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

BRIEF OF *AMICUS CURIAE* MYLAN PHARMACEUTICALS INC. IN SUPPORT OF THE PETITION FOR CERTIORARI

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Pages**

Statutes and Regulations

TABLE OF AUTHORITIES (continued)

Other Authorities **Pages**

STATEMENT OF INTEREST*

Mylan is a manufacturer of generic drugs that frequently files Abbreviated New Drug Applications (ANDAs) under the Hatch-Waxman Act seeking approval of the Food and Drug Administration (FDA) to market drugs for particular uses. Mylan often relies on "section viii" statements when the methods of use that it proposes are not patented. *See* 21 U.S.C. § 355(j)(2)(A)(viii). The FDA, however, will not grant approval if a proposed use falls within the description of a patented method of use that is listed in the FDA's "Orange Book." The accuracy of Orange Book patent information is thus critical.

Regrettably, branded manufacturers often overstate the scope of their patents, and the FDA does not police the accuracy of Orange Book information. In *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (2002), the Federal Circuit held that generic drug manufacturers had no right to sue to correct Orange Book listings. The very next year, Congress responded by expressly authorizing ANDA applicants to file counterclaims to correct or delete erroneous Orange Book patent information. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). The availability of such counterclaims serves as a much-needed check on branded drug manufacturers and deters them from supplying misinformation to the FDA.

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* No party or counsel for a party authored or contributed monetarily to the preparation or submission of any portion of this brief. Mylan gave all the parties' counsel of record notice of its intention to file this brief more than 10 days before it was due, and all parties have consented to the filing of this brief.

The decision below, however, has read the counterclaim provision extraordinarily narrowly, holding that correctable "patent information" is limited to patent numbers and expiration dates and that counterclaims are available only in extreme cases when no approved uses at all have been patented. The decision effectively eviscerates the counterclaim provision and enables incumbent branded manufacturers to block legitimate section viii applications with false Orange Book listings.

Mylan urges the Court to grant certiorari and reverse because the result, if upheld will be devastating to the generic drug industry and to consumers—and costly to taxpayers as well. The counterclaim provision may seem obscure at first blush, but it is critical to ensuring effective operation of the Hatch-Waxman Act.

SUMMARY OF ARGUMENT

Congress authorized ANDA applicants to counterclaim to "correct" Orange Book "patent information" that overstates patent coverage, not merely to "delete" listings where none of the approved uses is patented. Correctable "patent information" includes information about patents' scope, not merely their serial numbers and expiration dates. The term "patent information" should be read in light of Congress's purpose (to have patentees identify which drugs and methods remain patented so that ANDA applicants can avoid infringement), not in a vacuum. The courts should also defer to the FDA's longstanding construction of "patent information," which covers use code narratives and other patent-related information, not just serial numbers and expiration dates.

The Federal Circuit's artificially narrow construction will not only gut the counterclaim provision, but upset the careful balance of the Hatch-Waxman Act. If the decision in this case stands, brand-name drug manufacturers will be able to abuse the Orange Book listing system with impunity because the FDA does not review the accuracy of those listings. With no agency oversight and no judicial review, branded drug companies can and will deter and delay legitimate, noninfringing generic competition.

The practical ramifications are very significant. Section viii certifications are common and increasingly important. Patents on the chemical compositions of many leading drugs have expired, and branded drug companies have responded by seeking patents on uses of those drugs. The decision in this case effectively enables branded drug companies to delay generic competition for nonpatented uses, greatly increasing costs to consumers and taxpayers.

Review cannot await another case. Because the Federal Circuit has exclusive jurisdiction over these kinds of cases, there will be no next case. At a minimum, the Court should call for the views of the Solicitor General because this case raises important questions of competition and health care policy in which two agencies have already expressed interest.

ARGUMENT

A. Congress Did Not Limit Counterclaims to Extreme Cases in Which None of the Approved Uses Have Been Patented

Congress's 2003 amendments to the Hatch-Waxman Act authorized ANDA applicants to assert coun-

terclaims to "correct or delete the patent information submitted by the holder … on the ground that the patent does not claim … an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb). Naturally read, the statute authorizes relief when one or more of the approved uses is not claimed in a patent, despite its inclusion in the Orange Book. The Federal Circuit, however, has read it to apply only when *none* of the approved uses is patented. The latter reading may be linguistically *possible*, but it is strained and makes no sense when the language is read in context and in light of the underlying object and policy of the statute.

To begin with, the statutory text belies the Federal Circuit's conclusion that Congress intended to limit counterclaims to extreme cases in which a listed patent covers no approved uses whatsoever. In such cases, the remedy would be to delete the patent from the Orange Book entirely. But Congress authorized counterclaims to "correct" as well as to "delete" erroneous patent information. 21 U.S.C. § 355(j)(5)(C)(ii)(I). By authorizing correction as well as deletion, Congress plainly intended to cover situations where a listing is partly right and partly wrong.

Furthermore, the purpose of the counterclaim provision was to provide a remedy when patent holders submit erroneous information to the FDA about patent coverage of drugs or methods of using them. The goal was not simply to correct the Orange Book for the sake of correcting it, but to enable ANDA applicants to enter the market when the ANDA does not infringe. Under the Federal Circuit's narrow reading, a patentee may misidentify a patent as covering an approved use, yet competitors will have

no way to correct the misinformation or to file a section viii certification. That is the kind of abuse that Congress sought to eliminate and the kind of loophole that it intended to close. *See* 149 Cong. Rec. 31121, 31200 (Nov. 24, 2003) (sponsoring Sen. Schumer: "The provisions close loopholes in the law and end the abusive practices in the pharmaceutical industry which have kept lower-priced generics off the market and cost consumers billions of dollars.").

The majority below assumed that Congress merely intended to reverse the result on the particular facts of *Mylan v. Thompson*, but the statute was not limited to just those facts. *Mylan v. Thompson* was indeed a gross example of the problems with existing law, but it was far from the only abuse about which Congress was concerned. The year before, the Federal Trade Commission ("FTC") had issued a 129-page study describing a wide range of dubious strategies that branded drug manufacturers had used to delay generic entry.[1] Nothing in the legislative history of the 2003 amendment suggests that Congress limited its authorization of counterclaims to the particular facts of *Mylan v. Thompson.* The solution was general.[2]

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[1] *See* FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrug study.pdf; *see also* 149 Cong. Rec. 15490, 15514 (Jun. 19, 2003) (Sen. McCain noting abuses).

[2] *See* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Regime on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005) (describing the legislative history).

B. As the FDA Determined, "Patent Information" Includes Information About Patent Scope, Not Just Serial Numbers and Expiration Dates

Congress adopted the counterclaim provision to ensure that generic drug makers have judicial recourse to correct or delete misinformation about patent coverage that branded drug makers have submitted to the FDA. In holding that correctable "patent information" is limited to patent numbers and expiration dates and excludes the uses that the patents purportedly cover, the Federal Circuit has defied the language of the statute and the FDA's longstanding interpretation of "patent information."

The Hatch-Waxman Act requires NDA applicants to list patents claiming a drug or method of use "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G). The statute thus expressly contemplates that the patent holder will describe the scope of the patents and relate them to the drug or method of use for which approval is sought. The resulting Orange Book listings are supposed to notify later ANDA applicants which drugs or methods of use are patented so that those applicants can submit appropriate certifications under 21 U.S.C. § 355(j)(2)(A)(vii) and (viii). "Patent information" must be read in light of that purpose, not in a vacuum.

Furthermore, when Congress adopted the counterclaim provision in 2003, the FDA had already adopted a regulation (the Patent Listing Rule) that broadly construed the scope of "patent information" required under Hatch-Waxman. Under 21 C.F.R. § 314.53, the FDA required patentees to submit not

only patent numbers and expiration dates, but also use code narratives and other patent-related information. The FDA's interpretation deserves deference, as courts "have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer[.]" *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1984). What is more, Congress was not just constructively aware but actually aware of the FDA's broad reading of "patent information" when it adopted the amendment authorizing counterclaims to correct or delete erroneous "patent information."[3] Such awareness indicates that Congress intended to adopt the FDA's broad view of "patent information."

C. The Federal Circuit's Decision Will Have Pernicious Practical Effects

Certiorari should also be granted because the decision below will have terrible consequences. If left standing, it will allow brand-name drug manufacturers to abuse use codes with impunity, effectively blocking generic competition and providing unwarranted patent protection for drug uses that are not patented. The inevitable result will be restricted supply and higher prices for critical drugs.

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[3] *See Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong., 1st Sess. 19 (2003) (sponsoring 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.").

1. The Decision Below Will Deter and Delay Legitimate Competition

Congress recognized the signal importance of generic competition both when originally adopting the Hatch-Waxman Act in 1984 and when amending it in 2003 to authorize counterclaims to delete or correct misinformation in the Orange Book. As noted above, even before Congress adopted the counterclaim provision, the FTC had issued a study describing a broad range of anticompetitive strategies that branded manufacturers were using to delay generic entry, including the listing of patents that "do not appear to claim the approved drug product or an approved use of the drug."[4] The Federal Circuit's decision effectively ratifies this stratagem.

Under the decision below, a branded drug manufacturer may submit overly broad use descriptions covering both patented and unpatented methods of use, yet generic competitors cannot counterclaim to correct such misdescriptions. Counterclaims are an indispensable remedy because the FDA does not scrutinize Orange Book listings on grounds that it lacks expertise on patent issues. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 885 (D.C. Cir. 2004) (FDA "refuses to determine independently what use a patent covers and instead accepts at face value the use claimed by the patent holder"); 21 C.F.R. § 314.53(f) (FDA "will not change the patent information in the list" unless the patentee requests).

With no FDA oversight and no judicial remedy, nothing will stop branded manufacturers from artifi-

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[4] *See* FTC generic drug study, *supra* note 1, at 40.

cially extending the scope of their patent protection. As one commentator recognized even before the decision in this case, "[i]nstead of appropriately assigning the use code, pioneers may be motivated to assign an extremely broad use code to its method of use, thereby optimizing patent protection."[5] After the Federal Circuit's decision, they will be especially motivated—and unimpeded.

For example, assume a branded manufacturer's patents on a compound and a method of using it to treat disease 1 have expired, but a patent on using it to treat disease 2 remains in force. If the statute worked as Congress intended, a generic drug maker could file a section viii certification and enter the market with a carve-out label limited to treating disease 1. The branded manufacturer, however, can stifle that competition by submitting an overbroad description covering both uses. The FDA will not approve the generic's ANDA because the proposed use falls within the Orange Book description submitted by the patent holder, even though the patent on its face does not cover the use of the drug to treat disease 1. The FDA also will not review the accuracy of the Orange Book description, and the Federal Circuit has now held that the courts are impotent too, even though Congress adopted the counterclaim provision to prevent just this type of chicanery.

Technically, the generic competitor may still file a paragraph IV certification of noninfringement, but

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[5] Julie Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 164 (2007).

that is cold comfort, as even the concurring judge below recognized, Pet. App. 19a–20a. Even though the generic manufacturer has no desire to promote the patented use of the drug, the statute normally will require it to match the original drug labeling covering both patented and unpatented uses. *See* 21 U.S.C. § 355(j)(2)(A)(v). The patentee will then claim that the generic has induced infringement by selling the drug with broad labeling that has no carve-out.

Mylan hopes that the courts would find remedies for such abuse, perhaps finding that the generic manufacturer lacked specific intent to induce infringement or, alternatively, that the patent is unenforceable for misuse. Those defenses, however, would be fraught with danger, and the law in those areas is unsettled.[6] Furthermore, paragraph IV litigation is expensive, time-consuming, and leads to an automatic 30-month stay of FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii). That delay would not occur if the generic manufacturer could carve out the unpatented use under section viii. Ironically, but inevitably, generic entry will be stalled in the very cases where Congress sought to accelerate it.

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[6] Federal Circuit decisions broadly construing intent to induce infringement and narrowly construing patent misuse are now before this Court. *See Global-Tech Appliances, Inc. v. SEB, S.A.*, No. 10–6 (U.S.) (to be argued Feb. 23, 2011); *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc), *petition for cert. filed*, No. 10–898 (Jan. 5, 2011).

2. Blocking Generic Entry Will Have Broad and Harmful Effects on the Public at Large

Section viii certifications are common and becoming increasingly important. Many patents on the basic chemical composition of blockbuster drugs have expired or soon will. Foreseeing this, branded manufacturers have secured follow-on patents on particular methods of use in an effort to maintain "evergreen" patent protection.[7] Section viii certifications allow entrants to enter the market yet still respect incumbents' limited remaining patent rights. Moreover, section viii applications are especially useful and popular because, unlike paragraph IV certifications, they are not considered technical acts of infringement under 35 U.S.C. § 271(e)(2)(A) and thus do not automatically trigger the 30-month delay of FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii).

As a practical matter, the decision below will severely reduce the availability of section viii applications, and the resulting lengthy delays in generic entry will result in significant, tangible costs to consumers and taxpayers. On average, generic drugs cost 80 to 85% less than brand-name drugs.[8] Thus, where, as here, generic entry is artificially delayed,

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[7] *See*, *e.g.*, Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH L. & POL'Y 379 (2007) (describing patents procured by pharmaceutical companies to extend the length of patent protection on their products).

[8] *See* Somnath Pal, *Directions in Generic Drugs*, 35 U.S. PHARMACIST 8 (Jun. 17, 2010), *available at* http://www.uspharmacist.com/content/s/127/c/21064.

drug prices will remain artificially high. Branded drug companies claim they need patent protection as a reward for undertaking research, but that excuse rings hollow where patent protection on the use at issue has expired. In such cases, the patentee has already received its just reward. Strategic gamesmanship that improperly broadens and extends patent coverage should not be tolerated.

D. Certiorari Should Be Granted Now

The issues raised by the petition are critical to proper operation of the Hatch-Waxman Act. Congress overturned *Mylan v. Thompson* and authorized counterclaims because it recognized that its carefully balanced statutory scheme will not work if misinformation in the Orange Book cannot be corrected. The Federal Circuit's decision not only renders the counterclaim provision largely useless; it allows drug patent holders to nullify section viii and block entry even when a generic manufacturer seeks approval only for unpatented uses. Mylan urges the Court to grant certiorari and correct it now.

Waiting is not an option. Decisions in other areas may be refined as they percolate through later cases, and this Court sometimes refrains from granting review to see how the law develops. The decision here, however, rules out counterclaims in the vast majority of cases of Orange Book misuse. Moreover, the Federal Circuit has denied rehearing *en banc*, and no other court of appeals can hear these issues: an action to correct or delete Orange Book information must be brought as a counterclaim to a patent infringement claim, 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb), and the Federal Circuit has exclusive appellate juris-

diction over patent infringement claims, 28 U.S.C. § 1295(a)(1). If the decision below stands, counterclaims will not be allowed, and patently erroneous Orange Book listings will stand uncorrected. Certiorari should be granted now because there will be no next case tomorrow.

At a minimum, the Court should call for the views of the Solicitor General. This case raises important issues regarding both competition and health care policy. The FDA and the FTC have substantial interests, and the Federal Circuit's decision has already evoked serious concern from both agencies. The federal government can also speak to interest of federal taxpayers, who will pay much more for prescription drugs if the decision below is not reversed.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

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