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 FOR CONSUMER FEDERATION OF AMERICA AND U.S. PIRG AS AMICI CURIAE IN SUPPORT OF PETITIONERS' PETITION FOR CERTIORARI

DAVID A. BALTO
Counsel of Record
LAW OFFICES OF DAVID A. BALTO
1350 I Street NW
Washington, DC 20005
david.balto@yahoo.com
202-789-5424

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – Continued

Page

OTHER AUTHORITIES

TABLE OF AUTHORITIES – Continued

INTERESTS OF AMICI CURIAE[1]

Amici Curiae Consumer Federation of America and U.S. PIRG are leading advocates for competitive and transparent pharmaceutical markets, including generic pharmaceuticals' access to markets, which benefit all consumers by maintaining lower prices, promoting innovation, and developing efficiencies. These goals would be significantly compromised if brand pharmaceuticals are further encouraged to circumvent the unambiguous text, structure, and purpose of the Hatch-Waxman Act by manipulating patent use codes without allowing injured generic pharmaceutical companies the opportunity to assert relevant counterclaims.

The Consumer Federation of America (CFA) is composed of over 280 state and local affiliates representing consumer, senior-citizens, low-income, labor, farm, public power, and cooperative organizations. CFA represents consumer interests before federal and state regulatory and legislative agencies, participates in court proceedings as amicus curiae, and conducts research and public education.

---

[1] The parties were timely informed of the intent to file the amici brief. The parties have consented to the filing of this brief, and the parties' letters of consent to the filing of this brief are on file with the Clerk. Pursuant to Rule 37.6, amici curiae state that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the amici curiae, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

U.S. PIRG, the federation of state Public Interest Research Groups (PIRGs) is a not for profit consumer advocacy organization that stands up to powerful special interests on behalf of the American public. With a strong network of researchers, advocates, organizers and students across the country, it takes on the special interests when they stand in the way of reform and progress.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court's review is urgently needed to prevent the decision below from greatly increasing the cost of generic drugs for ordinary Americans. The Hatch-Waxman has saved American consumers, including members of the amici curiae, literally hundreds of billions of dollars in unnecessary expenses for needed medicine. The decision below threatens to take a large bite out of those savings, and is contrary to Congress' intent and the plain text and structure of the Act.

Congress updated the Medicare Prescription Drug Improvement and Modernization Act (collectively, the "Hatch-Waxman Act") in 2003 to ensure the effectiveness of the Act's streamlined procedure for a generic product to reach the market when its use is different from the use patented by the brand manufacturer. Under what is known as "section viii" of the Act, the generic manufacturer files an abbreviated new drug

application (ANDA) demonstrating a permitted use of a patented product. This procedure contains a mechanism to safeguard the patent holder by allowing the patent holder to pursue an injunction within forty-five days of the ANDA filing. At the same time, to ensure that the patent-holding brand manufacturer does not abuse its position by merely enjoining any ANDA filed, Congress in 2003 passed a counterclaim provision that provides generic pharmaceutical manufacturers with a method for challenging brand actions.

It was Congress' intent to balance the interests of brand and generic manufacturers in an effort to promote innovation and facilitate consumer access to affordable medicine. For instance, to allow for future consumer benefits, Congress and the FDA have acted to ensure that brand manufacturers whose "method" patents cover only specific uses of a drug do not expand those patents beyond their lawful bounds. Thus, if a given pharmaceutical is proven useful for a non-patented use, it is Congress' will that this drug reach the consumers through generic manufacturing without having to wait for the expiration of yet another patent.

The gamesmanship employed by Novo/Nordisk when it changed its patent use code – admittedly incorrectly – in response to Caraco's ANDA filing is a brazen abuse of the Hatch-Waxman Act, FDA regulations, and the intent of legislators and policymakers. Congress was aware that the complexities of FDA pharmaceutical approval lend themselves to creative

manipulations, and provided generics with the opportunity to counteract such strategies through the counterclaim provision. The counterclaim provision is wide-reaching, both because "section viii" ANDA applications are so common and because the provision is designed to allow generics to combat a wide array of deceptive tactics. Blocking a brand manufacturer from a post-hoc, incorrect change to its patent use code certainly falls within the scope of intended counterclaims.

The harm to consumers from this action is both immediate and far-reaching. Immediately consumers face one fewer generic on the market that they should otherwise have access to. This action also opens the door for other brands to employ similar tactics, thereby effectively ending any hope that a non-patented use will ever reach consumers through generics, as intended. Furthermore, this rewards and encourages brand manufacturers to continue to devise new ways to circumvent the rules, and virtually ensures consumers will continue to suffer the effects of limited access to the medicine they need.

Review is needed now to prevent these unfortunate results of the Federal Circuit's fractured ruling.

ARGUMENT

I. THE FEDERAL CIRCUIT THREATENS THE VIABILITY OF MECHANISMS VITAL TO GENERIC COMPETITION AND THEREFORE CONSUMER ACCESS TO GENERIC PRODUCTS

Consumer access to generic pharmaceuticals is a key initiative for both Congress and regulatory agencies. Representative Waxman summarized the Congressional approach to generics during his 2009 testimony, explaining:

> Generic drugs play a crucial role in promoting public health where they are available. They promote competition, which in turn lowers prices. Lowering drug prices reduces overall health care bills. More importantly though, lower drug prices means access to important medications for many patients who might not otherwise be able to afford them. Today in the U.S. a remarkable 67% of prescriptions are filled with generic medicines, saving consumers and the federal and state governments tens of billions of dollar annually.[2]

As the Department of Health & Human Services recently observed, "[d]ramatic growth in the use of generic drugs has generated substantial savings for

---

[2] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the H. Subcomm. on Com., Trade and Consumer Protection, H. Comm. on Energy and Com.*, 111th Cong. 11 (2009) (statement of Rep. Henry Waxman, Chairman, House Comm. on Energy and Comm.).

American consumers." *ASPE Issue Brief: Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy – U.S. Department of Health and Human Services*, *Expanding the Use of Generic Drugs* at 2 (Dec. 1, 2010). Indeed, generic products have saved American consumers over $824 billion over the past decade and almost $140 billion in 2009 alone.[3] Clearly this is an important program for consumers, as access to generics is becoming a virtual necessity for those that cannot afford brand name pharmaceuticals.

The Hatch-Waxman Act and the counterclaim provision in particular both serve as integral defenses for the generic pharmaceutical industry. Removing the teeth from the counterclaim provision invites brand name pharmaceutical manufacturers to sue each and every generic product that appears, obtaining the benefit of an automatic 30-month stay of FDA approval of generic marketing. This litigation, whether successful or not, delays market entry by years and raises the cost of business for generics to the point where entry may no longer be an option. Like other tactics that garner more of the headlines, blocking

[3] Press Release, Generic Pharmaceutical Association, Generic Medicines Saved U.S. Health Care System $139.6 Billion in 2009; $824 Billion Saved over the Last Decade (July 26, 2010), *available at* http://www.gphaonline.org/sites/default/files/July%2026%20National_Savings_Study_Press_Release.pdf.

generics through patent use code manipulation is substantially capable of derailing an entire initiative.[4]

Simply put, the counterclaim provision is vital to enabling generics to follow the path laid out in "section viii" of the Act. There are numerous examples of instances in which section viii generics have succeeded and saved consumers a considerable amount of money. For instance, Kremers Urban Development Company, operating as Schwartz Pharma, succeeded in obtaining section viii approval for a generic version of the heartburn medicine Prilosec in November of 2002.[5] Consumers enjoyed access to critical medicine while Schwarz Pharma experienced a 55% growth in sales in the following year.[6] This is a two-fold benefit to consumers. First, the specific drug in question is available at a more affordable price. Second, another competitor is able to gain traction in an otherwise consolidated pharmaceutical market. Without section

---

[4] *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the H. Subcomm. on Com., Trade and Consumer Protection, H. Comm. on Energy and Com.,* 110th Cong. 9 (2007) (Oral Statement of Jon Leibowitz, FTC Commissioner), *available at* http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf.

[5] U.S. Food and Drug Administration Center for Drug Evaluation and Research, Approval Package for Application Number 75-410, November 1, 2002, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/075410.pdf.

[6] L.J. Sellers, *Pharm. Exec. 50*, PHARMACEUTICAL EXECUTIVE, May 2004, at 4, *available at* http://pharmexec.findpharma.com/pharmexec/data/articlestandard//pharmexec/202004/95192/article.pdf.

viii as a viable means for obtaining FDA approval, AstraZeneca would still be able to demand exorbitant prices for brand Prilosec, and Schwartz Pharma would still be a relatively obsolete competitor.

Without a functioning and employable counterclaim option, generics will continue to experience difficulties in marketing their drugs for non-patented uses. This will lead to fewer attempts to market and, ultimately, the erosion of the entire industry. Frustratingly, this scenario was foreseen. The counterclaim is merely a tool to prevent the brands from preventing the generics to pursue their legally available avenue. It is not as though the counterclaim provision avails generics to a path for dismantling the brand manufacturers. It is merely an opportunity to correct abuses by the brands.

This Court's review is needed to prevent the counterclaim provision from being eviscerated, to the ultimate detriment of consumers.

II. THE FEDERAL CIRCUIT'S OPINION REWARDS AND ENCOURAGES CONTINUED GAMESMANSHIP AND MANIPULATION BY BRAND MANUFACTURERS

Federal courts have acknowledged that the FDA lacks the resources to 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 practical inability to conduct 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.

Brand manufacturing companies will 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.[7]

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,[8]

---

[7] FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. 36,676, at 36,683 (2003).

[8] Julie Dohm, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling*

(Continued on following page)

and the facts here confirm, brand manufacturers have already begun employing this strategy.[9] 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.

Judge Gajarsa's dissent acknowledged this fact. He explained, "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." *Novo Nordisk A/S & Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 615 F.3d 1374, 1377 (Fed. Cir. 2010) (Gajarsa, J., dissenting).

This does not even take into account the broader effect that such a ruling has on the pharmaceutical industry. By granting brand manufacturers this allowance for deceitfulness and gamesmanship, we are opening the door to future litigation over deceptive or manipulative practices.

Requirement: Closing the Patent Litigation Loophole, 156 U. PA. L. REV. 151, 162-63 (2007).

[9] 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 without review. 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 Judges Clevenger and Dyk acknowledge that Paragraph IV litigation 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."). *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1381 (Fed. Cir. 2010) (Dyk, J., dissenting).

III. THE FEDERAL CIRCUIT'S NARROW INTERPRETATION OF THE COUNTERCLAIM PROVISION OF THE HATCH-WAXMAN ACT CIRCUMVENTS THE CLEAR LEGISLATIVE INTENT

Congress' intent when enacting the Medicare Prescription Drug, Improvement, and Modernization

Act of 2003[10] was clear. Senator Schumer best summarized the purpose of the bill, emphasizing that:

> [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.[11]

As indicated by this statement, Congress identified brand manufacturers and generics as competing interests, recognized the abusive and deceptive tactics employed by brand manufacturers, and designed a counterclaim provision as a direct and immediate remedy to these tactics.

The Federal Circuit's ruling has the effect of disassociating the patent use code narrative from the essential features of the patent, such as the patent number and expiration date. However, the Food, Drug, and Cosmetic Act[12] refers to "patent information"[13] by

---

[10] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §1101(a)(2)(C), 117 Stat. 2066, 2452 (codified at 21 U.S.C. §355(j)(5)(C)(ii)).

[11] 149 Cong. Rec. 31200 (Nov. 23, 2003) (statement of Sen. Schumer) (emphasis added).

[12] 21 U.S.C. §301 et seq.

[13] 21 U.S.C. §355(b).

incorporating the patent number and expiration date in combination with "method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[14] As such, this bifurcation of what constitutes a patent under the counterclaim provision is incongruous with how the very statute identifies "patent information." This court has consistently held that, when interpreting a statute, it "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1955) (quoting *United States v. Boisdo's Heirs*, 49 U.S. 113, 122 (1850)). The divided ruling below contravenes these principles, at the expenses of those who need timely access to low-cost generic drugs.

As recently as 2009, Chairman Henry Waxman – one of the authors of the bill in question – opined that the Hatch-Waxman Act is being misused to accomplish the opposite of its intended goal. Representative Waxman stated "[T]his 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."[15]

---

[14] *Id.*

[15] *Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the H. Subcomm. on Comm., Trade and Consumer Protection, H. Com. on Energy and Com.*, 111th

(Continued on following page)

The rationale behind the amendments is clear. The Hatch-Waxman Act provides ample incentives for brand manufacturers to develop innovative drugs. However, the brand manufacturers 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."[16] The counterclaim provision presents the generics with their only realistic opportunity to combat systematic abuses of this ministerial system.

Just as he acknowledged the ultimate effect this ruling would have on section viii and generic access to a path of entry, Judge Gajarsa also recognized that the Federal Circuit's ruling was in complete abrogation of Congress' intent, explaining "the majority decision likely leaves generic manufacturers such as Caraco with no other remedy . . . Caraco also cannot disprove infringement in the infringement lawsuit . . . [t]his is an untenable and absurd result, and contravenes the intent of Congress in adopting the counterclaim provision." *Novo Nordisk A/S,* 615 F.3d at 1378 (Gajarsa, J., dissenting).

Cong. 12 (2009) (statement of Rep. Henry Waxman, Chairman, House Comm. on Energy and Comm.).

[16] 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.

Review of the divided ruling below is needed to prevent the very consequences that Congress specifically sought to prevent.

Certiorari is therefore warranted.

CONCLUSION

Because of the clear disregard for legislative intent, the immediate harm to consumers who should have access to generic drugs, and the pervasive effect the Federal Circuit's ruling will have on the generic pharmaceutical industry, the petition for a writ of certiorari should be granted.

Respectfully submitted,

DAVID A. BALTO
Counsel of Record
LAW OFFICES OF DAVID A. BALTO
1350 I Street NW
Washington, DC 20005
david.balto@yahoo.com
202-789-5424