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.

2010-1001

Appeal from the United States District Court for the Eastern District of Michigan in case no. 2:05-CV-40188, Judge Avern Cohn.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before RADER, *Chief Judge*,[*] NEWMAN, CLEVENGER,[**] LOURIE, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, *Circuit Judges*.

PER CURIAM.

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[*] Randall R. Rader assumed the position of Chief Judge on June 1, 2010.

[**] Raymond C. Clevenger, III took part in the decision on the panel rehearing.

GAJARSA, *Circuit Judge*, with whom DYK, *Circuit Judge*, joins, dissents from the denial of the petition for rehearing en banc.

JAMES F. HURST, Winston & Strawn LLP, of Chicago, Illinois, filed a combined petition for panel hearing and rehearing en banc for defendants-appellees. With him on the petition were CHARLES B. KLEIN, STEFFEN N. JOHNSON, SCOTT H. BLACKMAN, and ANDREW C. NICHOLS, of Washington, DC; DAVID S. BLOCH, of San Francisco, California.

JOSH A. KREVITT, Gibson, Dunn & Crutcher LLP, of New York, New York, filed a response to the petition for plaintiffs-appellants. With him on the response were MARK A. PERRY, of Washington, DC; WAYNE BARSKY, of Los Angeles, California; and MICHAEL A. SITZMAN, of San Francisco, California.

WILLIAM A. RAKOCZY, Rakoczy Molino Mazzochi Siwik LLP, of Chicago, Illinois, for amicus curiae Generic Pharmaceutical Association.

SHASHANK UPADHYE, Apotex, Inc., of Toronto, ON Canada, for amicus curiae Apotex, Inc. With him on the brief was MICHAEL A. BERTA, Wilson Sonsini Goodrich & Rosati, of San Francisco, California, for Impax Laboratories, Inc.

DAVID A. BALTO, The Law Offices of David A. Balto, of Washington, DC, for amici curiae Consumer Federation of America and National Legislative Association on Prescription Drug Prices.

SHANNON M. BLOODWORTH, Perkins Coie LLP, of Washington, DC, for amicus curiae Mylan Pharmaceuticals Inc.

MICHAEL D. SHUMSKY, Kirkland & Ellis LLP, of Washington, DC for amicus curiae Teva Pharmaceuticals USA, Inc.

O R D E R

Defendants-Appellees Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. ("Caraco and Sun") filed a combined petition for panel rehearing and rehearing en banc. The panel invited a response from Plaintiffs-Appellants Novo Nordisk A/S and Novo Nordisk, Inc. The court granted leave to file briefs amici curiae to Teva Pharmaceuticals, USA, Inc., Mylan Pharmaceuticals Inc., Apotex Inc. and Impax Laboratories, Inc., Consumer Federation of America and National Legislative Association on Prescription Drug Prices, and Generic Pharmaceutical Association.

The petition for rehearing was considered by the panel that heard the appeal, and thereafter the petition for rehearing en banc, the response to the petition, and briefs amici curiae were referred to the circuit judges who are authorized to request a poll on whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition of Defendants-Appellees Caraco and Sun for panel rehearing is denied.

(2) The petition of Defendants-Appellees Caraco and Sun for rehearing en banc is denied.

(3) The mandate of the court will issue on August 5, 2010.

FOR THE COURT

July 29, 2010 /s/ Jan Horbaly

Date Jan Horbaly
Clerk

cc: Josh A. Krevitt, Esq.
James F. Hurst, Esq.
William A. Rakoczy, Esq.
Michael D. Shumsky, Esq.
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ON PETITION FOR REHEARING EN BANC

GAJARSA, *Circuit Judge*, with whom DYK, *Circuit Judge*, joins, dissenting from the denial of the petition for rehearing en banc.

This case involves the statutory construction of 21 U.S.C. § 355(j)(5)(C)(ii) ("counterclaim provision"), a critical provision of the Hatch-Waxman Act ("HWA") that has not previously been construed.[1] In 2003, Congress

[1] The counterclaim provision provides:

enacted the counterclaim provision in order to prevent patent holders from making unwarranted or inaccurate claims of patent coverage in the Orange Book.[2] Patent holders previously made such claims in order to delay the onset of competition from generic drug manufacturers, by preventing or delaying FDA approval of a generic manufacturer's Abbreviated New Drug Application ("ANDA").[3] In *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), this court held that generic drug manufacturers could not sue to correct inaccurate and expansive Orange Book listings, thus inspiring Congress

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ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

[2] Under the HWA, Congress required the Food and Drug Administration ("FDA") to maintain and publish a list of patents associated with approved drugs and methods of use. *See* 21 U.S.C. § 355(b)(1) (2006). The Orange Book, or the Approved Drug Products with Therapeutic Equivalence Evaluations, implements this statutory mandate. *See* 21 C.F.R. § 314.53(c)(2)(i)(O).

[3] A generic manufacturer may piggyback on the safety and efficacy data the original drug manufacturer submitted in its "New Drug Application" ("NDA"), and may seek approval for an identical method of use for its identical generic product by submitting an ANDA. *See* 21 U.S.C. § 355(j).

to amend the HWA to include the counterclaim provision. 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. Therefore, I respectfully dissent from the court's denial of Caraco's petition for rehearing en banc.

The background and facts of this case are well laid out in Judge Dyk's dissent in the original panel decision. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1370-78 (Fed. Cir. 2010) (Dyk, J., dissenting). As the dissent explains, the majority's opinion adopts an overly narrow construction of "patent information" and an overly broad construction of "an approved method of using the drug." *See id.* at 1370-72, 1376-78. Both constructions are irreconcilable with pre-existing FDA regulations, the text of the HWA, and Congressional intent. *See id.* at 1370-78. I believe rehearing the case en banc is necessary to rectify these improper constructions.

Not only is the majority's construction of the counterclaim provision erroneous, it also eliminates the careful balance Congress has struck between encouraging pharmaceutical discoveries and ensuring that the American people have access to low cost generic drugs. Specifically, the majority's opinion seriously undermines Section viii, a critical provision of the HWA that facilitates the approval and marketing of lower-cost generic drugs for uses no longer protected by a patent.

Under the HWA, Section viii comes into play when a patent listed in the Orange Book "claims one, but not all, approved methods of using a drug." *Id.* at 1365. Sec-

tion viii permits a generic manufacturer seeking to market an approved use of a drug to certify that its method of using the drug (as described on its label) is not covered by a patent in the Orange Book. Normally, the label associated with the generic version of a drug must be exactly the same as the label associated with the drug approved in the original New Drug Application. 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 14.94(a)(8)(iv). A Section viii statement allows a generic manufacturer to avoid infringement by deleting patented used from its proposed label information, thus allowing it to avoid infringement. 21 U.S.C. § 355(j)(2)(A)(viii).

Congress intended Section viii to facilitate the approval and marketing of lower-cost generic drugs, while still respecting the patent rights of pioneering drug manufacturers. Pioneering drug manufacturers, however, have found another way to game the system by subverting Section viii carve-out statements and delaying the onset of generic competition by submitting overbroad and inaccurate use codes. Use codes are codes created by patent holders in Orange Book listings to identify the scope of their Orange Book patents. The FDA will not approve a generic manufacturer's Section viii proposed label amendment if a use code covers the proposed label. Importantly, the FDA makes no effort to determine the accuracy of use codes.[4]

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[4] The FDA has maintained, and we have affirmed, that its role in listing patents in the Orange Book is "ministerial"; it simply lists the patent information that it receives from brand manufacturers, expecting those parties to properly abide by the statutory and regulatory mandates. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003); Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on

In this case, Novo Nordisk (the brand drug manufacturer) owns a patent on the chemical composition of repaglinide, which expired on March 14, 2009. *See* U.S. Patent No. RE 37,035 ('the '035 patent). Novo also owns a patent on the use of repaglinide in combination with metformin to treat diabetes, which does not expire until 2018. *See* U.S. Patent No. 6,677,358 ("the '358 patent"). In addition to its combination with metformin to treat diabetes, the FDA had approved repaglinide for two other uses: (1) by itself, i.e. monotherapy and (2) in combination with thiazolidinediones. *See Novo Nordisk*, 601 F.3d at 1362. Novo does not own any patents covering the latter two approved uses.

In anticipation of the '035 patent's expiration, Caraco, the generic manufacturer, sought to market the monotherapy use of repaglinide to treat diabetes, a use no longer covered by a patent. In June 2005, Novo sued Caraco, claiming that if Caraco marketed repaglinide, it would nonetheless infringe the '358 patent because Caraco's label would suggest the use of repaglinide together with metformin. Following the FDA's suggestion, Caraco sought a Section viii carve-out statement, making clear that it was not seeking approval to market the use of repaglinide in combination with metformin and limiting its label to the monotherapy use.

To defeat this Section viii carve-out statement, Novo changed the Orange Book use code associated with the '358 patent from "use of repaglinide in combination with metformin to lower blood glucose" to "a method for improving glycemic control in adults with type 2 diabetes

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Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (codified at 21 C.F.R. pt. 314).

mellitus." *See id.* at 1362-63. The latter use code unmistakably covering both patented and unpatented uses. Because the FDA declined to police this inaccurate listing, Caraco asserted the counterclaim provision in the underlying HWA litigation and requested that Novo revise its use code to reflect the '358 patent's true scope.[5] The majority opinion, however, held that counterclaim relief is not available because the '358 patent covered at least one approved use. *See id.* at 1364-65. This effectively allows a patent holder to extend its monopoly to unpatented uses.

The majority opinion thus eviscerates Section viii. A generic, like Caraco, cannot use Section viii if the pioneering manufacturer's use code is erroneously broad. With the majority's blessing, pioneering drug manufacturers now have every incentive to follow Novo's lead and draft exceedingly broad use codes thereby insulating themselves from generic competition and rendering Section viii a dead letter.

The evisceration of Section viii is exacerbated by the fact that, as Judge Clevenger points out in his concurring opinion in the panel decision, the majority decision likely leaves generic manufacturers such as Caraco with no other remedy. *See Novo Nordisk*, 601 F.3d at 1367-68 (Clevenger, J., concurring). The FDA declined to grant Caraco's Section viii carve-out because the broad use code for the '358 patent now appears to cover Caraco's pro-

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[5] Novo argued, and the majority and concurrence agreed, that this predicament was somehow the fault of the FDA, which had required Novo (and all oral diabetes drug manufacturers) to change the "Indications" part of the drug label for therapeutic reasons. As explained in the dissenting opinion, Novo admits that the FDA did not require Novo's inaccurate listing. *Novo Nordisk*, 601 F.3d at 1380 (Dyk, J. dissenting).

posed carve-out label. Caraco also cannot disprove infringement in the infringement lawsuit because the FDA requires it to use Novo's original label, which includes information regarding the patented combination therapy. Thus, Caraco will apparently have to wait to launch its generic repaglinide product until 2018, the date on which Novo's '358 patent on the combination therapy expires—despite the fact that the '358 patent *concededly does not cover the use for which Caraco seeks to market the drug*. This is an untenable and absurd result, and contravenes the intent of Congress in adopting the counterclaim provision.

Finally, the majority opinion effectively invalidates the FDA's effort to define "patent information" for the purposes of the counterclaim provision. *See Novo Nordisk*, 601 F.3d at 1366-67. This invalidation is especially troubling given Congress's explicit approval of those regulations. *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. 19 (2003) (Statement of 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."). Without even requesting the views of the FDA, the majority opinion refuses to give effect to the FDA's interpretation of an important statutory term. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1351-52 (Fed. Cir. 2003) ("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 regulatory scheme created pursuant to the Hatch-Waxman Act." (citation and quotations omitted)).

Because the majority's statutory construction of the counterclaim provision abrogates the HWA and frustrates the clear intent of Congress, I dissent from the court's denial of Caraco's request for rehearing en banc.