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

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
CASE NO. 2:05-CV-40188, JUDGE AVERN COHN

BRIEF FOR CONSUMERS FEDERATION OF AMERICA, ET AL as *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLEES' PETITION FOR REHEARING *EN BANC*

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**Application for Admission Pending*

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *Amici Curiae* Consumers Federation of America and the National Legislative Association on Prescription Drug Prices, certifies the following:

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

   Consumer Federation of America

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:

   None.

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

   None.

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:

   None

Dated: May 28, 2010

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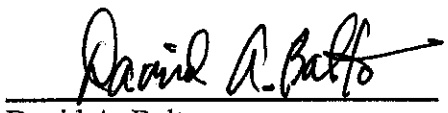

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INTRODUCTION

Amici Curiae Consumers Federation of America and the National Legislative Association of Prescription Drug Prices, (collectively "Amici") are leading advocates for competitive health care and pharmaceutical markets, which benefit all consumers of health care and needed medicines. Amici respectfully submit this brief in support of Defendant-Appellee Caraco's petition for panel rehearing or rehearing en banc. By providing inaccurate "patent information" to the Food and Drug Administration ("FDA"), Plaintiff-Appellant Novo Nordisk is blocking Caraco from marketing drugs that Novo admits do not infringe its patent. Because the panel's divided ruling sanctions such abuse of the regulatory process—and because that abuse directly interferes with affordable access to needed generic drugs—the petition presents a "precedent-setting question of exceptional importance" and en banc review of the panel's ruling is urgently needed. Fed. Cir. R. 35(b).

Specifically, the divided panel ruled that the Medicare Prescription Drug Improvement and Modernization Act of 2003 (collectively, the "Hatch-Waxman Act") does not provide a statutory basis for Caraco, a generic pharmaceutical company, to assert a counterclaim and obtain an order enjoining Novo, a name-brand pharmaceutical company, to provide the FDA with correct "patent information"

describing the scope of the patent's coverage.[1] Well after this litigation began, Novo supplied a misleading "use code" to the FDA in an effort to block a generic product that Caraco sought to market for admittedly non-infringing uses. In response, Caraco filed a counterclaim seeking to correct this "patent information." And as Judge Dyk noted in dissent, the Hatch-Waxman Act counterclaim provision was specifically designed to prevent pharmaceutical companies from engaging in manipulative tactics to delay the entry of generic competitors. Dissent 1. The panel's holding that the counterclaim provision permits such "manipulation of the Orange Book," thus leaving generic drug makers "without any remedy," "cannot be what Congress intended." Diss. 27.

Congress enacted the Hatch-Waxman Act "to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers."[2] Generic manufacturers may rely on the safety and efficacy data submitted by brand distributors provided they certify

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[1] The Act authorizes a "counterclaim seeking an order requiring the [patent] 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 . . . an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Caraco unquestionably satisfied this statute because (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) all panel members agreed that Novo's use code narrative does not accurately describe its patent and, therefore, such "patent information" submitted to FDA should be "correct[ed]."

[2] Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, i (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. *See also,* (explaining)

that their use of the drug will not infringe upon any of the patents associated with the branded drug, as outlined in the "Orange Book". Nonetheless, the regulatory framework remains vulnerable to manipulative schemes by drug companies, many of which exploit the rules designed to promote consumer welfare to maintain monopoly power, charge monopoly rents, and limit consumer alternatives.

This delicate balance of incentives and procedure underscores one fact: "Congress sough to get generic drugs into the hands of patients at reasonable prices--fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). The panel's decision accomplishes the very opposite. Allowing Novo to circumvent the counterclaim protection offered by the Hatch-Waxman Act will permit and encourage the continued identification and exploitation of regulatory loopholes by the pharmaceutical industry. Drug companies will then be able to delay the entrance of generic drugs for *non-patented uses*, thereby increasing the cost of pharmaceuticals to consumers. The panel's decision makes neither legal nor policy sense, and it has generated interest by not only consumer groups and the generic industry but outside legal commentators as well (see attached *American Lawyer* article). This Court should grant Caraco's petition for panel rehearing or rehearing en banc under Fed. R. App. P. 35 and reverse the panel's 2-1 ruling.

STATEMENT OF INTEREST OF *AMICI CURIAE*

All of the amici are public interest groups and advocates for competitive health care markets. Amici participants include Consumers Federation of America, which is a non-profit organization founded in 1968 to provide consumers a well-reasoned and articulate voice in decisions that affect their lives. NLARx is a nonprofit, nonpartisan organization of state legislators across the country.

These leading consumer organizations have a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, Amici have a strong interest in the continued entry of generic pharmaceuticals into the market.

LEGAL ARGUMENTS FOR EN BANC REVIEW

The Court should grant the petition for rehearing or rehearing en banc, and reverse the panel's decision. The Hatch-Waxman Act is designed to limit loopholes and encourage competition in the pharmaceutical industry. As Caraco's petition demonstrates, the panel's decision misinterprets the language, structure, and purpose of the Hatch-Waxman Act to encourage and reward regulatory gamesmanship by drug companies as they devise methods – including misrepresentation and fraud – to prolong and expand their monopoly power. This

decision immediately poses a significant threat to consumer welfare by removing an important line of defense against pharmaceutical company abuse – the counterclaim provision – and virtually ensures that consumers will pay higher prices for fewer products, with fewer approved uses. The divided panel's ruling thus presents a question of "exceptional importance," justifying en banc review. Fed. R. App. P. 35; Fed. Cir. R. 35(b).

I. CONGRESS CLEARLY INTENDED THE COUNTERCLAIM PROVISION TO ALLOW INJUNCTIONS TO "CORRECT OR DELETE" INACCURATE PATENT INFORMATION SUBMITTED TO THE FDA.

As Judge Dyk indicted in dissent, Congress enacted the Hatch-Waxman Act to "prevent manipulative practices by patent holders with respect to the Orange Book listings," which "were designed to delay the onset of competition from generic drug manufacturers." Dissent 1. In 2003, Congress amended the Act to respond to a study by the Federal Trade Commission ("FTC") that thoroughly discussed different strategies employed by brands to delay entry by generics.[3] The legislative history emphasizes the Congressional intent behind the amendments: "The purpose of Title I of the Bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs." H.R. Rep. No. 98-857 at 14-15.

[3] *See,* Generic Drug Entry Prior to Patent Expiration, *supra* note 1.

Amendment author Senator Schumer set forth the purpose of the 2003 amendments – and the counterclaim provision in particular – when he explained "[t]he 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. . . . [T]he provisions enforce the patent listing requirements at the FDA by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand drug company delist the patent or correct the patent information in FDA's Orange Book." 149 Cong. Rec. 31200 (Nov. 23, 2003) (statement of Sen. Schumer). The court should pay great credence to the legislative history and intent in this matter, which this Court has recognized is "unusually strong support" for deciding questions in favor of the generic manufacturers. *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (1996).

As recently as 2009 Amendment namesake Chairman Waxman opined that the Hatch-Waxman Act is being misused to accomplish the opposite of the intended goal, and explained "this is the last thing Congress intended when we enacted Waxman-Hatch. The law was intended to give consumers access to generics at the earliest possible opportunity, not to line the pockets of generic and brand-name drug companies." *H.R. 1706, Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcomm. On Commerce, Trade*

and Consumer Protection, Mar. 31, 2009 (statement of Rep. Henry Waxman, Chairman, House Committee on Energy and Commerce).[4]

The rationale behind the amendments is clear. The Hatch-Waxman Act provides ample incentives for brand manufacturers to develop innovative drugs. However, the brands expanded the scope and duration of these patents through numerous channels, always to the detriment of generic manufacturers and, ultimately, consumers. Abusive filings in the Orange Book are a particularly fruitful avenue of abuse, according to the FTC. The FDA does not police the Orange Book, nor does it seek out sham filings. Rather, its role is "solely ministerial."[5] The counterclaim provision presents the generics with an entry opportunity. Provided the generics comply with Hatch-Waxman Act, and do not manufacture in a method that will infringe upon the brand's patent, they can take advantage of a streamlined "section viii" process to gain approval for new uses. This opportunity, which is clearly the intent of the legislation, is moot if the scope of the patent is ambiguous and malleable. The panel's decision leaves patents in such a condition.

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[4] Preliminary transcript available at http://energycommerce.house.gov/Press_111/20090331/transcript_20090331_ct.pdf (12:218-222).

[5] *See,* Generic Drug Entry Prior to Patent Expiration, *supra* note 3, at *v*.

II. THE PANEL'S DECISION WILL ENCOUARAGE FURTHER ORANGE BOOK GAMESMANSHIP BY PHARMACEUTICAL COMPANIES THAT WILL DELAY GENERIC ENTRY

The Court should grant Caraco's petition for review en banc and reverse the panel's opinion because the holding will encourage a series of strategies by brand manufacturers that are anticompetitive and harmful to consumers. The most likely strategy are deceptive filings in the Orange Book, including defensive refilings and blatant misrepresentation on initial filings. Furthermore, the panel inappropriately relies on Paragraph IV litigation to address patent infringement concerns between a brand and generic manufacturer.

Federal courts have acknowledged that the FDA does not closely monitor compliance with Orange Book, and as a result misrepresentation and fraud is commonplace. For instance, one court explained, "we have no reason to believe that because applicants are *supposed* to submit information about approved uses only, they *in fact* do so." *Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 884 (D.C. Cir 2004). In explaining, the court upheld the district court's analysis that an agency's "self-abnegation" as to patent review "creates the possibility for conflict between NDA holders and ANDA applicants over the proper scope of a particular use patent." *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 205 (D.D.C. 2002). The courts agree with the consumer groups in this analysis: left unchecked, brand pharmaceutical companies will exploit regulatory procedural

loopholes, including the misrepresentation of required information. Both parties in the case at bar agree that the ***application does not seek approval for a patented use***. Op. 14.

Brand manufacturing companies will also be aware that they have freedom to engage in fraud during Orange Book filings. The law requires the brand manufacturer to include its method-of-use patent for its Orange Book filing. 21 C.F.R. § 314.53(c)(2)(ii)(P)(2). The method-of-use patent description should be precise to provide notice to generics regarding potential opportunities for carve outs. *FDA Approval To Market a New Drug: Patent Submission and Listing Requirements*, 68 Fed. Reg. at 36,683. However, with judicially sanctioned lack of oversight, brand name pharmaceutical companies are likely to begin obtaining use codes for extremely broad methods-of-use. As one commentator notes,[6] and the facts here confirm, brand manufacturers have already begun employing this strategy.[7] If the Court allows the panel's decision to stand, it will not be long until we start seeing highly generalized Orange Book use codes such as "treatment for cancer", thereby eliminating any possibility of entry for all generic manufacturers.

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[6] Julie Dohm, *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, 162-63 (2007).

[7] For instance, the FDA assigned a use code for the "treatment of neurodegenerative diseases". See Ctr. for Drug Evaluation & Research (CDER), FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (2007), available at http://www.fda.gov/cder/orange/obannual.pdf.

Nor will the panel's suggestion that Paragraph IV litigation serves as a satisfactory constraint on brand manufacturers' exploitation prove true. First, Congress has authorized the FDA — not the federal courts — to assess the potential health and safety risks of proposed drug labeling. To depend on Paragraph IV litigation would risk leaving health and safety concerns regarding the generic drug unreviewed. Second, Paragraph IV litigation is impractical. Brand manufacturers could engage in litigation strategies to raise the costs of generics, and ultimately make the prospect of entry unprofitable. Both Justices Clevenger and Dyk acknowledge that Paragraph IV is unlikely to satisfactorily resolve these issues. Conc. Op. 1 ("I am not as certain as Judge Rader that the ongoing Paragraph IV litigation will cleanly resolve the dispute between the parties."); Dissent 26 ("[T]he concurrence doubts that there is a remedy in the infringement suit, and I agree.").

CONCLUSION

This court's en banc review and overturning of the panel's decision is essential to protect consumers from the continued manipulation and exploitation of supposedly pro-consumer Hatch-Waxman Act at the hands of brand name pharmaceutical manufacturers.

Respectfully submitted,

May 28, 2010

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Federal Circuit Takes Another Look at Hotly Contested Hatch-Waxman Case

Andrew Longstreth
05-26-2010

As Hatch-Waxman Act cases go, they don't get much more interesting than Novo Nordisk v. Caraco Pharmaceutical. When the Federal Circuit last month ruled for Novo, which is seeking to block Caraco's version of a diabetes drug, the three-judge panel issued three separate decisions, including a very lengthy dissent. Then, on Friday, the Federal Circuit asked Novo to respond to Caraco's motion for a rehearing by June 1. And from what we gather, several amicus briefs from drug manufacturers are one their way.

What's got everybody so worked up? In short, it's what Novo told the Food and Drug Administration about the uses covered by the patent for its drug Prandin. Drug manufacturers are required to detail what patents cover what uses for their drugs. According to Caraco's lawyers at Winston & Strawn, Novo indicated to the FDA that its patent covered all three approved uses of the drug, but in reality the patent covered only one use. That was a problem for Caraco, which had wanted to introduce a generic version of Prandin for the two uses not covered by Novo's patent. Because the labeling information provided by Novo was so broad that it appeared to cover all three approved uses, the FDA rejected Caraco's application.

The issue before the Federal Circuit is whether courts can order a party to correct the information on patents given to the FDA. Detroit federal district court judge Avern Cohn said they could, and he issued an injunction ordering Novo to ask the FDA to update the information on the patent's use. But the Federal Circuit vacated the injunction order, finding that such relief was not available to Caraco under the Hatch-Waxman Act. In a concurring opinion, Judge Raymond Clevenger concluded that Caraco's plight was the fault of the FDA, which asked for the labeling change. "Nothing in the record suggests that Novo is responsible for the labeling change, which, given the statutory and regulatory framework, happens to benefit Novo at Caraco's expense," he wrote.

But according to a passionate dissent by Judge Timothy Dyk, Novo admitted that it made the labeling change to stop Caraco's drug application. And that's what has Jim Hurst of Winston & Strawn, who represents Caraco, so fired up. "We believe it's an abuse of the regulatory process and it costs consumers," said Hurst.

We called Novo's attorney, Mark Perry of Gibson, Dunn & Crutcher, but didn't hear back. Soon enough, however, we'll read Novo's response.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of May, 2010, I caused 2 copies of the foregoing brief to be served via overnight delivery and electronic mail upon the following counsel:

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