracterization of such patents had interfered with the agency's implementation of section viii, the provision authorizing an ANDA applicant to seek carve-out labeling to avoid a listed method-of-use patent. As FDA explained, "submission of inappropriate patent information led to confusion and then to litigation over an ANDA applicant's obligation to submit either a paragraph IV certification * * * or a 'section viii' statement." 68 Fed. Reg. at 36,682. The 2003 rule therefore "require[d] the NDA applicant * * * to identify specifically the approved uses claimed by the method-of-use patent," thereby enabling ANDA applicants and FDA to "determine whether the [ANDA] applicant must submit a patent certification or may submit a section viii statement." *Ibid.*; see *id.* at 36,685 ("The specific method-of-use claims are essential to our review [of section viii statements].").

FDA expected that the clarity and information-submission requirements of its new rule would "reduce confusion and help curb attempts to take advantage of th[e] [patent-information] process." 68 Fed. Reg. at 36,676. The agency acknowledged, however, that even its new system would ultimately depend on the accuracy of information submitted by NDA applicants. See, *e.g.*,

id. at 36,687 ("[W]e will not evaluate a patent to assess whether the declaration is accurate or whether the patent has been appropriately submitted for listing."); *id.* at 36,682 ("In determining whether an ANDA applicant can 'carve out' the method of use, * * * we will rely on the description of the approved use provided by the NDA holder or patent owner."). Although several commenters asked FDA to create an administrative process for challenging patent listings, *id.* at 36,683, FDA declined to do so. FDA explained that it "lack[s] both the resources and the expertise to resolve such matters," and that a "fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents." *Ibid.*

b. Later in 2003, Congress complemented FDA's rulemaking by creating a judicial mechanism to resolve disputes about patent information submitted to FDA. See 149 Cong. Rec. 15,516 (2003) (statement of Sen. Schumer) ("[W]hen the FDA actually talked about closing these loopholes, it was made clear that legislation would be needed to finish the job."). Congress authorized an ANDA applicant defending a patent-infringement action to

> assert a counterclaim seeking an order requiring the [RLD NDA holder] to correct or delete the patent information submitted by the holder under [21 U.S.C. 355(b) or (c)] on the ground that the patent does not claim either—
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. 355(j)(5)(C)(ii)(I) (added by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(C), 117 Stat. 2452). Like the original Hatch-Waxman scheme for paragraph IV litigation, the counterclaim provision assigns FDA no role in deciding the scope or validity of patents, and instead channels such disputes to courts.

3. a. Petitioner Caraco wishes to market a generic version of Prandin®, respondents' brand-name version of the diabetes drug repaglinide. Respondents' patent on the repaglinide compound expired in 2009. Respondents also own a patent (the '358 patent) that will expire in 2018 and that pertains to the combination of repaglinide with another drug, metformin. Claim 4 of the '358 patent claims "[a] method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin." J.A. 96.

Petitioner submitted an ANDA seeking approval of a generic version of repaglinide upon the expiration (in 2009) of respondents' patent on the repaglinide compound. When petitioner initially filed its ANDA, respondents' use code for the '358 patent described Claim 4 as pertaining to the "[u]se of repaglinide in combination with metformin to lower blood glucose." Pet. App. 8a. Petitioner's ANDA initially included a paragraph IV certification to the '358 patent, asserting that the patent was invalid or would not be infringed by petitioner's marketing of generic repaglinide. Respondents filed a timely infringement action, thus delaying FDA's approval of petitioner's ANDA. Petitioner later amended its ANDA to replace the paragraph IV certification to Claim 4 of the '358 patent with a section viii statement, which made clear that petitioner did not seek approval

for use of the repaglinide-metformin combination therapy. FDA indicated that, once petitioner's ANDA was otherwise approvable, FDA would approve carve-out labeling that excluded the combination-therapy use (but included, for example, use of repaglinide on its own, known as "monotherapy"). *Ibid*.

Meanwhile, as part of an effort to improve the labeling of oral anti-diabetic drugs (including Prandin®), FDA asked respondents to revise Prandin®'s labeling to "[r]eplace all the separate indications [for use of the drug] (e.g., monotherapy, combination therapy, and initial or second-line therapy) with the following sentence: 'Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.'" J.A. 164. Respondents complied, J.A. 31, though information about use of repaglinide in combination with metformin remained in the clinical-trials section of Prandin®'s labeling, J.A. 27. About a year later, respondents submitted to FDA an amended use code for the '358 patent that tracked the revised indication for Prandin®: "A method for improving glycemic control in adults with type 2 diabetes mellitus." Pet. App. 9a. FDA neither requested nor required that change.

Petitioner could not carve out the single approved indication that corresponded to respondents' new use code because that would leave petitioner's labeling without any approved indication, rendering its drug not safe and effective. Accordingly, FDA reversed course and disallowed a labeling carve-out. Petitioner then filed a counterclaim against respondents in the pending infringement suit, seeking an order directing respondents to revert to the old use code. That prior use code had made clear that the '358 patent does not claim the entirety of the single approved indication, but rather

claims only the use of repaglinide in combination with metformin to lower blood glucose.

b. The district court held that petitioner's counterclaim was proper and that respondents' new use code was overbroad. Pet. App. 65a-96a. The court explained that the counterclaim provision was designed to address the possibility that an ANDA applicant "could be seriously disadvantaged by an incorrect Use Code narrative." *Id.* at 93a. On the merits, the court agreed with petitioner that respondents' new use code misleadingly "suggests that [the '358] patent covers any method of improving glycemic control in adults with Type 2 diabetes." *Id.* at 71a. The district court accordingly enjoined respondents to "correct * * * [their] inaccurate description of the '358 patent by submitting to FDA [a use code] that * * * describes claim 4 of the '358 patent * * * as covering the 'use of repaglinide in combination with metformin to lower blood glucose.'" *Id.* at 65a-66a.

4. The court of appeals reversed. Pet. App. 1a-52a.

a. The court of appeals first discussed the counterclaim provision's reference to a patent that "does not claim * * * an approved method of using the drug." The court interpreted that language to apply only when the patent does not claim *any* approved method of using the drug. Pet. App. 11a-12a. The court therefore held that the counterclaim mechanism is unavailable if (as here) the listed patent claims at least one approved method of using the drug, even if the NDA holder's use code misleadingly suggests that the patent claims other approved methods of use as well.

The court of appeals found that conclusion to be further supported by the counterclaim provision's authorization of "an order compelling 'the holder to correct or delete *the patent information* submitted by the holder

under subsection (b) or (c).'" Pet. App. 15a (quoting 21 U.S.C. 355(j)(5)(C)(ii)(I)). The referenced provisions, 21 U.S.C. 355(b) and (c), require NDA applicants to submit only the patent number and expiration date of the relevant patents, not the more detailed information (including the use code) that is mandated by FDA regulations. Pet. App. 15a. The court of appeals inferred from that fact that the only relief available under the counterclaim provision is an order directing the NDA holder to delete or correct a patent number or expiration date, and that the provision is not concerned with errors or misrepresentations in a use code. *Id.* at 15a-16a.

b. Judge Clevenger concurred. Pet. App. 19a-21a. As relevant here, he agreed with the court's textual analysis, though he was skeptical that paragraph IV litigation would resolve the parties' dispute over respondents' use code. *Id.* at 19a.

c. Judge Dyk dissented. Pet. App. 22a-52a. He would have read the phrase "the patent does not claim * * * an approved method of using the drug" to encompass the situation in which information in the Orange Book incorrectly asserts that the patent claims a particular approved method of use. *Id.* at 40a. Judge Dyk further explained that, when the counterclaim provision was enacted in 2003, FDA had already "adopted detailed requirements for the submission of 'patent information' for both drugs and methods," including use codes, *id.* at 33a, and "Congress was well aware of this regulatory interpretation of 'patent information' when it enacted the counterclaim provision," *id.* at 36a. Judge Dyk therefore would have read the term "patent information" in the counterclaim provision to encompass the "method of use" information at issue in this case. *Id.* at 39a.

d. The court of appeals denied rehearing en banc with two judges dissenting. Pet. App. 53a-56a.

5. The district court subsequently held the '358 patent invalid for obviousness and unenforceable for inequitable conduct before the Patent and Trademark Office. Br. in Opp. App. 14a. Respondents' appeal from that judgment has been stayed pending this Court's decision in this case. *Novo Nordisk A/S* v. *Caraco Pharm. Labs., Ltd.*, No. 2011-1223 Docket entry (Fed. Cir. July 27, 2011).

SUMMARY OF ARGUMENT

A. The text and context of the counterclaim provision show that it authorizes an ANDA applicant to challenge an NDA holder's overbroad use code.

1. An ANDA applicant can obtain an order requiring the NDA holder "to correct or delete * * * patent information * * * on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. 355(j)(5)(C)(ii)(I). Because respondents represented to FDA that the '358 patent claims a method of using repaglinide, subsection (bb) applies here. Respondents contend that, so long as the patent claims some approved method of use—here, use of repaglinide in combination with metformin—subsection (bb) is unavailable. Petitioner argues that the '358 patent "does not claim * * * an approved method of using the drug" because it does not claim the use of repaglinide for monotherapy, the approved use for which petitioner seeks carve-out labeling under section viii. Petitioner is correct.

Petitioner's reading preserves more natural and distinct roles for the terms "correct" and "delete" in the

counterclaim provision than does respondents' interpretation. And by allowing "correct[ion]" of overbroad use codes, petitioner's reading allows the counterclaim provision to facilitate the section viii process, thereby preventing inaccurate or imprecise Orange Book listings from impeding FDA approval of generic drugs. Respondents' reading, by contrast, disregards the role of the counterclaim provision within the statutory framework and forecloses judicial relief no matter how great the disparity between the NDA holder's use code and the patent's actual coverage.

2. The remedy available through the counterclaim provision—an "order requiring the [NDA holder] to correct or delete the patent information submitted by the holder under [21 U.S.C. 355(b) or (c)]"—encompasses the remedy petitioner seeks here. In particular, the "patent information" that can be "correct[ed]" includes a use code. That use code is "patent information" both in the ordinary sense and in the sense FDA used the phrase in the 2003 rulemaking that set the stage for Congress's enactment of the counterclaim provision. And that use code was "submitted" by respondents "under"—that is, in a proceeding governed by—the referenced statutory sections governing NDAs.

B. Respondents' narrow interpretation of the counterclaim provision would undermine the Hatch-Waxman scheme.

1. The Hatch-Waxman Amendments were designed to achieve a balance between creating incentives that foster drug innovation and promoting competition that benefits consumers. Starting in the late 1990s, NDA holders had upset that balance by submitting to FDA inappropriate patent information that prevented or delayed generic competitors from entering the market.

The counterclaim provision enacted in 2003 provides a judicial mechanism to remedy such abuses. Petitioner's invocation of the counterclaim provision here protects the Hatch-Waxman balance in the way Congress envisioned.

2. In respondents' view, the counterclaim provision authorizes judicial enforcement of some of FDA's patent-listing requirements (in particular, FDA rules specifying that certain types of patents should not be listed at all), but not others (of relevance here, FDA's determination that an NDA holder should submit a use code that identifies specifically the approved uses claimed by a method-of-use patent). That distinction makes little sense. Both types of regulatory violation involve an NDA holder's submission of incorrect or misleading patent information; both exploit FDA's lack of resources, authority, or expertise to police patent claims; and both can delay or obstruct a generic drug's entry into the market. The concerns that prompted Congress to enact the counterclaim provision are therefore directly and fully implicated here.

ARGUMENT

In respondents' view, a brand-name manufacturer can prevent or delay generic competition by submitting to FDA an overbroad description of its method-of-use patent. Congress enacted the counterclaim provision, however, to combat precisely that sort of manipulation. The text and context of the provision show that it provides a remedy under the circumstances petitioner alleges here. Reading the counterclaim provision in the constricted way respondents propose would impair ANDA applicants' ability to secure FDA approval for their products, subvert Congress's effort to create a

meaningful judicial check on NDA holders' exaggerated claims of patent protection, and deprive consumers of the full benefit of generic competition.

A. The Text And Context Of The Counterclaim Provision Show That It Authorizes A Challenge To An Overbroad Use Code

The court of appeals made two errors in parsing the counterclaim provision. First, it read the provision to require a showing that a method-of-use patent listed in the Orange Book does not claim *any* "approved method of using" an approved drug. In fact, the text and context of the provision indicate that, even if a brand-name manufacturer's patent covers *some* approved method of using the drug, a counterclaim can be asserted if the NDA holder's use code falsely or misleadingly describes the patent's scope in a way that blocks approval of a generic equivalent for other approved uses that the patent does not claim. Second, in considering whether a remedy was available to petitioner, the court of appeals gave an unduly narrow reading to the phrase "patent information submitted by the [NDA] holder under [21 U.S.C. 355(b) or (c)]." Use codes are literally "patent information," and by regulation they are "submitted * * * under" the specified subsections.

1. a. The counterclaim provision states that an ANDA applicant can obtain relief "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. 355(j)(5)(C)(ii)(I). The phrase "on the ground that" indicates that subsections (aa) and (bb) state the exclusive bases on which the district court can "requir[e] the [NDA] holder to correct or delete the [Orange Book] patent information." *Ibid.*;

see *Black's Law Dictionary* 772 (9th ed. 2004) (defining "ground" as "the reason or point that something * * * relies on for validity"). By the time the counterclaim provision was enacted in 2003, "the FDA had adopted detailed requirements for the submission of 'patent information' for both drugs and methods." Pet. App. 33a (Dyk, J., dissenting). Those regulations and accompanying forms require each NDA holder or applicant, with respect to each patent listed in the Orange Book, "to identify whether the submitted patent claims a 'drug substance,' 'drug product,' or 'method of use.'" *Id.* at 36a; see pp. 8-9, *supra*.

When an NDA holder has identified a particular patent as claiming a drug substance or drug product (and thus does not assert that the patent claims a method of using the drug), an ANDA applicant who wishes to challenge that listing can rely on subsection (aa) of the counterclaim provision to assert that the patent does not claim "the drug for which the application was approved." The counterclaimant might contend, for example, that the patent actually claims a metabolite of the drug. See p. 8, *supra*. When the NDA holder identifies a patent as a method-of-use patent (and thus does not assert that the patent claims the drug itself), an ANDA applicant can invoke subsection (bb) of the counterclaim provision to allege that the patent does not claim "an approved method of use." The counterclaim provision is thus best understood as authorizing the would-be generic manufacturer to respond to the NDA holder's description of its own patent by asserting that the patent does not claim either the approved drug or an approved method of use, *as the case may be*.

b. In their revised Orange Book use code, respondents described Claim 4 of the '358 patent as claiming

"[a] method for improving glycemic control in adults with type 2 diabetes mellitus." Pet. App. 9a. Because respondents described their patent as claiming an approved method of use rather than the drug itself, petitioner's challenge to the Orange Book listing turns on the proper interpretation of subsection (bb) of the counterclaim provision. Respondents contend that, so long as the patent claims *some* approved method of use—here, use of repaglinide in combination with metformin—subsection (bb) is unavailable, even if their use code misleadingly suggests that the patent claims other approved methods of use as well. Petitioner argues that the '358 patent "does not claim * * * an approved method of using the drug" because it does not claim use of repaglinide for monotherapy, the approved use for which petitioner seeks carve-out labeling under section viii. Petitioner is correct.

First, petitioner's interpretation preserves distinct roles for the terms "correct or delete" in the counterclaim provision. Under respondents' view, an Orange Book listing of a method-of-use patent can be successfully attacked only if the patent does not claim *any* approved method of use. But if an ANDA applicant can make that showing, the patent should not be listed in the Orange Book at all, and the listing should accordingly be "delete[d]." The word "correct," by contrast, naturally covers situations where a particular method-of-use patent is appropriately listed in the Orange Book, but the use code submitted by the NDA holder falsely or misleadingly describes the method(s) of use that the patent claims. Thus, an NDA holder's use code may be judicially "correct[ed]" if the counterclaimant identifies an approved method of use that is encompassed by the use

code but that the patent does not actually claim. See Pet. App. 40a (Dyk, J., dissenting).

Second, respondents' argument disregards the role of the counterclaim provision within the larger statutory framework. See, *e.g.*, *Davis* v. *Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) (explaining that individual statutory provisions "must be read in their context and with a view to their place in the overall statutory scheme"). The section viii process, which long predated the 2003 enactment of the counterclaim provision, was specifically designed to ensure that an NDA holder's patent on *one* approved method of use did not foreclose the marketing of generic drugs for *other*, unpatented approved methods. In its 2003 rulemaking, moreover, FDA expressly linked its new patent-information requirements to the section viii process. The agency explained that it was requiring more specific information on method-of-use patents in order to enable ANDA applicants and FDA more accurately to "determine whether the applicant * * * may submit a section viii statement." 68 Fed. Reg. at 36,682; see p. 9, *supra*.

The purpose of the counterclaim provision was to afford a judicial remedy when inaccurate or imprecise Orange Book listings impede FDA approval of generic drugs. And subsection (bb) of the counterclaim provision makes clear that Congress specifically contemplated the provision's application to method-of-use patents. Allowing judicial "correct[ion]" of overbroad method-of-use listings ensures that the counterclaim provision can facilitate the section viii process, thereby furthering the objectives that FDA sought to achieve when it required more precise method-of-use information. As applied to method-of-use patents, the counterclaim provision would fail to serve its intended purpose

in an important category of cases if it could be invoked only when a listed patent claims no approved method of use at all.[2]

The general fact pattern involved in this case, in which an NDA holder's method-of-use patent remains in effect well after the patent on the drug itself has expired, is a common one. To prevent such patents from foreclosing generic competition with respect to *unpatented* uses, and thus effectively extending the NDA holder's monopoly on the approved drug, it is essential that Orange Book listings accurately and precisely describe the methods of use that NDA holders' patents claim. See Pet. App. 71a-72a (district court opinion). Under respondents' reading of the counterclaim provision, however, judicial relief is unavailable no matter how great the disparity between the NDA holder's use code and the patent's actual coverage. Respondents' reading thus invites an NDA holder to exploit a patent claiming one approved use of a drug to block generic competition in all other approved uses of the drug. To the extent the counterclaim provision is ambiguous, it should be construed to avoid that untoward result.

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[2] The court of appeals underappreciated the relevance of the statutory context because it "detect[ed] no ambiguity in the statutory language." Pet. App. 12a. But the court's reasoning—that "standard grammar generally provides that 'a' means 'any,'" *ibid.*—is mistaken. Context often informs whether "a" means "one" or "any." For example, when spoken to someone holding four tennis rackets, the statement "if you are not using a racket, I'd like to practice my serve" is naturally interpreted as asking whether *one* racket is not in use, while the statement "if you are not using a racket, my family would like to play doubles" is naturally interpreted as asking whether *any* rackets are in use.

2. The court of appeals also held that the counterclaim was unavailable to petitioner because the remedy it prescribes—"an order compelling 'the [NDA] holder to correct or delete the patent information submitted by the holder'"—did not encompass the correction of a use code. Pet. App. 15a-17a. The court construed the term "patent information" in the counterclaim provision to be limited to "the patent number and the expiration date." *Id.* at 15a.[3] That is mistaken.

a. A use code is "patent information" within any usual understanding of that term because it is "information"—a "description of the patented method of use," 21 C.F.R. 314.53(c)(2)(ii)(P)(3)—about a "patent." Use codes are also properly characterized as being "submitted * * * under subsection (b) or (c) of this section" (*i.e.*, 21 U.S.C. 355(b) or (c)). Sections 355(b) and (c) describe the entire process for seeking and obtaining approval for an NDA. In that context, "under" is best read to mean "in a proceeding subject to or governed by" Sections 355(b) and (c). Cf. *Ardestani* v. *INS*, 502 U.S. 129, 135 (1991) (reaching similar conclusion); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 666-667 (1990) (construing a Hatch-Waxman provision that refers to "submission of information *under* a Federal law" to "suggest[] [a submission] in furtherance of or compli-

[3] Based on its understanding of the term "patent information," the court of appeals concluded that "the counterclaim provision only authorizes suits to correct or delete an erroneous patent number or expiration date." Pet. App. 15a-16a. But the counterclaim provision does not authorize the court to order correction or deletion of patent information "on the ground that" the patent number or expiration date listed in the Orange Book is incorrect. Rather, subsections (aa) and (bb) of the counterclaim provision state the exclusive grounds on which the court can order patent information to be corrected or deleted. See pp. 18-19, *supra*.

ance with a comprehensive scheme of regulation"). The patent information encompassed by the counterclaim provision (*i.e.*, the information "submitted * * * under" Sections 355(b) and (c)) thus includes everything FDA requires NDA holders to submit in the course of seeking and maintaining approval of an NDA—including the use code at issue here.

Respondents would limit "patent information submitted * * * under subsection (b) or (c)" to "patent information described in" those subsections. Resp. C.A. Br. 24. To be sure, the only patent information that Sections 355(b) and (c) *require* to be submitted is the patent number and expiration date. But the counterclaim provision does not refer to patent information "described in" or "required by" or "prescribed by" Sections 355(b) or (c). Other provisions within Section 355, by contrast, do use such language. See 21 U.S.C. 355(d)(6) (directing FDA to refuse to approve an NDA if "the [NDA] failed to contain the patent information *prescribed by* subsection (b) of this section") (emphasis added); see also 21 U.S.C. 355(e)(4) (using same phrasing in identifying grounds for withdrawing NDA approval). Because "[t]he use of different terms within related statutes generally implies that different meanings were intended," *United States* v. *Bean*, 537 U.S. 71, 76 n.4 (2002) (citation omitted), the word "under" in the counterclaim provision reaches beyond the patent information expressly referenced in Sections 355(b) and (c).

b. The regulatory backdrop against which Congress enacted the counterclaim provision in 2003 reinforces the natural reading of the statutory language. Earlier that year, FDA had promulgated regulations specifying what "patent information" an NDA applicant must submit. Pet. App. 16a (citing 21 C.F.R. 314.53). Those reg-

ulations, entitled "Submission of Patent Information," require an NDA applicant to submit descriptions of the uses claimed by its method-of-use patents. 21 C.F.R. 314.53(c)(2)(i)(O) and (ii)(P); see 68 Fed. Reg. at 36,703. The accompanying forms for submitting that information to FDA state that information on the forms is "provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(b) and (c)]." 68 Fed. Reg. at 36,707, 36,710.[4]

Similarly, FDA regulations in effect since 1994 precluded an ANDA applicant from submitting a section viii statement if it sought approval for an indication that, "according to the patent information submitted under section 505(b) or (c) of the act [21 U.S.C. 355(b) or (c)] and [21 C.F.R] 314.53[,] * * * is claimed by a use patent." 21 C.F.R. 314.94(a)(12)(iii)(B). Thus, FDA has always understood the patent information listed in 21 C.F.R. 314.53—which as of 2003 included use codes—to be "submitted under section 505(b) or (c) of the act [21 U.S.C. 355(b) or (c)]."

"Congress was well aware of this regulatory interpretation of 'patent information' when it enacted the counterclaim provision." Pet. App. 36a (Dyk, J., dissent-

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[4] Relying on FDA's Federal Register notice regarding Office of Management and Budget clearance of the forms used for submitting patent information, respondents contend that FDA "require[s] use code narratives under its general rulemaking authority and [21 U.S.C. 355](j)." Br. in Opp. 27 (citing 72 Fed. Reg. 21,268-21,269 (2007)). But the forms refer to Sections 355(b) and (c), not Section 355(j). 68 Fed. Reg. at 36,707, 36,710. More fundamentally, respondents' argument conflates the *manner* in which the patent information is provided to FDA (as part of an NDA submitted under 21 U.S.C. 355(b) and (c)) with the *reason* the patent information is needed ("for effective implementation of the patent certification and 'section viii statement' provisions," 72 Fed. Reg. at 21,268).

ing) (discussing pertinent legislative history). Indeed, the purpose of the counterclaim provision was to authorize judicial enforcement of FDA's recently expanded requirements governing Orange Book listings. There is consequently no sound reason to suppose that the "patent information" to which the counterclaim provision refers is more limited than the "patent information" that FDA requires NDA holders to submit. See *id.* at 37a-38a & nn.11-12 (citing cases).

B. An Unduly Narrow Reading Of The Counterclaim Provision Would Undermine The Hatch-Waxman Scheme

Respondents' narrow interpretation of the counterclaim provision would frustrate Congress's purposes. Properly understood, that provision protects the Hatch-Waxman scheme's balance between encouraging brand-name manufacturers to develop and market new drugs and facilitating the entry of generic drugs that promote competition.

1. The counterclaim provision protects the Hatch-Waxman Amendments' balance between innovation and competition

The Hatch-Waxman Amendments were designed to achieve a balance between, on the one hand, fostering drug innovation by providing NDA holders a reasonable period of exclusivity and, on the other hand, promoting competition that benefits consumers by facilitating the timely entry of generic drugs. The time required to secure FDA approval—both initially for an NDA and later for an ANDA—can significantly affect the length of the NDA holder's exclusivity. See *Eli Lilly*, 496 U.S. at 671-672; p. 6, *supra*. In particular, the time needed to obtain approval for a generic version of a drug can "create an effective extension of the patent term" for the NDA

holder. *Eli Lilly*, 496 U.S. at 670. The Hatch-Waxman Amendments address that issue in part through the streamlined ANDA process, 21 U.S.C. 355(j)(1)-(4); in part by authorizing generic manufacturers to begin developing their drugs before the conclusion of the patent term without risking an infringement suit, 35 U.S.C. 271(e)(1); and in part by delaying ANDA approval only while a limited set of patent infringement issues are resolved in litigation, 21 U.S.C. 355(j)(5)(B).

As the Federal Trade Commission (FTC) found in its 2002 study, however, NDA holders had upset the Hatch-Waxman balance by submitting a host of inappropriate patent information to FDA that prevented or delayed FDA's approval of ANDAs, thereby delaying the entry of generic competitors and effectively extending NDA holders' periods of exclusivity. See p. 7, *supra*. The 2003 amendments were designed to restore the balance and facilitate the timely approval of generic drugs. See 149 Cong. Rec. at 15,515 (statement of Sen. Schumer) ("What our proposal does is encourages robust competition by allowing the generic to come on to the market in its fair time. It restores the balance of Hatch-Waxman.").

The root weakness that NDA holders were exploiting was FDA's need to rely unquestioningly on the patent information they submitted, even though NDA holders have an obvious incentive to overstate the scope of their patents. Shortly before the counterclaim provision was enacted, FDA had issued a final rule "clarif[ying] patent submission and listing requirements," which would, FDA expected, "reduce confusion and help curb attempts to take advantage of this process." 68 Fed. Reg. at 36,676. FDA explained, however, that because it lacks the expertise and resources to resolve questions of

patent law, it would be unable to evaluate the accuracy of NDA holders' patent listings and use codes. See pp. 9-10, *supra*. FDA acknowledged that NDA holders could "submit inappropriate patent information * * * to delay generic competition." 68 Fed. Reg. at 36,683. But it explained that "[a] fundamental assumption of the Hatch-Waxman Amendments is that the courts," not FDA, "are the appropriate mechanism for the resolution of disputes about the scope and validity of patents." *Ibid.*[5]

Embracing FDA's approach, Congress stepped in to supply the necessary mechanism for judicial resolution of disputes over patent information. See 149 Cong. Rec. at 31,200 (statement of Sen. Schumer) ("[T]he provisions enforce the patent listing requirements at the FDA by allowing a generic applicant * * * to file a counterclaim to have the brand drug company delist the patent or correct the patent information in FDA's Orange Book."). In channeling such disputes to the courts, Congress structured the new remedy exclusively as a counterclaim to existing patent infringement litigation. See 21 U.S.C. 355(j)(5)(C)(ii)(II). Although Congress might have made the remedy marginally more available to ANDA applicants by creating a freestanding cause of action, the counterclaim approach has several virtues. Because the counterclaim can be invoked only when a generic manufacturer genuinely seeks to market the

[5] The only administrative mechanism for deleting or correcting patent information entails FDA forwarding inquiries about patent information to the NDA holder, which retains discretion to maintain or alter its patent information. 21 C.F.R. 314.53(f). While this procedure can suffice to correct clerical errors, it was not intended to provide a mechanism for resolving substantive patent disputes, which require judicial resolution.

drug and a brand-name manufacturer asserts that doing so would infringe its patent, it will not embroil courts in abstract disputes over patent information. By consolidating all the litigation surrounding the drug and related patents, the counterclaim provision also ensures that the judge will be familiar with the issues and avoids potentially conflicting constructions of the patent from different courts. See 149 Cong. Rec. at 15,517 (statement of Sen. Gregg) (new bill "will not open up a whole new arena of litigation" but will instead operate "in the context of the already existing causes of action").

2. Respondents' interpretation of the counterclaim provision would frustrate Congress's purposes

In respondents' view, the counterclaim provision authorizes judicial enforcement of some of FDA's patent-listing requirements (such as FDA's determination that "patents claiming packaging, intermediates, or metabolites must not be submitted for listing," 68 Fed. Reg. at 36,676), but not others (of relevance here, FDA's determination that an NDA holder should submit use codes that "identify *specifically* the approved uses claimed by the method-of-use patent," *id.* at 36,682 (emphasis added)). That distinction cannot be squared with Congress's purposes in enacting the counterclaim provision. Respondents' approach is especially unwarranted because both types of regulatory violation involve an NDA holder's submission of incorrect or misleading patent information; both exploit the same weakness in the administrative scheme (FDA's lack of resources, authority, or expertise to engage in substantive review of patents); and both cause the same harm (unjustified delay or obstruction of a generic drug's entry into the market) to

the same victims (the ANDA applicant and, ultimately, consumers).

Respondents posit that "[t]he counterclaim was a congressional response to *Mylan Pharms., Inc.* v. *Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) [cert. denied, 537 U.S. 941 (2002)]." Resp. Supp. Br. 5-6. In *Mylan*, an ANDA applicant alleged that an NDA holder's patent should not have been listed in the Orange Book at all, and the Federal Circuit held that no judicial remedy for that assertedly improper listing was available under the pre-2003 statutory scheme.[6] Respondents contend that the counterclaim is available *only* to an entity that "finds itself in the same position as Mylan was in *Mylan*." *Ibid.*

Mylan was surely significant to Congress in that it established the gravity of the problem: an ANDA applicant was powerless to contest the accuracy or precision of patent information submitted by an NDA holder. But it does not follow that Congress aimed only to avoid *Mylan* redux. Even if "the decision in [*Mylan*] prompted the *proposal* of [the counterclaim provision],"

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[6] In *Mylan*, after marketing the anti-anxiety drug buspirone for many years, the NDA holder (Bristol) obtained a patent claiming the use of a metabolite of buspirone to treat anxiety. Bristol submitted this patent to FDA for listing in the Orange Book and represented that the patent claimed a method of using buspirone. *Mylan*, 268 F.3d at 1327-1328. The ANDA applicant (Mylan) then "sought a declaratory judgment that Bristol improperly listed the * * * patent, and a preliminary injunction requiring Bristol to take steps to delist the * * * patent." *Id.* at 1328. Mylan conceded there was no cause of action to enforce FDA's patent-listing requirements against Bristol. The Federal Circuit agreed, and it further held that a declaratory judgment action was unavailable because improper listing of the patent in the Orange Book would not have been a defense to an infringement suit by Bristol against Mylan in response to a paragraph IV certification by Mylan. *Id.* at 1329-1333.

"whether that alone accounted for its *enactment* is quite a different question." *Eli Lilly*, 496 U.S. at 670 n.3. For several reasons, respondents' argument should be rejected.

First, FDA had recognized in its 2003 rulemaking that, even when an NDA holder's method-of-use patent is entitled to be listed in the Orange Book, FDA's ability to administer the Hatch-Waxman scheme depends on precise and accurate information about the particular method(s) of use that the patent covers. The 2003 rule's requirement that each NDA holder "identify specifically the approved uses claimed by [its] method-of-use patent" enables FDA and ANDA applicants to "determine whether the applicant must submit a patent certification or may submit a section viii statement." 68 Fed. Reg. at 36,682; see pp. 4-5, 9-10, *supra*. At the same time, however, FDA made clear that it would "rely on the description of the approved use provided by the NDA holder." 68 Fed. Reg. at 36,682. "[S]tatutory prohibitions often go beyond the principal evil to cover reasonably comparable evils." *DePierre* v. *United States*, 131 S. Ct. 2225, 2235 (2011) (citation omitted). By foreclosing generic competition that FDA might otherwise have approved pursuant to a section viii statement, the submission of overbroad use codes can cause substantially the same ill effects as does Orange Book listing of patents that should not be listed at all, and FDA's lack of resources and patent expertise prevents the agency from adequately policing either type of abuse. The concerns that prompted Congress to enact the counterclaim provision are therefore directly and fully implicated here.

Second, if Congress had intended the counterclaim provision to serve the limited purpose that respondents posit, it could have authorized the court simply to order

that an improper listing be "delete[d]." Congress instead authorized judicial orders "requiring the [RLD NDA holder] to *correct or* delete the patent information submitted by the holder." 21 U.S.C. 355(j)(5)(C)(ii)(I) (emphasis added). The italicized language is naturally read to cover the situation in which a method-of-use patent is appropriate for listing in the Orange Book, but the NDA holder's submission overstates the range of approved uses that the patent covers. See p. 20, *supra*.

Third, even if the counterclaim provision had not been enacted, an ANDA applicant in Mylan's situation could make a paragraph IV certification to the relevant patent, accept the 30-month stay of approval provided by 21 U.S.C. 355(j)(5)(B)(iii), and litigate the question whether its generic drug would infringe the patent. But when an ANDA applicant alleges that an NDA holder's use code is overbroad, paragraph IV litigation cannot substitute for the counterclaim provision. A paragraph IV certification cannot be premised on proposed carve-out labeling. Cf. 59 Fed. Reg. 50,347 (1994). Rather, to submit a paragraph IV certification, the ANDA applicant must propose labeling the same as the RLD's, and must assert that the RLD NDA holder's patent "is invalid or will not be infringed" (21 U.S.C. 355(j)(2)(A)(vii)(IV)) even if the generic manufacturer uses that labeling. So long as the NDA holder's patent covers *some* approved method of using the approved drug, the proposed labeling will be infringing. See Pet. App. 50a (Dyk, J., dissenting). The court in paragraph IV litigation therefore will have no occasion to determine whether carve-out labeling could allow generic competition without infringing the NDA holder's method-of-use patent, or whether the use code submitted by the NDA holder accurately and precisely de-

scribes the method of use claimed in the patent. The practical need for the counterclaim provision is therefore even greater in the present context than in the *Mylan* scenario.

Fourth, the use-code issue is of substantial practical importance, and there is no reason to believe that Congress thought it could be safely ignored. FDA approval of carve-out labeling based on section viii statements is an important path to market entry for generic drugs. FDA has informed us that in Fiscal Year 2010, it approved 11 sets of ANDAs with carve-out labeling. And of the five top-selling brand-name drugs that "went generic" for the first time during that period, three of the corresponding ANDAs relied on a section viii statement. Indeed, the top two brand-name drugs that went generic—each with annual sales of approximately $2.5 billion—did so with carve-out labeling. Because the use of carve-out labeling depends on the accuracy and precision of NDA holders' use codes, an important aspect of the Hatch-Waxman balance would be subverted if the counterclaim provision were unavailable in this context.

* * *

For the foregoing reasons, the judgment of the court of appeals should be vacated, and the case should be remanded for further proceedings. Because the court of appeals incorrectly held that petitioner had no cause of action to challenge respondents' use code for the '358 patent, it did not pass on the district court's determination that respondents' use code misleadingly described the method of use claimed in the patent. That case-specific question should be left to the court of appeals in the first instance.

CONCLUSION

The judgment of the court of appeals should be vacated and the case remanded for further proceedings.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General
TONY WEST
Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
BETH S. BRINKMANN
Deputy Assistant Attorney General
BENJAMIN J. HORWICH
Assistant to the Solicitor General
DOUGLAS N. LETTER
DANIEL TENNY
Attorneys

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