No. 10-844

IN THE
Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD. & SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Petitioners,

v.

NOVO NORDISK A/S & NOVO NORDISK, INC.,
Respondents.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the Federal Circuit

BRIEF OF TEVA PHARMACEUTICALS USA, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Does 21 U.S.C. § 355(j)(5)(D)(ii)(I) authorize an applicant for a proposed generic drug product to file a counterclaim against the manufacturer of a previously approved brand-name drug in which the generic applicant seeks to correct certain misleading patent information that the brand manufacturer submitted to the Food and Drug Administration ("FDA") pursuant to FDA's longstanding Hatch-Waxman Act regulations, or is the counterclaim provision unavailable for those purposes because FDA's longstanding regulations are invalid?

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rules 24.1(b) and 29.6:

Petitioner Teva Pharmaceuticals USA, Inc. ("TUSA") is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: (i) Orvet UK Unlimited (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; and (ii) Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of TUSA. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of TUSA, and no other publicly traded company owns more than 10% of its stock.

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STATEMENT OF INTEREST AND SUMMARY OF THE ARGUMENT[1]

Amicus curiae Teva Pharmaceuticals USA, Inc. ("Teva") is the world's largest manufacturer of generic drug products, and every year files dozens of abbreviated new drug applications ("ANDAs") seeking FDA approval to market generic versions of previously approved brand-name drugs in the United States. The content of Teva's ANDAs are governed by the Hatch-Waxman Act and FDA's Hatch-Waxman implementing regulations, which among other things require the company to make representations to FDA regarding the applicability of brand-name pharmaceutical patents to Teva's proposed generic drug products. One key goal of those requirements is to help ensure that expired patents, invalid patents, unenforceable patents, and otherwise inapplicable patents do not block FDA's ability to promptly approve generic drug products.

Needless to say, brand manufacturers generally lose significant revenue once a lower-priced generic equivalent becomes available. And over the years, certain brand companies thus sought to delay the onset of generic competition by manipulating their

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[1] All counsel of record received timely notice of the intent to file the brief, all parties have consented to its filing, and letters evincing such consent have been filed with the Clerk. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel for a party authored any part of this brief and that neither such counsel, nor any party, nor any person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

own patent submissions to FDA. *See, e.g.*, *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1377-78 (Fed. Cir. 2002); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327-29 (Fed. Cir. 2001).

The original Hatch-Waxman Act gave generic applicants no effective recourse. As the lower courts repeatedly held, generic applicants could not compel the "delisting" (or withdrawal) of improperly submitted brand-name patent information through either a counterclaim in patent litigation or by bringing a claim against FDA directly. *See aaiPharma*, 296 F.3d at 243; *Mylan*, 268 F.3d at 1332. Generic applicants thus found the approval of their products blocked by regulatory provisions that never should have applied to their applications, because those approval-timing provisions were triggered by patent filings that the brand manufacturers should not have made in the first place—but which the generic applicants were powerless to correct.

In 2003, Congress decided that enough was enough. As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "MMA"), Congress for the first time gave generic applicants a shield against these tactics: a novel counterclaim right-of-action through which generic applicants can force brand companies to "correct or delete the patent information [they] submitted" to FDA. 21 U.S.C. § 355(j)(5)(D)(ii)(I) (the "counterclaim provision").

The Federal Circuit's deeply fractured decision in this case guts that critical provision. And *without*

even soliciting FDA's views, it effectively declares unlawful an FDA regulation that Congress knew about when it adopted the counterclaim provision and that otherwise plays what FDA itself has called an "essential" role in the Agency's administration of this complex regulatory scheme. The appellate court's decision ultimately frees brand companies to once again manipulate generic market entry—both by making improper patent submissions and, as a result of the court's effective invalidation of FDA's implementing regulations, by depriving generic applicants of the information they need to make appropriate patent certifications in the first place.

The impact of the appellate court's ruling has not been lost on industry observers. One Wall Street report predicts that the court's decision once again will allow "the innovative pharmaceutical industry to successfully delay US generic approval of select innovative drugs." *See* Morgan Stanley, *Pharmaceuticals: Potential Selective Upside For Industry Post Prandin Ruling* at 1 (Sept. 1, 2010). That outcome is impossible to square with the Hatch-Waxman Act's goal of expediting generic competition. And the financial consequences to the public will be enormous. As one recent study concluded, the widespread availability of generic drugs saved consumers $139.6 billion in 2009 alone—or nearly $382 million per day. *See* Generic Pharmaceutical Association, *Savings Achieved*

Through The Use Of Generic Pharmaceuticals, 2000-2009 at 1 (July 2010).[2]

If left uncorrected, the decision will directly impede Teva's ability to provide its affordable generic medications to the public. Congress gave generic applicants like Teva a specific mechanism to expedite FDA's approval for products that have multiple approved uses, by allowing them to sell their products for *unpatented* uses without being delayed by patents that cover *non-patented* uses that are not mentioned in the generic product's label. The appellate court's ruling eviscerates that "carve out" provision, in violation of both the language and the purpose of the applicable laws—and by allowing brand companies to mischaracterize the scope of their patents, will delay the approval of generic drugs despite the absence of any legitimate patent protection. Along with the millions of consumers who depend on the availability of safe and affordable generic drugs, Teva thus has a direct stake in the Court's resolution of this case, and respectfully urges this Court to grant the petition.

ABBREVIATED REGULATORY BACKGROUND

In an effort to balance the interest in promoting generic competition against the intellectual property rights of branded drug manufacturers, the Hatch-Waxman Act requires each generic applicant to submit a "certification" or "statement" regarding every patent that the product's brand manufacturer

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[2] *Available at* http://www.gphaonline.org/about-gpha/about-generics/case/generics-providing-savings-americans (last visited January 27, 2011).

has identified as claiming the approved brand-name drug. 21 U.S.C. § 355(j)(2)(A)(vii)-(viii). To make this system work, the statute requires brand manufacturers to submit patent information to FDA, 21 U.S.C. § 355(b)(1), and obligates FDA to "publish" the patent information it receives from brand companies. *Id.* § 355(j)(7)(A). FDA's official compendium of drug-related patent information is known as "the Orange Book," and generic applicants consult this official list in order to determine which patents require submissions. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

At the time it established the patent-certification regime, Congress recognized that not all pharmaceutical patents are created equal. On one hand, some drug patents claim the approved drug product's active pharmaceutical ingredient (the "drug substance"), and thus would be infringed *every time* another person manufactures or markets an identical drug substance (assuming the patent's underlying validity and enforceability). On the other hand, some drug patents merely claim a method of using the approved drug product, and thus *would not* be infringed if the identical drug substance were manufactured or marketed for unclaimed uses.

In order to promote the speedy approval of generic products for such unclaimed uses, the Hatch-Waxman Act and FDA regulations sharply distinguish between drug-substance patents and method-of-use patents. Generic applicants who wish to enter the market before an Orange Book-listed drug-substance patent expires must submit a so-called "Paragraph IV certification" challenging the patent's validity or enforceability, or asserting that

their proposed generic drug would not infringe the patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i).

Such certifications, however, carry significant risks. The first Paragraph IV challenger bears substantial research-and-development and legal costs to design around and/or contest the validity or enforceability of a drug-substance patent. And if those efforts succeed, merely filing such a certification is an act of infringement that could result in years of costly patent litigation. *See* 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Indeed, the statute encourages brand manufacturers to file patent-infringement lawsuits: Where the brand manufacturer promptly sues a Paragraph IV challenger, FDA may not approve the ANDA for either 30 months or until the patent is declared invalid, not infringed, or unenforceable, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii). This period of delay is known as the "thirty-month stay," and in many cases, its application postpones generic entry even after FDA has completed its scientific review of the generic drug and determined that—but for the pending patent litigation—the generic product could be approved for sale.

In contrast to their treatment of drug-substance patents, both the statute itself and FDA's implementing regulations give applicants a choice when addressing method-of-use patents. They can file either a Paragraph IV certification to such a patent (and thereby obtain approval for all previously approved methods of use), *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), or a so-called "Section viii

statement" that carves out the patent-protected use from the generic product's labeling and thereby authorizes immediate FDA approval for any approved method of use not covered by the patent. *Id.* § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii); *see also Purepac*, 354 F.3d at 880 (explaining that Section viii statements are "attractive" because they facilitate prompt generic market entry). Section viii statements are particularly appealing because they avoid any possibility of a thirty-month stay: By definition, a generic company that "carves out" a patented use from its label is not challenging any patent covering that use, and there is thus no possibility of a patent suit that would trigger the thirty-month stay.

The complex interplay between Paragraph IV and Section viii filings has plagued FDA throughout Hatch-Waxman's nearly 30-year history. Given the statutory dichotomy between drug-substance and method-of-use patents, it is essential for FDA to distinguish between those types of patents at the threshold. After all, if the Agency does not know whether a given drug patent covers the drug-substance or merely claims a method-of-use—and, for method-of-use patents, *which* particular method of use the patent claims—it would be virtually impossible for FDA to determine whether a Section viii statement is permissible in the first instance, and if so, which use or uses can be carved out through a Section viii statement.

As both FDA and the Federal Circuit have recognized, however, problems commonly arise in this area because FDA has no patent-law expertise and therefore lacks the institutional capacity to

determine the scope of pharmaceutical patents. *See, e.g.*, *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347-50 (Fed. Cir. 2003); *see also* Food and Drug Administration, *Applications for FDA Approval to Market a New Drug—Final Rule* ("*Final Rule*s"), 68 Fed. Reg. 36676, 36683 (June 18, 2003). Accordingly, FDA long ago adopted a "ministerial role" regarding patent information.

Under this approach, FDA relies exclusively on the brand manufacturer's representations about the scope of a given patent. *Apotex*, 347 F.3d at 1347. But in order to effectively administer the dichotomy between Paragraph IV and Section viii, FDA requires brand manufacturers to submit information to FDA about the type of patent it asserts as claiming the branded drug (*i.e.*, drug substance or method of use) and, for method-of-use patents, the particular method of use claimed. 21 C.F.R. § 314.53 ("Submission of Patent Information"); *see also Final Rules*, 68 Fed. Reg. at 36681-83; Food and Drug Administration, *Applications for FDA Approval to Market a New Drug—Proposed Rule* ("*Proposed Rules*"), 67 Fed. Reg. 65448, 65448-54 (Oct. 24, 2002).

As set forth below, the Federal Circuit's decision effectively invalidates these crucial regulations.

ARGUMENT

The Federal Circuit Misconstrued The Statute's Counterclaim Provision And Improperly Invalidated FDA's Longstanding Implementing Regulations Without Even Soliciting The Agency's Views.

All four of the Federal Circuit's opinions in this case recognize that FDA's ministerial approach to

patent listings enables brand manufacturers to postpone generic market entry by submitting improper patent information to FDA. And all four of its opinions likewise recognize that Congress intended the MMA's counterclaim provision, 21 U.S.C. § 355(D)(ii)(I), to thwart such manipulation by allowing generic applicants to seek a court order requiring the brand manufacturer to correct or delete improperly submitted patent information. *See* Pet. App. 13a (majority opinion); Pet. App. 21a (Clevenger, J., concurring); Pet. App. 22a (Dyk, J., dissenting); Pet. App. 57a-58a (Gajarsa, J., dissenting from denial of rehearing *en banc*). The majority and the dissenters disagreed about the scope of the cure Congress gave generic manufacturers when it enacted the MMA, and the dissenters clearly got it right.

As Judges Dyk and Gajarsa recognized, the majority's narrow interpretation of the phrase "patent information submitted by the [brand manufacturer]" once again enables the very kind of manipulation Congress sought to thwart. Pet. App. 22a (Dyk, J., dissenting) ("[T]he majority … now construes the statute contrary to its manifest purpose and allows the same manipulative practices to continue in the context of method patents."); Pet. App. 58a-59a (Gajarsa, J., dissenting from denial of rehearing *en banc*) ("The majority's opinion construes the counterclaim provision contrary to its manifest Congressional purpose. That construction renders 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii") carve-out statements a virtual nullity and leaves generic drug manufacturers without a remedy to challenge inaccurate Orange Book listings with respect to method of use patents.").

More important, the majority's interpretation of the statute conflicts with settled canons of interpretation, the statute's legislative history, and FDA's implementing regulations. Pet. App. 33a-39a (Dyk, J., dissenting); Pet. App. 63a-64a (Gajarsa, J., dissenting from denial of rehearing *en banc*). Indeed, by declaring FDA's patent-submission regulation inconsistent with the statute, the appellate court's opinion unquestionably will undermine FDA's ability to administer this regulatory regime.

A. The Federal Circuit Impermissibly Disregarded FDA's Interpretation Of The Hatch-Waxman Act's Patent-Submission Provisions.

As Judge Dyk explained in dissent, and as this Court long ago made clear, Congress is presumed to incorporate—rather than abrogate—prior agency interpretations. Pet. App. 37a & nn.11-12 (Dyk, J., dissenting) (citing *Traynor v. Turnage*, 485 U.S. 535, 546 (1988); *United States v. Bd. of Comm'rs of Sheffield, Ala.*, 435 U.S. 110, 131-35 (1978); *Cammarano v. United States*, 358 U.S. 498, 510 (1959); *Hartley v. Comm'r*, 295 U.S. 216, 220 (1935)). The appellate court, however, inexplicably disregarded that presumption here.

As set forth above, FDA's pre-MMA Hatch-Waxman regulations implemented the statute's patent-submission requirements at 21 U.S.C. § 355(b)-(c) by requiring brand manufacturers to submit patent information beyond the patent's number and expiration date—including information regarding any approved methods of use covered by method-of-use patents. 21 C.F.R. § 314.53. The relevant provisions of that regulation were:

consistent with FDA's prior practice between 1994 and 2003; proposed more than a year before the MMA became effective, *see Proposed Rules*, 67 Fed. Reg. at 65448, 65457 (explaining the proposed regulation and noting that "[o]ur principal legal authority for the proposed rule exists at sections 505 and 701 (21 U.S.C. 371) of the act. Section 505(b) of the act describes the contents of an NDA and 505(b)(2) applications, including the patent listing and patent certification requirements"); and finalized six months before the MMA became effective. *See Final Rules*, 68 Fed. Reg. at 36676, 36697-98 ("Our principal legal authority for the final rule is section 505 of the act, in conjunction with our general rulemaking authority in section 701(a) (21 U.S.C. 371) of the act. Section 505(b) and (c) of the act describes the contents of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements.").

The appellate court offered no basis for thinking that Congress intended *sub silentio* to abrogate FDA's prior interpretation of the law when it passed the MMA. Instead, the panel majority sought to downplay Congress's awareness of FDA's prior interpretation of the statute's patent-submission requirements by deeming it to be no more than an "'opaque timing observation.'" Pet. App. 16a (quoting *Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010)).

That was error. FDA's prior interpretation is not significant merely because it preceded the MMA. To the contrary, it matters because it bears directly on the meaning of the counterclaim provision's reference to the "patent information submitted by

[brand manufacturers]," 21 U.S.C. § 355(j)(5)(D)(II)(i), since Congress chose that language with full awareness that the "patent information submitted by [brand manufacturers]" included method-of-use information under FDA's regulations. Again, it is well-settled that Congress presumably incorporates prior agency interpretations, and the majority's attempt to dismiss that presumption as an "opaque timing observation"—when the presumption *necessarily* relates to timing—cannot be reconciled with this Court's longstanding case law.

Indeed, that presumption is virtually conclusive here, because the statute's legislative history demonstrates that the MMA's sponsors explicitly embraced FDA's regulations. Pet. App. 36a (Dyk, J., dissenting) ("Congress was well aware of [FDA's] regulatory interpretation of 'patent information' when it enacted the counterclaim provision.") (collecting sources). Congress drew heavily on FDA's expertise in crafting the MMA amendments, including the provisions at issue here. During the congressional hearings and debates over the MMA, senior FDA officials carefully detailed the Agency's current practices concerning the submission of patent information to the Agency. As the FDA's Chief Counsel thus explained, FDA's final regulation on patent submissions set forth "the patent information required to be submitted and … does not require claim-by-claim listing on the declaration form *except for method-of-use patents claiming approved methods of use*." S. Hrg. 108-390, Examining the Senate And House Versions of the "Great Access to Affordable Pharmaceuticals Act": Hearing Before the Committee on the Judiciary

United States Senate, 108th Cong., at 137-38 (Aug. 1, 2003) (statement of FDA Chief Counsel Daniel Troy).[3]

Moreover, he explained, nothing in the MMA would impact FDA's prior implementation of the statute's patent-submission requirements:

> The legislation, included as part of the Medicare bills in the House and Senate, does not address all of the provisions in the final rule. If such legislation were to pass, based on our review, we believe that *only the 30-month stay provision of the final rule would be impacted*.

Id. at 10 (emphasis added).

Congress in turn expressly sanctioned FDA's implementing regulations, by indicating that the law was intended to augment—rather than abrogate—them: "The bill provides *a critical complement* to the work the FDA has done in clarifying its regulations on patent listing." S. Hrg. 108-250, 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., at 19 (June 17, 2003) (statement of Sen. Schumer) (emphasis added).[4]

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[3] Reprint *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_senate_hearings&docid=f:91832.pdf (last visited January 26, 2011).

[4] Reprint *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_senate_hearings&docid=f:91212.pdf (last visited January 26, 2011).

As Judge Gajarsa thus recognized, the Federal Circuit's interpretation of the statutory scheme is unsustainable "given Congress's explicit approval of those regulations." Pet. App. 63a (Gajarsa, J., dissenting from denial of rehearing *en banc*).

B. The Federal Circuit's Effective Invalidation Of FDA's Patent-Submission Regulation Jeopardizes FDA's Ability To Administer This Complex Statutory Scheme.

Perhaps because it recognized those deficiencies in its analysis, the panel majority went further: It effectively declared that FDA's patent-submission regulation is unlawful, by baldly asserting that "this court owes no deference … to agency interpretations at odds with the plain language of the statute itself." Pet. App. 16a (quotation omitted).

It would be hard to overstate the radical implications of that holding. Without even bothering to solicit (much less consider) the government's views—and without any apparent consideration of the Agency's 2,200-word regulatory justification for its patent-submission rules, *see Final Rules*, 68 Fed. Reg. at 36,681-83—a fractured panel of the Federal Circuit struck down a now-firmly established FDA regulation and held that the Agency cannot lawfully compel brand manufacturers to submit method-of-use information at all. *See id.*

The appellate court's ill-advised decision already is complicating FDA's ability to administer the statutory scheme. Pet. 26-27 (discussing recent statements by FDA's principal Hatch-Waxman counsel concerning the impact of this case on the Agency). And that is no surprise—FDA adopted its

implementing regulations precisely to avoid the problems it now is experiencing.

> To effectively implement the certification and section viii statement provisions set out in the statute, *we must have* adequate information concerning method-of-use patents.... Since the *Purepac* case and other instances have raised questions about what aspects of the approved drug are claimed by a listed use patent, we believe that *it is necessary* that an NDA holder submit more specific information on the approved methods of use protected by a submitted patent. *Only with this information can we determine what submission is required of the ANDA and 505(b)(2) applicants referencing the approved drug*.

Final Rules, 68 Fed. Reg. at 36682-83 (emphasis added); *see also id*. at 36682 (discussing *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002)).

Indeed, as FDA long ago explained, knowing in advance what patent certifications generic applicants may submit is critical, because the different types of submissions lead to significant differences in the timing of approval—and because any uncertainty inevitably delays generic market entry. *Id*. at 36682; *id*. at 36685 ("The specific method-of-use claims are essential to our review because sections 505(j)(2)(A)(viii) and 505(b)(2)(B) of the act allow ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not

claim a use for which the applicant is seeking approval.").

Unless this Court grants the petition, however, the panel majority's bald rejection of FDA's patent-submission regulation will remain the law—sowing confusion for both FDA and the generic industry over what certifications are required; generating unnecessary and inefficient litigation over threshold filing requirements; and ultimately delaying the public's access to affordable generic drugs.

CONCLUSION

For the foregoing reasons, this Court should grant the writ and reverse the Federal Circuit's decision.

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