Case No. 2010-1001

In The United States Court of Appeals For The Federal Circuit

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

Plaintiffs/Appellants,

v.

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

Defendants/Appellees,

On Appeal from the United States District Court for the Eastern District of Michigan (No. 2:05-CV-40188, Judge Avern Cohn)

BRIEF *AMICUS CURIAE* OF TEVA PHARMACEUTICALS USA, INC. IN SUPPORT OF APPELLEES' COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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May 28, 2010

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *amicus curiae* Teva Pharmaceuticals USA, Inc. certifies the following:

1. The full name of every party represented by us is:

Teva Pharmaceuticals USA, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

Teva Pharmaceuticals USA, Inc.

3. All parent corporations and any publicly held companies that own 10% of more of the stock of any party represented by us are:

Orvet UK Ltd.
Teva Pharmaceuticals Europe (Holland)
Teva Pharmaceutical Industries Ltd.
Teva Pharmaceutical Holdings Cooperatieve U.A.
Ivax LLC.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or expected to appear in this Court are:

From KIRKLAND & ELLIS LLP, Michael D. Shumsky.

May 28, 2010

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INTRODUCTION

The panel's deeply fractured decision in this case guts one of the Hatch-Waxman Act's most important provisions. And without even soliciting FDA's views, it effectively declares unlawful an FDA regulation that Congress knew about when it adopted the statutory provision at issue here and that otherwise plays a critical role in FDA's administration of this complex statute. In the process, the majority opinion ignores controlling canons of statutory interpretation; disregards key aspects of the statute's legislative history; and fails to meaningfully engage the question of *Chevron* deference in rejecting FDA's implementing regulations.

Perhaps more important, the panel decision will free brand manufacturers to manipulate the statutory scheme, both by making improper patent submissions and by depriving generic applicants of the information they need to make appropriate patent certifications in the first place—thwarting FDA's ability to efficiently process generic applications, and ultimately depriving consumers of prompt access to affordable generic drugs. Given the panel's deep division; the majority's own confusion about the consequences of its decision, *compare* Slip Op. at 11-12 (asserting that Paragraph IV litigation can solve the problem presented in this case) *with* Concur. at 1 ("I am not as certain … that the ongoing Paragraph IV litigation will cleanly resolve the dispute."); and the panel's decision to declare unlawful a federal regulation without first hearing the government's views, the petition should be granted.

STATEMENT OF INTEREST

Teva is the world's largest manufacturer of generic drugs, and thus has a profound interest in this case—which implicates the certifications that Teva is entitled to submit when it files a generic application; the company's ability to use the statutory remedy that Congress provided in cases where brand manufacturers abuse the patent-listing process; and FDA's ability to properly and efficiently administer this complex statutory scheme. On each of those issues, however, the fractured panel's majority opinion reaches conclusions at odds with Teva's interests, by sharply constraining the company's ability to file Section VIII statements; precluding it from countering manipulative patent listings by using the statute's delisting counterclaim provision; and ultimately thwarting FDA's ability to implement this complex statutory scheme. Accordingly, Teva has a direct stake in the court's ultimate resolution of this case, and respectfully urges the Court to grant the petition.

ABBREVIATED REGULATORY BACKGROUND

The Hatch-Waxman Act has always distinguished between patents that claim an approved drug's *active ingredient* (in FDA's terms, the "drug substance") and those that claim *a method of using* the approved drug. While generic applicants that wish to enter the market before a relevant patent expires must submit a Paragraph IV certification to a drug-substance patent, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the statute gives applicants a choice when certifying to 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), *id.*, *or* a Section VIII statement that carves out the patent-protected use from the generic product's labeling (and thereby authorizes immediate FDA approval of that product for any approved method of use not covered by the patent). *Id.* § 355(j)(2)(A)(viii); *see also Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (explaining that Section VIII statements are "attractive" because they facilitate generic market entry).

The complex interplay between these provisions has plagued FDA throughout Hatch-Waxman's 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. And given how Section VIII statements work, it likewise is crucial for FDA to know which particular method of use a given patent claims. After all, without such information, it would be exceedingly difficult for FDA to determine *whether* a Section VIII statement is permissible in the first instance, and if so, *which* approved use can be carved out through a Section VIII statement.

As both FDA and this Court have recognized, however, problems commonly arise because FDA has no patent-law expertise and thus lacks the institutional capacity to determine the scope of submitted patents. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347-50 (Fed. Cir. 2003); *see also* FDA, *Final Rule: Applications for FDA Approval to Market a New Drug*, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

Accordingly, FDA long ago adopted a "ministerial role" in the patent-listing process, pursuant to which the Agency relies exclusively on the brand manufacturer's representations about the scope of a given patent's claims. *Apotex*, 347 F.3d at 1347. But in order to effectively administer the statute's dichotomy between Paragraph IV and Section VIII, FDA requires the brand manufacturer to submit information to FDA about the type of patent it seeks to list and, for method-of-use patents, the particular method of use claimed by the submitted patent. *See* 21 C.F.R. § 314.53 ("Submission of Patent Information"); *see also* 68 Fed. Reg. at 36,681-83 (explaining the basis for this approach); FDA, *Proposed Rule: Applications for FDA Approval to Market a New Drug*, 67 FR 65,448, 65,448-54 (proposed Oct. 24, 2002) (same).

ARGUMENT

I. THE PANEL'S NARROW CONSTRUCTION OF THE STATUTE CONFLICTS WITH ITS TEXT, STRUCTURE, AND HISTORY, AND WILL JEOPARDIZE FDA'S ABILITY TO ADMINISTER THE LAW.

All three of the panel's opinions recognize that FDA's ministerial approach to patent listings enables brand manufacturers to manipulate generic market entry by submitting improper patent information to FDA. And all three 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* Slip Op. at 10-11; Concur. at 2-3; Diss. at 1.

As the dissent recognized, the panel majority's unduly narrow interpretation of that provision—under which it construed the phrase "patent information submitted by the [brand manufacturer]," 21 U.S.C. § 355(D)(ii)(I), to limit the counterclaim provision to cases seeking to correct or delete the "number and … expiration date" of a listed patent, but "not … the use code narrative" required by FDA, Slip Op. at 13—will enable the very manipulation Congress sought to thwart. Diss. at 1. More important, it conflicts with settled canons of interpretation, the statute's legislative history, and FDA's implementing regulations. *Id*. at 13-16. Indeed, by declaring FDA's patent-submission regulation inconsistent with the statute, the panel majority's opinion threatens to undermine FDA's ability to administer this complex regime.

A. The Majority Improperly Dismissed The Import Of FDA's Prior Interpretation Of The Law's Patent-Submission Requirements.

As Judge Dyk explained in dissent, it long has been presumed that Congress intends to incorporate—rather than abrogate—prior administrative interpretations. Diss. at 14-15 & nn. 11-12 (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 majority erred by disregarding that presumption here. As set forth above, FDA's pre-MMA regulations interpreted the statute's patent-submission requirements at 21 U.S.C. § 355(b)-(c) to require the submission of patent information beyond the patent's number and expiration date—including use-code

designations for method-of-use patents. 21 C.F.R. § 314.53. Indeed, 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 took effect; and finalized 6 months *before* the MMA became effective. 68 Fed. Reg. at 36,676, 36,697-98 (explaining the rule and noting that "[o]ur principal legal authority for the final rule is … Section 505(b) and (c) of the act"); 67 Fed. Reg. at 65,448, 65,457 (same).

The panel majority offered no basis for thinking that Congress intended *sub silentio* to abrogate FDA's prior interpretation of the law when it passed the counterclaim provision. Yet it nonetheless sought to downplay Congress's awareness of FDA's prior interpretation, by deeming it to be no more than an "'opaque timing observation.'" Slip op. at 14 (quoting *Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010). That was error. FDA's prior interpretation isn't significant merely because it preceded the MMA. It bears directly on the *meaning* of the MMA's reference to the "patent information submitted by [brand manufacturers]," 21 U.S.C. § 355(d)(II)(i), since Congress chose that language with full awareness that the "patent information submitted by [brand manufacturers]" included use-code information under FDA's regulations. Again, Congress presumably incorporates prior agency interpretations, Diss. at 14-15 & nn. 11-12, and that presumption (which *necessarily* relates to timing) cannot be dismissed as an "opaque timing observation."

Indeed, the statute's legislative history conclusively demonstrates that FDA's

regulation compelling brand manufacturers to submit use-code information was embraced by the MMA's principal sponsors. For its part, FDA carefully explained its patent-submission rules during the MMA debate. *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., 7-10 (Aug. 1, 2003) (statement of FDA Chief Counsel Daniel Troy) (explaining that FDA's patent-submission regulation details "*the patent information required to be submitted and provides declaration forms for submitting that information to FDA*," and stating that "[t]he current required text of the declaration is described in FDA's regulations [and includes] a declaration form that must be used for *the submission of patent information*") (emphasis added). And Congress in turn expressly sanctioned that regulation, by indicating that the law was intended to augment—rather than abrogate—it: "The bill provides a critical *complement* to the work the FDA has done in clarifying its regulations on patent listing." *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. 19 (2003) (emphasis added) [hereinafter "*Legislative and Regulatory Responses*"].

The panel majority's reliance on *Wyeth* thus missed the mark. That case did not remotely address the significance of a prior administrative interpretation, much less a situation where the responsible federal agency informed Congress of its prior

interpretation and the statute's legislative history indicates that Congress embraced that interpretation. Instead, *Wyeth* dismissed interpretive claims based on the timing with which Congress itself added various provisions to draft legislation, without any reference to a federal agency's prior implementation of the same statutory scheme or Congress's explicit reliance on that interpretation. 591 F.3d at 1372.

B. The Panel's Decision To Effectively Invalidate FDA's Patent-Submission Regulation Was Improper And Will Jeopardize FDA's Administration Of 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." Slip Op. at 14 (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, the fractured panel's majority effectively declared that FDA cannot lawfully compel brand manufacturers to submit use-code information at all, because the statute (at least according to the panel majority) requires brand manufacturers to submit *only* the patent's number and expiration date and not anything else. *See id*.

That ill-advised decision is likely to destabilize FDA's administration of the statutory scheme. As FDA explained when it promulgated this regulation:

> *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.*

68 Fed. Reg. at 36,682-83 (emphasis added). Indeed, as FDA 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 approvals. *Id*. at 36,682 (discussing *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), and explaining FDA's "need for accurate and detailed information related to the approved methods of use claimed in the patent" in order to efficiently administer the law). And, again, Congress intended the counterclaim provision to *augment* FDA's prior patent-submission regulation by providing a safety valve in cases where brands use improper listings to force improper patent certifications—not to invalidate FDA's interpretation. *See Legislative and Regulatory Responses*, 108th Cong. 19 (2003).

In any event, Congress charged FDA with implementing this notoriously complex statute, and the Agency's views typically warrant great deference from the courts. *See, e.g.*, *Apotex*, 347 F.3d at 1351-52 ("Deference is due to an administrative agency's regulations particularly when the subject matter of the regulatory authority

is a highly detailed regulatory program to which the agency has brought its specialized expertise, a characterization that aptly describes the FDA's role in the context of … the Hatch-Waxman Act.") (citations and quotations omitted). Yet the panel majority failed to address FDA's 2,200-word regulatory justification for its patent-submission rules, *see* 68 Fed. Reg. at 36,681-83, paid no heed to Congress's acceptance of FDA's interpretation during the debate over these provisions, and did not otherwise invite FDA to express its views on this critical issue. Unless this Court reconsiders the panel's deeply fractured decision, however, the panel majority's bald rejection of FDA's patent-submission regulation will remain the law in this Circuit—sowing confusion for both FDA and generic industry over what certifications are required; generating unnecessary and inefficient litigation over threshold filing requirements; and ultimately delaying FDA's approval of generic drugs.

That, of course, is music to the brand manufacturer's ears—as all three of the panel's opinions recognized, *see* Slip op. at 12; Concur. at 2; Diss. at 23—but it cannot possibly be squared with Hatch-Waxman's goal of expediting generic market entry, *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991), or the MMA's attempt to end manipulation by brand manufacturers. *See, e.g., Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317-18 (D.C. Cir. 2010).

CONCLUSION

For the foregoing reasons, the petition should be granted.

May 28, 2010

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CERTIFICATE OF SERVICE

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