No. 10-844

# In the Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD. AND SUN PHARMACEUTICAL INDUSTRIES, LTD., PETITIONERS

*v.*

NOVO NORDISK A/S AND NOVO NORDISK, INC., RESPONDENTS

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

## SUPPLEMENTAL BRIEF FOR PETITIONERS


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## RULE 29.6 STATEMENT

The disclosures in the petition remain accurate.

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## SUPPLEMENTAL BRIEF FOR PETITIONERS

As the United States confirms, the Federal Circuit's splintered decision "mak[es] it easier for NDA holders to extend their periods of exclusivity by submitting inaccurate or misleading patent information," and "will likely impair the market entry of generic drugs, with consequent harm to consumers" to the tune of "billions of dollars each year." U.S. Br. 19. Further, any "administrative steps" that "FDA might be able to take" to ameliorate this problem "are likely to be inefficacious * * * 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." *Id.* at 17, 18. What is more, the recurring nature of the question presented is confirmed by five amicus briefs, the views of Wall Street analysts, and the out-of-court statements of respondents' own counsel. Reply to Br. in Opp. 1-2.

As explained below, nothing in respondents' supplemental brief diminishes the importance of that question. Eight pages of respondents' 12-page brief raise merits arguments that, even if correct (and they are not), would not diminish the importance of review. Many of respondents' points mischaracterize the record or the governing statute and regulations. And respondents fail to cast doubt on the United States' conclusion that "the Court can be confident of reaching the question presented." U.S. Br. 19.

The United States' recommendation is especially significant given the rarity of such recommendations: The Acting Solicitor General has supported review on the merits in just four of 25 invitation briefs filed this Term. The petition should thus be granted.

### A. Respondents' supplemental brief largely rehashes merits arguments that, even if colorable, would not diminish the importance of review.

1. Respondents lead off by repeating their merits argument that a counterclaim is unavailable because the '358 patent does claim one of three FDA-approved uses of repaglinide. Resp. Supp. Br. 1. But they continue to ignore critical aspects of the counterclaim's "text, structure, and purpose." *Id*. at 3.

Most notably, the counterclaim places the burden of proof on the *generic* drug maker. Pet. 31-32; Reply to Br. in Opp. 8. That is, the counterclaim asks not whether the *brand* can show that its patent *claims* "an approved method," but whether the *generic* can point to "an approved method" that the patent "*does not* claim." And when (as here) there are two or more FDA-approved uses of a drug, whether the patent claims an approved use is not a simple either/or proposition. It follows that, as the United States puts it: "Petitioners * * * properly invoked the counterclaim 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.'" U.S. Br. 12-13.

While acknowledging that "courts have no license to rewrite statutes," respondents continue to insist that "an approved method of using the drug" really means "*any* approved method of using the drug." Resp. Supp. Br. 2. Here again, however, they ignore our showing that this changes the meaning of the statute, which uses the word "any" in the very same provision. Pet. 31-32; Reply to Br. in Opp. 7-8.

Nor have respondents reconciled their interpretation, which limits the counterclaim to authorizing injunctions that require *deletion* of improperly listed patents, with the statutory language that authorizes injunctions to "*correct or* delete" inaccurate patent information. Reply to Br. in Opp. 8-9; Pet. 32-33. That too forecloses the suggestion that respondents' reading is "textually plausible." See Resp. Supp. Br. 2; see also Pet. 32a (Dyk, J., dissenting).

Even if the counterclaim reflected "legislative imprecision" (*Eli Lilly*, 496 U.S. at 679), respondents do not explain why Congress would want courts to order "deleting" misleading patent information when brands' patents claim *no* approved use, but not "correcting" misleading patent descriptions used to block marketing for *some subset of* approved uses. As the United States explains, "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." U.S. Br. 16.

Respondents (Br. 3) deride the United States for noting that its reading of the counterclaim is "superior" to respondents' because the latter reading "directly impedes the effective implementation of the Hatch-Waxman scheme." U.S. Br. 13. But respondents concede that the statute's "purpose" is relevant to its interpretation. Resp. Supp. Br. 3. And the United States' argument is but one of many reasons why its reading is superior. Reply to Br. in Opp. 7-8.

Finally, respondents again say the counterclaim is available only "to any entity that finds itself in the same position as Mylan was in *Mylan*." Resp. Supp.

Br. 5-6. But notably absent from this argument is a citation to the actual legislative history, which nowhere cites *Mylan*. And even if "[*Mylan*] prompted the *proposal* of [the counterclaim]," "whether that alone accounted for its *enactment* is quite a different question." *Eli Lilly*, 496 U.S. at 670. As confirmed by the counterclaim's text and structure, Congress intended to do more than simply reverse that decision.

2. As the United States attests, the Federal Circuit also "gave an unduly restrictive reading to the phrase 'patent information submitted by the [NDA] holder under [21 U.S.C. 355(b) or (c)].'" U.S. Br. 12. Respondents ask the Court to accept the Federal Circuit's revision of the counterclaim to read: "information 'submitted under' (*and thus specified in*) Section 355(b) or (c)." Resp. Supp. Br. 4. But the statute does not say "specified in." It says "submitted under."

As FDA explained in 2003, "Section 505(b) and (c) of the act describes the contents of an NDA * * * application, including the patent *submission* * * * *requirements*," which are implemented by the FDA regulations entitled "*Submission of Patent Information*." 68 Fed. Reg. at 36698 (emphasis added); see also 21 C.F.R. § 314.53. Respondents thus submitted their inaccurate use code description as "patent information" on FDA Form 3542 "in accordance with Section 505(b) and (c) of the [FDCA]," just like the form says:

| Department of Health and Human Services<br>Food and Drug Administration | Form Approved: OMB No. 0910-0513<br>Expiration Date: 7/31/10<br>*See OMB Statement on Page 3.* |
|---|---|
| **PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT**<br>***For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use*** | NDA NUMBER<br>20-741<br>NAME OF APPLICANT/NDA HOLDER<br>Novo Nordisk Inc. |
| ***The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.*** | |
| TRADE NAME<br>Prandin | |

Respondents say "the government does not agree with petitioners that FDA's information-gathering regulation was promulgated under Section 355(b) or (c)," and they again argue that the "*Submission of Patent Information*" regulation "was adopted pursuant to [FDA's] general rulemaking authority." Resp. Supp. Br. 5. But the United States' brief states only: "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." U.S. Br. 15 n.2 (citing 21 U.S.C. § 371(a)). This footnote simply recognizes that 21 U.S.C. § 371(a) grants the Secretary authority "to promulgate regulations for the efficient enforcement of [the Food, Drug, and Cosmetic Act]"; it does not (and could not) disavow FDA's statements in the Federal Register upon adoption of the "*Submission of Patent Information*" rule. And respondents do not engage our showing that FDA expressly invoked Section 505(b) and (c) as statutory authority for that regulation. Reply to Br. in Opp. 10-11.

The similarity between the term "submitted under" in the counterclaim provision and FDA's regulation entitled "Submission of Patent Information" is no coincidence. As the United States notes, "Congress was fully aware of that recent regulatory action when it enacted the counterclaim provision." U.S. Br. 14 (citing legislative history). There can be no question, therefore, that respondents "submitted" their overbroad use code description "under" FDA regulations that implement Section 505(b) and (c).

### B. As the United States has confirmed, respondents' vehicular and other arguments are foreclosed by the record and otherwise lack merit.

The United States also rightly deems this case "a suitable vehicle for resolving the question presented." U.S. Br. 19.

1. Attempting to paint the case as an anomaly, respondents observe that "[t]he government does not dispute that this is the first appellate decision to construe the Hatch-Waxman counterclaim." Resp. Supp. Br. 8. But the same was true in *Eli Lilly*, in which this Court granted certiorari to address the scope of a new Hatch-Waxman defense to infringement adopted just five years prior—presumably because a definitive ruling was needed and percolation was unlikely to generate a split. See Reply to Br. in Opp. 5-6. The same factors warrant review here.

The recurring nature of the issue and the need for immediate review are confirmed by five amicus briefs —representing both industry and consumers groups —and the views of Wall Street pharmaceutical analysts. See Reply to Br. in Opp. 1-2; Pet. 23. As one commentator put it, "Wall Street * * * has signaled that, if the status quo continues, brand-name drugmakers will have found a new means of fending off unwanted generic rivals."[1] Furthermore, the United States' brief confirms that, even using "modest" assumptions, "it is reasonable to estimate that consum-

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[1] Ed Silverman, *The Supreme Court and How to Delay Generics, Pt. 2*, available at: http://www.pharmalot.com/-2011/05/the-supreme-court-how-to-delay-generics-pt-2/.

ers save billions of dollars each year from approval of ANDAs with section viii statements." U.S. Br. 8.

In the end, however, one need look no further than the statements of respondents' own counsel to confirm that this is an "important" and "groundbreaking case" that, if not reversed, promises to "benefit innovator drug companies facing Hatch-Waxman counterclaims"—"especially * * * in the method of use context, where the FDA looks to use codes provided by NDA holders * * * in evaluating requests by ANDA applicants for section viii carve-outs."[2] Review is warranted to prevent this result.

2. Citing an out-of-context snippet from the United States' brief, respondents make the remarkable assertion that "the use code issue could 'be of no continuing importance' depending on how the Federal Circuit resolves the pending appeal on the merits." Resp. Supp. Br. 8 (quoting U.S. Br. 21). But as the United States notes in the following sentence: "The parties have informed us * * * 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." U.S. Br. 21. That is indeed the parties' agreement, as confirmed by a recent motion filed by respondents.[3] The parties have thus rec-

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[2] Mark A. Perry, *Federal Circuit Issues Important Decision Construing the Hatch-Waxman Counterclaim and Section viii Carve-Outs*, available at: http://www.gibsondunn.com/publications/pages/FederalCircuitDecisionConstruingHatchWaxmanCounterclaim.aspx.

[3] See Unopposed Motion for Additional Extension of Time to File Principal Brief for Appellants Novo Nordisk A/S and Novo Nordisk Inc., Dkt. 25, No. 2011-1223 (Fed. Cir. Apr. 26, 2011).

ognized that this Court's disposition of the question presented could be case-dispositive. It is troubling that respondents would suggest that a Federal Circuit ruling could moot this case without acknowledging the parties' agreement to seek a stay of that decision if certiorari is granted. But regardless, the United States is correct that "[t]he case is not moot and is not likely to become moot." U.S. Br. 21.

3. Respondents continue to press a jurisdictional challenge to their own lawsuit—the frivolity of which is evidenced by their extended delay in raising it. See Reply to Br. in Opp. 3-4. As the United States notes, this argument "lacks merit": "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." U.S. Br. 21, 22.

Respondents cite no authority to support their view that a Paragraph IV certification is necessary to jurisdiction. They have taken the opposite view in other cases (Reply to Br. in Opp. 4-5), and have yet to explain their about-face. But in any case, respondents' jurisdictional challenge not only fails as a matter of law; it rests on mischaracterizations of both the United States' position and the record.

Respondents assert: "As the government is forced to acknowledge, petitioners do not have a 'Paragraph IV certification with respect to the patent claim at issue.'" Resp. Supp. Br. 9 (quoting U.S. Br. 7 n.1). But the government acknowledged no such thing. It stated that "FDA will not publicly confirm or deny" the status of petitioners' patent certification. U.S. Br

n.1. In fact, as the district court found, Caraco's ANDA has contained a Paragraph IV certification throughout this lawsuit. Opp. App. 10a. Respondents' statement (at 9) that "petitioners have not had a Paragraph IV certification since April 2008, before the counterclaim was filed," is false. Indeed, respondents have never denied that Caraco maintained a Paragraph IV certification as to at least one asserted patent claim (claim 5) until October 2009—*after* Caraco filed its counterclaim in June 2009 and *after* the use code injunction that forms the basis of this appeal. And even if jurisdiction over the underlying suit had lapsed, jurisdiction over the counterclaim would remain.

In sum, even if a Paragraph IV certification as to an asserted claim were a jurisdictional prerequisite for Caraco's counterclaim (and it is not), that prerequisite would be satisfied here. And the United States is right to declare with confidence: "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." U.S. Br. 22.[4]

4. Respondents also misrepresent the governing regulations. Contrary to their assertion, FDA's rules do not authorize what respondents provided here—a use code description that tracks the labeled indication but is divorced from the patent's claims. Ironically, respondents criticize the United States for not quoting "the pertinent portion of FDA's regulation [21

[4] A full summary of the facts supporting jurisdiction is available at: U.S. D. Ct. No. 2:05-cv-40188-AC-DAS, Dkt. No. 505 (statement of undisputed facts concerning subject matter jurisdiction).

C.F.R. § 314.53(c)(2)(ii)(P)(1)]." Resp. Supp. Br. 10. But it is respondents who fail to quote the relevant portion of the rule, which requires providing a "description of the patented method of use":

> (P) Information on each method-of-use patent including the following:
>
> (1) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;
>
> (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; *and*
>
> (3) *The description of the patented method of use* as required for publication.

21 C.F.R. § 314.53(c)(2)(ii)(P) (emphasis added). The United States' submission is consistent with these regulations (U.S. Br. 20); respondents' brief is not.

5. Finally, respondents cannot seriously challenge the United States' conclusion that "a judicial order directing respondents to 'correct' their use code would have tangible benefits for petitioners." U.S. Br. 19. Respondents state that petitioner Caraco is not currently able to manufacture repaglinide from its facility. But they cannot dispute that an order correcting respondents' overbroad use code (thus ending this litigation) would have enormous tangible benefits for petitioners Caraco and Sun. Petitioners enjoy "first applicant" status, entitling them to 180 days of generic marketing exclusivity upon FDA approval. If review is granted and the ruling below reversed, peti-

tioners will thereafter have the option to market repaglinide through Caraco, Sun, or, if necessary, a third party—long before respondents' method patent expires in 2018. Yet respondents' misrepresentation of their patent's scope has caused petitioners to have to litigate infringement for years, when the patent covering the repaglinide compound expired in 2009. This Court's intervention is needed to eliminate such delay in both this case and others.

## CONCLUSION

The United States' brief confirms both the importance of the question presented and the suitability of this case as a vehicle to resolve it. Moreover, respondents' arguments on the merits do not diminish the importance of the issues or the need for immediate review. The petition should therefore be granted.

Respectfully submitted.

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