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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Case:

Constitution, statutes and regulations:

Statutes and regulations—Continued: Page

Regulations—Continued: Page

Miscellaneous:

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This brief is filed in response to the Court's order inviting the Acting Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be granted.

STATEMENT

1. a. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, the Food and Drug Administration (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*, proposed labeling that describes the uses for which the new drug may be marketed. See 21 U.S.C. 355(b)(1)(F). A drug

approved under the NDA process is often referred to as a "brand-name" drug.

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. 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, establishes a process for submitting an abbreviated new drug application (ANDA) for a generic drug. 21 U.S.C. 355(j). The ANDA approval process does not require the 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 equivalent. 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 the NDA holder's patent rights. See 21 U.S.C. 355(j)(2)(vii)-(viii). To facilitate that process, NDA holders submit patent information to FDA, and FDA reprints 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 regulations require the applicant to submit additional information during the NDA approval process. See 21 C.F.R. 314.53. 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." 21 C.F.R. 314.53(c)(2)(ii)(P). If a new patent issues after the application is submitted, the NDA applicant must update the patent information it previously submitted to FDA. 21 U.S.C. 355(b)(1) and (c)(2).

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). "[F]or each use patent," FDA also publishes "the approved indications or other conditions of use covered by a patent" (commonly called a "use code"). *Ibid.* The Hatch-Waxman Amendments do not direct FDA to verify the patent information, and FDA lacks the resources and the patent expertise to do so. See 68 Fed. Reg. 36,683 (2003). Accordingly, FDA does not compare the NDA holder's use codes to the claims of the underlying patent; rather, it plays the "ministerial" role of publishing the patent information as submitted by the NDA holder. *Ibid.*

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. And 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 only permitted, however, if the drug so labeled will remain safe and effective. See *ibid.* FDA will not approve an ANDA with a section viii statement if the ANDA applicant's proposed labeling includes information related to a method of use claimed by an unexpired patent listed in the Orange Book—*i.e.*, 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. at 36,682-36,683.

Alternatively, if a section viii statement is inappropriate (because the patent's use code effectively precludes carve-out labeling) or undesirable (because the ANDA applicant wishes to market its drug without carv-

ing 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 new drug for which the [ANDA] is submitted," 21 U.S.C. 355(j)(2)(A)(vii)(IV), and seek approval for an ANDA that does not include a labeling carve-out. This certification is known as a "paragraph IV certification."

Rather than embroiling FDA in controversies over patent validity and infringement, Congress channeled disputes about the correctness of paragraph IV certifications to the courts. Thus, an ANDA applicant that makes a paragraph IV certification must provide notice to the patent owner, 21 U.S.C. 355(j)(2)(B), which may in turn file a patent infringement suit in district court on the basis of the ANDA alone, without waiting for some other potentially infringing act, see 35 U.S.C. 271(e)(2)(A). If the patent owner sues within 45 days after receiving notice from the ANDA applicant, FDA generally may not approve the ANDA until the court finds the patent invalid or not infringed, or 30 months elapse from receipt of notice from the ANDA applicant. 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. In 2003, 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) (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.

2. 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." C.A. App. 79.

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 application 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 that petitioner did not seek approval for use of the repaglinide-metformin combination therapy. Although other matters prevented FDA from immediately approving petitioner's ANDA, FDA indicated that it 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.'" C.A. App. 667-668. Respondents complied. About a year later, respondents submitted 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.

Because petitioner was unable to carve out the single approved indication that corresponded to respondents' new use code yet maintain a safe and effective drug, FDA reversed course and disallowed a labeling carve-out.[1] Petitioner then filed a counterclaim against re

[1] Petitioner states that although it submitted a section viii statement, it also is "maintaining [a] [Paragraph IV] certification under

spondents in the pending infringement litigation, seeking an order directing respondents to revert to the old use code, which would make clear that the '358 patent does not claim the entirety of the single approved indication.

b. In a series of orders, 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 fails to identify with any specificity whatsoever the patented method and, read literally, 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.

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

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protest." Pet. Reply Br. 4 (quoting Br. in Opp. App. 10a) (brackets in original). FDA does not recognize certifications "under protest," nor does it permit a simultaneous paragraph IV certification and section viii statement to the same claim of a particular patent. If an ANDA applicant's latest submission to FDA was a section viii statement—something FDA will not publicly confirm or deny with respect to petitioner's ANDA because pre-approval applications to FDA are confidential, see 21 C.F.R. 314.430(d)(1)—then the applicant's ANDA would currently be considered to contain a section viii statement rather than a paragraph IV certification.

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." 21 U.S.C. 355(j)(5)(C)(ii)(I). 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 thus 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. *Ibid.* The court of appeals inferred from that fact that "the [Hatch-Waxman Amendments] defined the term 'patent information' as the patent number and the expiration date." *Ibid.* (internal quotation marks and citation omitted). The court concluded on that basis 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. He agreed with the court's textual analysis, though he was skeptical that paragraph IV litigation would resolve

the parties' dispute over the accuracy of respondents' use code. *Id.* at 19a. He also expressed the view that FDA's request for changes to Prandin®'s approved labeling had precipitated the problem here, and that respondents had done "nothing that was illegal or forbidden" when they "changed [the] use code to match the new PRANDIN® indication." *Id.* at 19a-20a.

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 that is at issue in this case. *Id.* at 39a. He also observed that "there is absolutely nothing in the statute or regulations that required [respondents] to change the use code to track [the] new indication" for oral anti-diabetic drugs. *Id.* at 47a-48a.

4. The court of appeals denied rehearing en banc. Pet. App. 53a-56a. Judge Gajarsa, joined by Judge Dyk, dissented. *Id.* at 57a-64a. They concluded that the court's construction of the counterclaim provision "seriously undermines Section viii" and "eliminates the careful balance Congress has struck between encouraging pharmaceutical discoveries and ensuring that the Ameri-

can people have access to low cost generic drugs." *Id.* at 59a.

5. Proceedings in the underlying infringement litigation resumed in district court after the court of appeals' ruling. After a bench trial, the district court 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 is pending. *Novo Nordisk A/S* v. *Caraco Pharm. Labs., Ltd.*, No. 2011-1223 (Fed. Cir.) (filed Feb. 23, 2011).

DISCUSSION

Under the Federal Circuit's decision, a brand-name manufacturer can effectively preclude generic competition by submitting an overbroad description of its method-of-use patent to FDA. Congress enacted the counterclaim provision at issue here to combat precisely that sort of manipulation. The court's ruling significantly impairs ANDA applicants' ability to secure FDA approval for their products, and hence deprives consumers of the full benefit of generic competition. There will be no opportunity for a circuit split to develop because the counterclaim is available only in patent infringement actions, see 21 U.S.C. 355(j)(5)(C)(ii)(I), as to which the Federal Circuit has exclusive appellate jurisdiction, see 28 U.S.C. 1292(c)(1), 1295(a)(1). The petition for a writ of certiorari should be granted.

A. The Federal Circuit's Decision Is Incorrect

The court of appeals' decision is incorrect for three related reasons. First, the court held that the counterclaim mechanism is available only when a patent listed in the Orange Book does not claim *any* "approved method of using" an approved drug. In fact, the text

and purposes of the provision indicate that a counterclaim may be asserted if the NDA holder's use code misleadingly suggests that the patent covers the *particular* method of use for which the ANDA applicant seeks approval, even if the patent does cover a different method of use. Second, the court gave an unduly restrictive 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. Third, the court's interpretation of the counterclaim provision subverts Congress's effort to create a meaningful judicial check on NDA holders' exaggerated claims of patent protection.

1. The statute authorizes counterclaims "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). It is undisputed in this case that requirement (aa) is satisfied because Claim 4 of the '358 patent does not claim a compound (*i.e.*, "the drug for which the application was approved"). To satisfy requirement (bb), an ANDA applicant must identify an approved method of using the drug—presumably the method of use for which the ANDA applicant seeks approval—that the relevant patent does not claim. To be sure, even if those requirements are satisfied, a court cannot order the NDA holder to "correct or delete" its use code if that use code accurately reflects the limited scope of the patent's coverage. An order to "correct or delete" the patent information is appropriate, however, if the use code misleadingly suggests that the patent claims approved methods of use that it does not actually cover. Petitioners therefore properly invoked the coun-

terclaim provision by alleging that, contrary to the apparent implication of the amended use code that respondents submitted to FDA, the '358 patent does not claim the use of repaglinide as monotherapy, which is "an approved method of using the drug."

The court of appeals, by contrast, held that the counterclaim provision is available only when the relevant patent does not claim *any* approved method of using the drug. Pet. App. 11a-12a. On that view of the statute, petitioners' counterclaim failed because the '358 patent claims the use of repaglinide in combination with metformin. See *ibid.* But as Judge Dyk explained in dissent below, the phrase "*an* approved method" is naturally used to refer to a *particular* approved method. *Id.* at 41a-42a (citing *Webster's Third New International Dictionary* 1 (2002)). And as between the two textually plausible interpretations of the disputed statutory language, the more flexible reading is superior because (as discussed below) the type of misrepresentation alleged in this case directly impedes the effective implementation of the Hatch-Waxman scheme.

2. The court of appeals also erred in holding (Pet. App. 15a-17a) that the "patent information" that may be corrected or deleted through the counterclaim provision is limited to the patent number and expiration date. 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."

The regulatory backdrop against which Congress acted reinforces the natural reading of the statutory text. Shortly before the counterclaim provision was enacted, FDA promulgated regulations specifying what "patent information" an NDA applicant must submit.

Pet. App. 16a (citing 21 C.F.R. 314.53). Those regulations, entitled "Submission of Patent Information," require NDA applicants to submit descriptions of the uses claimed by their method-of-use patents. 21 C.F.R. 314.53(c)(2)(i)(O) and (ii)(P); see 68 Fed. Reg. at 36,703. Congress was fully aware of that recent regulatory action when it enacted the counterclaim provision later in the same year. See, *e.g.*, 149 Cong. Rec. 15,516 (2003) (statement of Sen. Schumer) ("In fact, when the FDA actually talked about closing these loopholes, it was made clear that legislation would be needed to finish the job.").

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)). 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 "required by" or "specified in" Sections 355(b) or (c), and the actual statutory language encompasses a broader range of information. Sections 355(b) and (c) lay out the entire process for seeking and obtaining approval for an NDA, and for providing updates to FDA after the drug is approved. 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). 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.[2]

3. The court of appeals' decision also hinders the effectuation of Congress's purposes in enacting the counterclaim provision. Shortly before the counterclaim provision was enacted, FDA had issued a final rule specifying the patent information an NDA applicant must submit. FDA explained that, because it lacks the expertise and resources to resolve questions of patent law, it would "rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book" when evaluating a generic manufacturer's request for carve-out labeling. 68 Fed. Reg. at 36,682. FDA acknowledged that its reliance on NDA holders might tempt them "to submit inappropriate patent information * * * to delay generic competition." *Id.* at 36,683. It explained, however, 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.* Accordingly, FDA decided—for the same reasons that prompted it to rely on NDA holders in the first place—not to create an administrative process for challenging NDA holders' patent submissions, but instead to maintain its "ministerial" role in the patent-listing process. *Ibid.*

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[2] We do not understand the Federal Circuit to have held that FDA lacks authority to collect patent information beyond the patent number and expiration date. Regardless of the proper construction of the counterclaim provision, FDA's broad regulatory authority includes the power to require NDA applicants proceeding under 21 U.S.C. 355(b) and (c) to submit information relevant to drug approval. See 21 U.S.C. 371(a).

Later that year, Congress enacted the counterclaim provision. As a leading proponent of the provision explained, the counterclaim provision built on FDA's rulemaking by supplying a mechanism for judicial resolution of disputes about the accuracy of the patent information that FDA had recently required NDA holders to submit. See *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the Senate Comm. on the Judiciary*, 108th Cong., 1st Sess. 19 (2003) (statement of Sen. Schumer) ("The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing, but it goes much further."); 149 Cong. Rec. 31,200 (2003) (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.").

The practical effect of the court of appeals' decision, however, is to preclude judicial enforcement of FDA's directive that NDA holders accurately describe their method-of-use patents. Far from "enforc[ing] the patent listing requirements at the FDA," the counterclaim provision as construed by the Federal Circuit applies only when an NDA holder misstates information that is specifically required by the statute. That result is especially unwarranted because submission of an overbroad or otherwise misleading use code can cause the same practical harm (unjustified delay in a generic drug's entry into the market) as does the listing of a patent that claims *no* approved uses of the relevant drug.

B. This Court's Review Is Warranted

1. The Federal Circuit's decision makes it easier for brand-name manufacturers to disrupt and delay the entry of generic competitors

The Federal Circuit's decision prevents the courts from performing their traditional function of resolving disputes about the scope of patent rights, while leaving no alternative decision-maker to fill their shoes. The unavailability of a judicial remedy harms consumers of prescription drugs by making it easier for NDA holders to extend their periods of exclusivity by submitting inaccurate or misleading patent information.

a. Because respondents continue to maintain that their use code appropriately describes Claim 4 of the '358 patent, FDA cannot direct that the use code be changed without making a substantive judgment about the scope of that patent's coverage. But FDA has neither the resources nor the expertise to make such judgments, and to do so would assume precisely the substantive role the agency forswore in its 2003 rulemaking. See 68 Fed. Reg. at 36,683. Congress embraced that sound policy choice in 2003 when it created the counterclaim provision to authorize judicial resolution of disputes over the scope of use patents.

To be sure, even without engaging in substantive patent analysis, FDA might be able to take additional administrative steps to increase the accuracy and precision of patent information submitted by NDA holders. For example, FDA could amend the instructions accompanying the patent information declaration to state explicitly that a drug's approved indication may be recited as a patent use code only if the indication precisely describes the method of use claimed by the patent. FDA

could even abandon the use code approach and instead seek a certification from the NDA holder regarding whether specific carve-out labeling proposed by an ANDA applicant would infringe the NDA holder's patent. Any such measures are likely to be inefficacious, however, if no judicial check is available to determine whether the information an NDA holder submits accurately describes the scope of its use patent's coverage. The court of appeals' decision removes that judicial check.

b. Contrary to the court of appeals' suggestion, (Pet. App. 13a-14a), paragraph IV litigation is not an adequate substitute for the counterclaim provision. The ANDA applicant cannot carve out an infringing use and then make a paragraph IV certification; the two are mutually exclusive. 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. The court in paragraph IV litigation therefore will have no occasion to determine whether some hypothetical carved-out labeling would infringe the NDA holder's method-of-use patent, or whether the use code submitted by the NDA holder accurately and precisely describes the method of use claimed in the patent.

c. Lower-priced generic drugs save consumers many billions of dollars each year. See, *e.g.*, Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (July 2002). Carve-out labeling

approved based on a section viii statement is an important path to approval for generic drugs. FDA has informed us that in Fiscal Year 2010 it approved 11 ANDAs with carve-out labeling. Of these, the top three brand-name equivalents alone had nearly $6 billion in annual sales. A number of factors may affect the percentage of those sales that is diverted to generic drugs. But even if that fraction is modest, it is reasonable to estimate that consumers save billions of dollars each year from approval of ANDAs with section viii statements. Although many NDA holders might not submit inappropriate use codes, the trade sources petitioners cite (see Pet. 23) suggest that NDA holders are aware of the tactic. By eliminating the only judicial check on that tactic, the Federal Circuit's decision will likely impair the market entry of generic drugs, with consequent harm to consumers.

2. This case is a suitable vehicle for resolving the question presented

a. For two reasons, this case is a suitable vehicle for addressing the proper scope of the counterclaim provision. First, the Court can be confident of reaching the question presented. Petitioner concedes that the '358 patent was appropriately listed in the Orange Book; its sole contention is that respondents' use code is inappropriate and should be corrected. Second, the history of petitioner's ANDA makes clear that a judicial order directing respondents' to "correct" their use code would have tangible benefits for petitioners. When respondents' prior use code was in effect, FDA stated that it would approve a repaglinide ANDA with a section viii statement; the agency reversed course only after respondents submitted a new use code.

b. Respondents (Br. in Opp. 30-31) and Judge Clevenger below (Pet. App. 19a-20a) suggest that FDA has categorically authorized NDA holders to submit use codes that track the approved indications for their drugs, even when a particular approved indication does not accurately describe the method of use claimed in a listed patent. That is incorrect. FDA regulations require an NDA applicant, upon approval of its new drug, to submit 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)(3). FDA's instructions accompanying the declaration form on which the NDA holder supplies patent information permit using the approved indication as a use code *if* the approved indication appropriately describes the scope of the patent. But neither the regulations nor the form indicates that the approved indication will *always* constitute an appropriate "description of the patented method of use."

In any event, the question that warrants this Court's review is whether the counterclaim provision may be used to challenge an allegedly deficient use code. The Court can decide that question without determining whether respondents' own use code was deficient. If the court of appeals had held that petitioner's challenge to respondents' use code was cognizable under the counterclaim provision, but that the challenge failed on the merits because the use code conformed to FDA's instructions, FDA could respond to the decision administratively by revising the instructions. See p. 17, *supra*. Even if FDA makes such revisions, however, the court of appeals' actual holding will deprive generic manufacturers of any opportunity to persuade a court that an NDA holder's use code misdescribes the relevant method-of-use patent. And FDA cannot fill that reme-

dial gap administratively without undertaking the type of substantive patent analysis that it has heretofore viewed as beyond its competence. See pp. 15-16, *supra*.

c. The case is not moot and is not likely to become moot. Petitioner's ANDA cannot be approved absent (1) relief under the counterclaim provision, (2) expiration of the '358 patent many years from now, or (3) a paragraph IV certification to Claim 4 of the '358 patent. Approval subject to a paragraph IV certification cannot presently afford petitioner the relief it seeks here. Although the district court held the '358 patent invalid and unenforceable, respondents have appealed that ruling. If petitioner marketed repaglinide under an ANDA approved subject to a paragraph IV certification, a reversal by the Federal Circuit would likely expose petitioner to significant infringement liability. By contrast, if petitioner's ANDA is approved subject to a section viii statement and carve-out labeling, then the product would be less likely to infringe the '358 patent.

Of course, if the Federal Circuit ultimately affirms either the district court's invalidity or unenforceability determination, and that decision becomes final and unreviewable, the '358 patent will be no obstacle to petitioners' marketing of their generic drug. The question whether respondents' current use code accurately describes the patented method of use would then be of no continuing importance. The parties have informed us, however, that, if this Court grants the petition, they will jointly move to stay proceedings in the court of appeals pending the Court's decision on the merits.

3. Respondents' jurisdictional objection lacks merit

Respondents contend that the district court lost subject matter jurisdiction over petitioner's counterclaim

when petitioner amended its ANDA to replace its paragraph IV certification with a section viii statement. See Br. in Opp. 14-17. Whether or not the premise of that argument is accurate, see note 1, *supra*, respondents are incorrect as a legal matter.

The dispute over respondents' use code for the '358 patent is a live controversy under Article III because the resolution of that question will determine whether petitioner may proceed with a section viii statement. See pp. 7-8, *supra*. Because the counterclaim provision creates a federal cause of action, the district court had federal-question jurisdiction under 28 U.S.C. 1331 or patent-law jurisdiction under 28 U.S.C. 1338. And the Federal Circuit had appellate jurisdiction because the district court's jurisdiction over respondents' original infringement suit was based on 28 U.S.C. 1338. See 28 U.S.C. 1292(c)(1), 1295(a)(1).

The counterclaim mechanism is available whenever "an owner of the patent * * * brings a patent infringement action against the applicant." 21 U.S.C. 355(j)(5)(C)(ii)(I). That prerequisite (whether jurisdictional or not) was satisfied here. All agree that the district court had jurisdiction over respondents' infringement action when it was filed, and that the infringement action was pending when petitioner filed the counterclaim.

Whatever effect any amendments to petitioner's ANDA may have had on respondents' infringement action—a question now before the Federal Circuit on which we express no view—nothing in the Hatch-Waxman Amendments states that the counterclaim becomes unavailable simply because post-filing events render the initial infringement suit non-justiciable. Absent any statutory directive to that effect, this case is subject to

the general rule that "[a]s long as a court has jurisdiction, it may hear and render a separate judgment on a counterclaim even if the opposing party's claim has been [or should have been] dismissed." 3 James W. Moore, *Moore's Federal Practice* § 13.95, at 13-91 (3d ed. 2011); cf. 28 U.S.C. 1367(c)(3) (permitting district court to exercise supplemental jurisdiction over remaining claims even after it "has dismissed all claims over which it has original jurisdiction.").

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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