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

REPLY TO BRIEF IN OPPOSITION

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PARTIES TO THE PROCEEDINGS

The Rule 29.6 Statement included in the petition for a writ of certiorari, as updated by the brief in opposition for respondents, remains accurate.

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REPLY TO BRIEF IN OPPOSITION

Respondents' brief in opposition does not diminish our showing that the ruling below raises vital issues warranting immediate review. Respondents concede that they are using their patent to block Caraco from marketing drugs that do not infringe. And as confirmed by five *amicus* briefs—representing millions of consumers, generic and branded manufacturers, and the leading trade association—the Federal Circuit's splintered ruling enabling this easy-to-replicate tactic threatens not only settled intellectual property rights in a $300 billion industry, but the interests of consumers and the FDA's ability to administer Hatch-Waxman.

The Court need not take our word for it, however. After the Federal Circuit sanctioned respondents' use code abuse, their own counsel hailed the ruling as an "important decision construing the Hatch-Waxman counterclaim and section viii carve-outs"—a "groundbreaking case" that 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."[1] Read: Name-brand drug makers now have unchecked power to circumvent Section viii by submitting overbroad use codes.

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[1] 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.

Now, however, respondents say "the counterclaim has *nothing to do* with section viii carve-outs" and "there is nothing to suggest that [the question presented] will arise again." Opp. 13. But as their out-of-court statements confirm, the issue here is important, recurring, and integrally related to the FDA's administration of Section viii.

Indeed, as the D.C. Circuit has recognized, the counterclaim is pivotal to Hatch-Waxman's "incentive structure" (Pet. 27-29), and use codes have doubled since 2003 (Pet. 23). Moreover, the problem is certain to worsen now that brands have the go-ahead to "evergreen" their patents using this unstoppable tactic. Not surprisingly, leading Wall Street analysts predict that use code manipulation will now flourish—that brands "will extract significant [earnings per share] and [net present value] upside from utilization of PUC (Patent Use Code) narrative strategies."[2] Similarly, the FDA's counsel has stated that a "solution" to the problems created by the ruling below "has eluded the agency," as alternative approaches are "a recipe for marketplace confusion" and "complications in terms of intellectual property rights." Pet. 26-27. At a minimum, these statements warrant seeking the Solicitor General's views.

Unable to discount the importance of the question presented, respondents resort to unconvincing arguments that this case is a poor vehicle for resolving it. For example, they now say petitioners' Section viii request eliminated jurisdiction over *their own law-*

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[2] Morgan Stanley Research Europe, *Pharmaceuticals: Potential Selective Upside for Industry Post Prandin Ruling* 2 (Sept. 1, 2010), *available at* http://www.fdalawblog.net/files/morgan-stanley-rpt---puc-decision.pdf.

suit. But petitioners have confirmed with the FDA, in writing, that they are "maintaining [a] [Paragraph IV] certification under protest." Opp. App. 10a. That is sufficient to maintain jurisdiction under 35 U.S.C. § 271(e)(2)(A).

Nor does the interlocutory nature of the decision below warrant denying certiorari. No further factual development is necessary, the legal issue is squarely presented, and this Court often reviews interlocutory rulings involving critical federal issues. Indeed, in *Eli Lilly* this Court granted interlocutory review to decide whether 35 U.S.C. § 271(e)(1) provided a defense to infringement, even though (unlike here) the Federal Circuit had "remanded for the District Court to determine whether in fact [the] condition[s] [for applying the defense] had been met." 496 U.S. at 664. Given the importance of the issues, the Court should do likewise here.

I. Respondents' jurisdictional and vehicular arguments do not withstand scrutiny.

A. Respondents' belated challenge to jurisdiction over their *own* suit lacks merit.

1. After years of litigation over the counterclaim, respondents now say the courts lack jurisdiction over their own lawsuit. But this argument is foreclosed by the governing statute, as construed by this Court. Respondents' lawsuit is authorized by 35 U.S.C. § 271(e)(2)(A), which makes it "an act of infringement to submit * * * [an ANDA] * * * for a drug claimed in a patent or the use of which is claimed in a patent." This provision "creat[es] * * * a highly artificial act of infringement that consists of submitting an ANDA * * * containing a [Paragraph IV] certification." *Eli Lilly*, 496 U.S. at 678. Here, there is no dispute that

Caraco filed an ANDA with a Paragraph IV certification as to every claim of Novo's patent. That created federal jurisdiction. 28 U.S.C. § 1338.

That Caraco later invoked Section viii is irrelevant. Respondents say their patent claim is "subject only to a section viii statement." Opp. 16. Not so. Thanks to their overbroad use code, "FDA declined to allow [petitioners'] section viii carve-out." Opp. 9. But petitioners thereafter confirmed with the FDA, in writing, that they are "maintaining [a] [Paragraph IV] certification under protest." Opp. App. 10a. This is undisputed. And it explains why respondents delayed before raising the jurisdictional theory they now say precludes review.

Respondents' delay speaks volumes about their newfound argument's merit. As the district court admonished their counsel: "[D]on't play games with me." Addendum, *infra*. The games continue.

2. Indeed, respondents have played this game before—on the other side, no less—in the very case they say "conflicts" with the ruling below, but which does no such thing. Opp. 16. As the court there explained: "Novo Nordisk asserts that * * * the filing of an ANDA that *should* include a Paragraph IV Certification constitutes a jurisdictional 'act of infringement' under Section 271(e)(2)(A)." *Novo Nordisk Inc.* v. *Mylan Pharm. Inc.*, 2010 WL 1372437, *8 (D.N.J. Mar. 31, 2010). The court agreed, finding no jurisdiction only because the complaint was "missing * * * an allegation that [the] proposed [carve-out] *has been rejected* by the FDA." *Id.* at *12. Had that occurred, the court "would indeed [have] f[ou]nd that it had jurisdiction to entertain [the] patent infringement action," because "the filing of an ANDA that *should* in-

clude, but does not include, a Paragraph IV certification nevertheless constitutes an act of infringement." *Ibid.* *A fortiori*, jurisdiction exists here, where petitioners *did* invoke Paragraph IV. Opp. App. 10a.

Like their use codes and statements on this case's importance, respondents' jurisdictional positions depend on their convenience. Their newfound view is an "attempt[] to manipulate the Court's jurisdiction to insulate a favorable decision from review." *City of Erie* v. *Pap's A.M.*, 529 U.S. 277, 288 (2000).

B. Respondents' other vehicle arguments are a diversionary tactic.

1. Respondents also say review is unwarranted because the ruling below was "interlocutory." Opp. 18. But no further factual development is necessary, and this Court frequently grants interlocutory review of "important and clear-cut issue[s]" in circumstances such as these. E. Gressman, *et al.*, *Supreme Court Practice* § 4.18, at 281 (9th ed. 2007)(collecting cases).

Indeed, this Court has granted interlocutory review under Hatch-Waxman even when factual development *was* needed. In *Eli Lilly*, the Court reviewed an interlocutory decision that 35 U.S.C. § 271(e)(1) provided a defense to patent infringement in medical device cases, even though the Federal Circuit had "remanded for the District Court to determine whether in fact [the] condition[s] [for applying § 271(e)(1)] had been met." 496 U.S. at 664. The need for further fact-finding—absent here—did not deter review, presumably because the issue was important to the industry and the Federal Circuit's ruling was otherwise the final word. Similar considerations warrant review here.

2. *Eli Lilly* likewise disposes of the notion that review is premature because the ruling below marks "the first appellate decision construing the Hatch-Waxman counterclaim." Opp. 3. That case "raise[d] a question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1) * * * applies to medical devices." 872 F.2d 402, 404 (Fed. Cir. 1989). Yet this Court granted certiorari—again, presumably because a definitive ruling was needed and percolation was unlikely to generate a split. Cf. *Am. Fed'n of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964) (reviewing "an important [question] of first impression"). So too here.

3. Respondents warn against "piecemeal" review (Opp. 18), but the validity issues below are separate and distinct from the counterclaim's meaning. Respondents do not suggest that the case has become moot. Nor could they, given their recent notice of appeal (Opp. 18) and the district court's decision to stay various issues pending appeal. If the invalidity ruling were reversed, moreover, it would likely generate further proceedings involving claims for damages.

4. Respondents' suggestion (at 17-18) that deferring resolution of the question presented would entail "no attendant prejudice to any party" rings especially hollow. But for respondents' new use code, Caraco would have received Section viii approval to market its drug for concededly non-infringing uses years ago —*without further litigation*. Delay will only reward gamesmanship, amplify brands' "incentive to follow Novo's lead," and "subvert[] Section viii" (Pet. 62a, 60a)—which Congress designed to *eliminate* litigation over non-infringing uses. It is therefore perverse for Novo to suggest waiting until distinct issues play out

below. As the *amicus* briefs confirm, review is needed now, to prevent this cycle from repeating itself.

II. Respondents' merits arguments fail to rehabilitate the decision below.

Lacking a persuasive vehicle argument, respondents retreat to the merits. Opp. 19-32. They ignore many of our statutory points, however, and mischaracterize others as "policy-based." Opp. 21. Further, the arguments they do make run headlong into the text and "structure of the * * * Act taken as a whole." *Eli Lilly*, 496 U.S. at 669.

A. Respondents ignore critical textual and structural signals that preclude reading "*an* approved method of use" to mean "*any* approved method of use."

The court below overlooked five textual and structural problems with reading the phrase "*an* approved method of use" to mean "*any* approved method of use." Pet. 29-34. Respondents seize on our acknowledgment that the word "'an,' when qualified by a negative, *can* mean 'any'" (Pet. 30), calling this a "fatal" "concession" (Opp. 22). But they ignore multiple reasons why that meaning is foreclosed *here*.

1. *First*, respondents ignore our showing that the very provision at issue elsewhere uses the term "any" —thus confirming that, *in Hatch-Waxman's counterclaim*, "an" cannot mean "any." Pet. 32.

Second, respondents ignore that using "any" in "negative assertions * * * creates an *emphatic* negative," and thus changes the counterclaim's meaning. Pet. 30-31.

Third, respondents ignore that it takes "strong evidence" to conclude that Congress "enact[ed] provi-

sions" that "create an effective extension of the patent term." *Eli Lilly*, 496 U.S. at 670, 672. That is the effect of the decision below. Pet. 33.[3] But such evidence is lacking here.

Fourth, respondents ignore that the counterclaim places the burden of proof, not on the *brand*, to show that its patent "does claim" an approved use, but on the *generic*, to show what the patent "does not claim." Pet. 31-32. When there is but one FDA-approved use, that is one and the same inquiry. But when there are additional FDA-approved uses, whether the patent claims an approved use is not necessarily an either/or proposition.

2. Nor are the arguments that respondents *do* advance convincing. For example, their reading renders superfluous the counterclaim's language authorizing courts to "*correct or* delete" patent information. Pet. 32-33. Respondents answer that the term "correct" would serve a purpose "[i]f an error were made"—*e.g.*, by listing "the wrong patent number." Opp. 23. But even then the remedy would be "deleting" the patent. Further, inasmuch as generic manufacturers' Paragraph I-IV obligations extend only to listed patents, 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV), brands already have ample incentive to fix incorrect patent numbers. Respondents cannot explain why Congress would authorize a counterclaim so generics could force brands to correct typos.

It is far less strained to read "correct" as authorizing courts to order brands to fix use codes that overstate their patents' scope. "Congress used two terms"

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[3] Respondents' compound patent expired in 2009; their method patent expires in 2018.

—correct *and* delete—"because it intended each term to have a particular, nonsuperfluous meaning." *Bailey* v. *United States*, 516 U.S. 137, 146 (1995). And the fact that respondents' reading renders "correct" superfluous forecloses their suggestion (Opp. 23-24) that the counterclaim addresses only the fact pattern of *Mylan*—where the patent claimed *neither* the listed drug *nor* any method of using it, and the proper remedy was thus to "delete" it. Pet. 32a (Dyk, J.).

Respondents support reading laws "*in pari materia*" (Opp. 22), but reject reading the counterclaim in light of Section viii, which uses similar language. 21 U.S.C. § 355(j)(2)(A)(viii). Finally, they deride as "policy-based" our position that the counterclaim extends beyond *Mylan* (Opp. 21); but as the foregoing makes clear, our arguments are textual and structural.[4]

B. Congress ratified the FDA's definition of "patent information."

The petition presented three independent reasons why the Federal Circuit's reading of "patent information" cannot stand: (1) the FDA read "patent information" to include use codes before 2003, and Congress adopted that reading (Pet. 34); (2) the counterclaim refers to patent information "*submitted* * * * *under* subsection (b) or (c)," not to patent information "*referenced in*" those subsections, and thus includes all FDA-required patent information (Pet. 35); (3) "at a minimum, [the FDA's] interpretation is reasonable,

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[4] Respondents cite *Buckman Co.* v. *Plaintiffs' Legal Committee*, but that case held only that federal enforcement of the FDCA preempted "unpredictable civil liability" under *state* law. 531 U.S. 341, 348, 350 (2001). The counterclaim provides *federal* authority for ordering brands to correct misleading patent information.

warranting *Chevron* deference" (*ibid.*). Respondents blur our first and third points, and ignore the second.

1. As to ratification and *Chevron*, respondents say deference is not warranted because the FDA "did not justify th[e] requirement [to submit use codes] as an interpretation of 'patent information' in subsection (b) or (c) [of Section 505]." Opp. 27. But as Judge Dyk explained, the 2003 final rule "makes clear that the FDA is defining what constitutes 'patent information' for purposes of subsections (b) and (c)." Pet. 34a. Indeed, the FDA fully "explain[ed] why we (FDA) issued the proposal," and "the statutory provisions" supporting it—citing §§ 505(b)(2), 505(b)(1), and 505(c)(2) of the Act. 68 Fed. Reg. at 36676. Similarly, since 2003 FDA Form 3542 has stated that "patent information submitted" with an NDA is "provided in accordance with Section 505(b) and (c)." Pet. 211a. Thus, when Congress referenced "patent information * * * submitted under subsection (b) or (c) of this section," it was adopting the FDA's definition.

Respondents nonetheless focus on events *after* the counterclaim's adoption. Citing FDA comments from *2007*, they say the *2003* rule was based on the FDA's "general rulemaking authority and subsection (j)." Opp. 27. The very pages they cite, however, reiterate that "the basis for requiring a description of each individual method of use for which a patent is submitted for listing" was "discussed in the June 2003 final rule" (72 Fed. Reg. at 21268)—which, as noted, invoked § 505(b) and (c). Moreover, even in 2007 the agency continued to invoke § 505(b). 72 Fed. Reg. at 21268-21689.

In any case, events in 2007 are irrelevant to what Congress ratified in 2003. For that, one must look to

the 2003 final rule and Form 3542. The FDA may be "the sorcerer's apprentice," but "the sorcerer himself" has now spoken (Opp. 28), adopting the agency's prior interpretation.

2. Because Congress ratified the FDA's interpretation, the decision below is wrong even apart from *Chevron*. But since the meaning of "patent information" under the counterclaim is tied to § 505(b) and (c) —which the FDA has undisputed authority to interpret and implement—reading that term to include use code narratives is valid under *Chevron* if reasonable. And it is plainly reasonable for the FDA to require "detailed information related to the approved methods of use," which is "essential" to "review of ANDA * * * applications that do not seek approval for all the approved uses." 68 Fed. Reg. at 36682, 36685.

Respondents dismiss our showing that the decision below threatens the FDA's ability to administer Section viii. But as the FDA's counsel has explained, that decision has caused the agency to "assess[] ways to alter how it handles patent use codes," and "a straightforward solution so far has eluded [FDA]." Pet. 26-27. Thus, the urgency of review is confirmed by the fact that "the majority opinion effectively invalidates the FDA's effort to define 'patent information,'" "[w]ithout even requesting the [FDA's] views." Pet. 63a (Gajarsa, J.).[5]

3. Finally, respondents insist that their revised use code is technically "correct." Opp. 30. But they do not dispute that their use code is *materially misleading*, and in that sense it is incorrect under any

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[5] Caraco cannot effectively sue FDA, which lacks authority to police use codes. Pet. 51a-52a (Dyk, J.); Pet. 24.

definition. http://www.merriam-webster.com/dictionary/correct (defining "correct" as "to make or set right: amend <correct an error>"; "counteract, neutralize"; and "to alter or adjust so as to bring to some standard or required condition"). As the governing regulations explain, to serve its statutory purpose, "the description of the patented method of use" must be both "accurate and detailed." 68 Fed. Reg. at 36682. Yet respondents' new use code "is so broad as to incorrectly suggest that [their] patent generically covers three (3) different FDA-approved methods of use," when "[they] admit[] that the first two (2) uses are not covered." Pet. 68a. Thus, Novo's submission "seriously misrepresents the approved method of use," requiring correction. Pet. 70a.

CONCLUSION

In sum, respondents' arguments do not diminish the importance of the question presented or the need for immediate review. Lest Section viii and the counterclaim be "render[ed] * * * a dead letter" (Pet. 62a), this Court should grant certiorari. Alternatively, the Court should call for the Solicitor General's views.

Respectfully submitted.

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