No. 10-844

In the Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES AND SUN PHARMACEUTICAL INDUSTRIES, LTD.
PETITIONERS,
v.
NOVO NORDISK A/S AND NOVO NORDISK, INC.,
RESPONDENTS.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR AARP AND U.S. PIRG AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICI CURIAE*[1]

Amicus Curiae AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2 (July 2000), *available at* http://famil iesusa2.org/assets/pdfs/drugod852b.pdf. Significantly, in a 2005 AARP survey, one in four Americans, ages 50 and older, who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., AARP, *Prescription Drug Use Among Midlife and Older*

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[1] The parties have consented to the filing of this brief. 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 *amici curiae* has made a monetary contribution to this brief's preparation or submission.

Americans (2005), a*vailable at* assets.aarp.org/rg center/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See e.g.,* AARP, *Rx Watchdog Report*: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate, May 2010, *available at* http://www.aarp.org/health/medicare-insurance/info-04-2009/rx_watchdog.html. (AARP, *Rx Watchdog Report*).

Amicus Curiae U.S. PIRG (Public Interest Research Group) is a federation of 28 non-profit, non-partisan state Public Interest Research Groups. The PIRGs have worked on behalf of American consumers since 1970 for a fair and competitive marketplace, a sustainable economy, and a responsive, democratic government. Its staff of policy experts, researchers, organizers, and advocates have authored reports, generated media coverage, organized citizens, and lobbied in the state and federal legislatures winning important victories in the areas of consumer protection, public transportation, product safety, health care, and good government. U.S. PIRG is supported by contributions from its tens of thousands of citizen members, and also receives significant funding from foundation grants. It has long advocated for safer, more affordable prescription drugs, and promoted the availability of generic alternatives to brand-name medicines.

SUMMARY OF ARGUMENT

The American healthcare system is in turmoil. Costs continue to rise while access to care continues to shrink, leaving millions of Americans wondering how they are going to obtain the care they require. This is especially true for pharmaceuticals. For at least the past fifteen years, the increase in prescription drug costs has outpaced other healthcare costs. Kaiser Family Foundation, *Prescription Drug Costs: Background Brief*, *available at* http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx (Fe b. 2010). During the period of highest average annual increase, from 1995-2002, the pharmaceutical manufacturing industry was the single most profitable industry in the United States. *Id.*

The Drug Price Competition and Patent Term Restoration Act of 1984, colloquially known as the Hatch-Waxman Act, provides a solution to the growing concern of pharmaceutical costs and prevent the very situation in which we find ourselves today. Pub. L. No. 98-417, 98 Stat. 1585. The original Hatch-Waxman Act established the abbreviated new drug application (ANDA) process. ANDA sought to strike a balance between the pharmaceutical industry's need for continued innovation, the pharmaceutical manufacturers' desire to capitalize on their efforts and protect their work through the patent system, and the public's interest in affordable healthcare.

Through ANDA, generic manufacturers may bypass submissions of independent clinical testing

by showing that the generic drug contains the same active ingredients and is bioequivalent to a brand pharmaceutical already on the market. 21 U.S.C. § 355 (j)(2)(A)(ii) and (iv). The Act further protect the brand pharmaceutical manufacturers by requiring ANDA applicants to carry the burden of showing how the proposed generic drug will not infringe upon any of the patents held by the brand bioequivalent drug. 21 U.S.C. § 355(j)(2)(vii)-(viii). The Food and Drug Administration (FDA) maintains the *Approved Drug Products with Therapeutic Equivalence Evaluations*, colloquially referred to as the "Orange Book." Among the information collected in the Orange Book is a "description of the patented method of use as required for publication." 21 C.F.R. § 314.53(c)(2)(ii)(P). There is, however, no oversight regulating brand manufacturers' accurate representation of their method of use patents in the Orange Book. The FDA's interaction with the Orange Book is "solely ministerial." Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, v (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (Fed. Trade Comm'n, *Generic Drug Entry*).

Notwithstanding the Hatch-Waxman Act, prescription drug prices continued to escalate. Despite the intent of the legislation to incentivize and facilitate generic entry, loopholes, ambiguities, and procedural gamesmanship prevented most generics from using the ANDA process as Congress intended. Most notably, brand pharmaceutical companies learned to amend their method of use patent information to expand the scope of protection

and duration, even when the patent did not in fact protect this enlarged scope. This strategy affects not only generic manufacturers that seek to compete directly with the patent holder, but also generic manufacturers seeking "carve out" approval through a section viii statement. 21 U.S.C. § 355(j)(2)(A)(viii). A section viii statement allows a generic version of a drug to be used through a method of use that is not protected by the underlying patent. A generic may only receive a carve-out labeling if it is completely different from the Orange Book listing. Thus, when a brand manufacturer provides an all-encompassing description of its method of use patent, a generic has no opportunity to bring the drug to market, despite the fact that the brand does not use the drug in the manner proposed by the generic.

Congress recognized the shortcomings of the ANDA system, and enacted the 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). This Amendment allows a generic ANDA applicant to assert a counterclaim against a brand to "correct or delete the patent information submitted by the holder" under the Hatch-Waxman Act. A valid patent holder can delay the entry of a generic for 30 months by filing a patent infringement claim within 45 days of learning about an ANDA application, unless a court determines that the patent is invalid or not subject to infringement. 21 U.S.C. § 355(j)(5)(B)(iii). This, however, is not true for section viii applications, since the ANDA

application claims not to infringe. 21 U.S.C. § 355 (j)(5)(B)(i)-(iii). A misreading of the counterclaim provision led the Federal Circuit Court to conclude that the counterclaim is only available when the patent at issue does not claim any approved method of using the drug. Simply put, as long as a brand manufacturer has a method of use patent that covers at least one approved use, the counterclaim provision provides no recourse for a generic ANDA application forestalled from market entry.

The narrative today focuses on whether brand pharmaceutical manufacturers will be able to again thwart the efforts of Congress and the Food and Drug Administration to facilitate and expedite the entry of generic pharmaceuticals on the market. As it stands with the Federal Circuit Court's holding, a brand pharmaceutical manufacturer will always be able to further delay any generic ANDA application by 30 months so long as it has a viable method of use patent, even if that method of use patent is not at all related to the ANDA application. This has dramatic effects on the American consumer, who realizes the full benefits of generics in the marketplace only when there is competition between brands and generics, and between generics themselves. By circumventing the counterclaim provision through manipulation of inaccurate method of use codes, brand manufacturers are directly harming millions of consumers by denying them the benefits of generic drugs and thereby imposing unreasonably high costs on healthcare.

ARGUMENT

Following the rationale of the Federal Circuit, a brand manufacturer can prevent competition from a generic competitor by submitting a method use patent description that overstates the actual scope of the patent. The Federal Circuit's opinion is especially puzzling because the counterclaim provision in question was enacted to address this very harm. The legislative history of the 2003 Amendment verifies this intention, as sponsor Senator Charles Schumer 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 the Orange Book." 149 Cong. Rec. 31200 (Nov. 23, 2003) (statement of Sen. Schumer). The addition of the counterclaim provision sought to end, once and for all, the practice of brand manufacturers evading generic entry by engaging in Orange Book trickery.

Perhaps overlooked in this battle between powerful pharmaceutical companies is the importance of generic drugs to the American consumer, both directly and indirectly. It is no surprise that brand name drugs are more expensive than their generic counterpart – in fact the average brand medication cost $1880 more than the average

generic medication over a twelve-month period ending in 2010. AARP, *Rx Watchdog Report*.

Consumers are harmed in two distinct ways from this ruling. First, the misreading of the counterclaim provision ensures a prolonged monopoly for brand manufacturers – including for uses never considered or not patented by the brand – which protracts higher prices and limits choice on the market. Direct consumers of this particular drug, and the tax-paying citizenry at large, both suffer when paying these higher prices. Second, sanctioning this pernicious activity further emboldens brand manufacturers to game the system, by devising new ways to prevent generics from succeeding. This in turn disincentivizes generic manufacturers from entering the market at all. Thus, the Federal Circuit opinion, if left intact, virtually insures compounded consumer harm through higher prices and less choice over both the short and the long-term.

I. The Federal Circuit Opinion Undermines the Effort of the Hatch-Waxman Act to Combat Escalating Health Care Costs

The purpose of the Hatch-Waxman Act, and subsequent Medicare Amendments, is clear. The Federal Trade Commission explained that the Hatch-Waxman Act "established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers." Fed.

Trade Comm'n, *Generic Drug Entry*. Perhaps Judge Dyk best articulated the importance of the Hatch-Waxman Act and subsequent 2003 amendment in his dissent: "Congress enacted the counterclaim provision of the Hatch-Waxman Act in order to prevent manipulative practices by patent holders with respect to the Orange Book listings. These practices were designed to delay the onset of competition from generic drug manufacturers . . . the majority . . . construes the statute contrary to its manifest purpose." *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd*, 601 F.3d 1359, 1368-69 (Fed. Cir. 2010).

Healthcare costs are alarmingly high, and generic drugs provide an opportunity for consumers to receive the care they need at a more affordable price. When generics are precluded from avenues for market entry, the anticipated market effects will not occur, and consumers will suffer. The harmful effects are felt both by direct purchasing consumers, as well as the citizenry as a whole.

A. Generic Pharmaceuticals Are Vital To Providing Affordable Health Care to Millions of Consumers

It is unquestionable that the presence of generics that successfully navigate the ANDA system results in lower prices. The National Association of Chain Drug Stores estimates that a generic version of a drug is 76% less than the brand price. U.S. Dept. of Health and Human Services, *Expanding the Use of Generic Drugs*, December 2010, *available at*

http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml (HHS, *Expanding the Use of Generic Drugs*). Savings continue to amass as more generics enter for a particular drug. *Id*. The Generic Pharmaceutical Association estimates that the use of generics has saved the entire healthcare industry $139.6 billion in 2009 alone, and up to $824 billion over the past decade. Generic Pharm. Ass'n., *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009*, July 2010, *available at* http://gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul 23%2010_0.pdf.

There are three pathways through which generic drugs reduce healthcare costs. First, generics may serve as a direct substitute for the original branded drug. The generic manufacturer does not enjoy the same monopoly power that the brand enjoyed, and does not have the same research and development costs to recoup. Second, generics make therapeutic substitution more viable. Consumers benefit either by paying a lower price for a particular treatment or by having access to treatments that might have otherwise been unavailable. Third, the presence of generics in the marketplace forces brands to lower their prices. Even if a consumer chooses to forego the opportunity to purchase generics, their mere presence in the marketplace ensures that brand prices will come down. *Id.*

The totality of these factors represents considerable benefits for consumers, either through savings or increased choice. The Hatch-Waxman Act

strives to ensure that benefits not only persist, but also expand. The lost savings from precluded generics is likely to be exacerbated in the coming years, as numerous high-profile and widely distributed drugs are set to come off patent by 2015. *See* Melly Alazraki, *The 10 Biggest-Selling Drugs That Are About to Lose Their Patent*, Daily Finance, (Feb. 27, 2011), *available at* http://www.dailyfinance.com/2011/02/27/top-selling-drugs-are-about-to -lose-patent-protection-ready/.

Even a thirty month delay in the access to generic versions of previously patented drugs will cost the consumer base billions of dollars. The ANDA process and the counterclaim provision are absolutely vital to ensuring that the system operates as designed. However, if the Federal Circuit's opinion stands, it is a virtual certainty that the manufacturers in charge of these drugs and others will exploit the loophole and prolong their monopoly beyond the expiration dates.

B. The United States Government, as a Market Participant, Also Benefits Significantly From Generic Entry

Consumers also benefit indirectly when healthcare prices decrease. The Congressional Budget Office (CBO) estimated in 2007 that purchasing generic drugs under Medicare Part D resulted in savings of approximately $33 billion. Congressional Budget Office, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending*, Sept. 2010, at 18, a*vailable at*

http://www.cbo.gov/ftpdocs/118xx/doc11838/09-15PrescriptionDrugs.pdf. Furthermore, the CBO also projects that the federal government would save another $14 billion through 2012 if generic substitutes become available for those drugs that will lose their patent protection during that time. *Id.* at 18-19. This data does not account for therapeutic substitution which might occur as more generics enter the market, which the CBO projects to provide an additional savings of at least $4 billion. *Id.* at viii.

The gamesmanship of brand manufacturers prevents government healthcare programs the opportunity to use generic alternatives at significant savings to the taxpayers. This harm occurs at the end of a cycle of sole manufacturing and distribution rights for the brands. The ANDA process is well-balanced to ensure that proper incentives remain with the brand manufacturers to compel future innovation. The law does not and should not provide these manufacturers with the opportunity to demand higher prices for artificially extended periods merely by misrepresenting their patent information to a government body compelled to obey this information but powerless to verify it.

II. If Left Unchecked, the Federal Circuit's Opinion Will Render ANDA Ineffective and Jeopardize the Viability of Generic Manufacturers

It has been established that brand manufacturers will deploy any number of strategies to undermine

the economic viability of generic manufacturers. Tactics such as knowingly supplying false use codes have two pernicious effects on the market. First, the pharmaceutical industry is certain to see an increase in incorrect use codes. More incorrect and overbroad use codes will only stall the eventual entry of those generics poised to enter the market. Second, when taken as an industry practice, the strategy has the long-term effect of dissuading generic manufacturers from entering the marketplace at all.

A. The Practice of Patent Use Code Abuse Inappropriately Stalls the Entry of Generic Drugs and Is Certain to Become More Prevalent as Manufacturers Learn How to Exploit the Loophole

If Respondent is successful in thwarting Petitioners' attempts at bringing its generic to market, all brand manufacturers will follow suit. Soon, all NDAs in the Orange Book will have method of use patents covering the entire array of potential applications. Use codes are already becoming more prevalent. Ten years ago there were 360 total use codes in the Orange Book. Today there are over 1,000, and the number is only growing. See Kurt R. Karst, Analysis Shows Patent Use Codes Have Doubled Since August 2003 (July 8, 2010), a*vailable at* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/07/analysis-shows-patent-use-codes-have-doubled-since-august-2003--by-kurt-r-karst-http.wwwhpmcomvattorneycfmrid22.html.

Limiting the effectiveness of ANDA would devastate the generic pharmaceutical industry, which would ultimately further burden consumers. ANDA functions by providing a 180 day window of exclusive generic status to the first ANDA to successfully complete the process. This window serves as an incentive for generic manufacturers to compete in the creation of generic drugs. Once the 180 day window expires, all generics may obtain FDA approval. It is at this stage that the consumer reaps the greatest benefit from the program. HHS, *Expanding the Use of Generic Drugs*.

Investors agree. Brand manufacturers are likely to employ the patent use code strategy to stall generics from entering the market moving forward. *See* Morgan Stanley Research Europe, *Pharmaceuticals: Potential Selective Upside for Industry Post Prandin Ruling* 2 (Sept. 1, 2010), *available at* http://www.fdalawblog.net/files/Morgan stanley-rpt---puc-decision.pdf. This is a very profitable maneuver for the brand pharmaceutical industry, and a very threatening reality for generics. Unless courts intervene and curb this tactic, brands simply will continue to exploit the loophole unabashedly.

Adding insult to injury in this case is the brazen nature in which Respondent admits that Petitioners' method of use would not infringe upon its patent. Respondent is flaunting the loophole in front of all, showing that even legislation specifically enacted to achieve the opposite result is no match for the brand

pharmaceutical industry's ability to expand and prolong its patents.

B. Generic Manufacturers Will be Dissuaded From Pursuing ANDA Status as Brand Manufacturers Continue to Devise Methods to Block Generic Entry

In this case, Petitioners' diligence in developing a generic version of repaglinide will certainly lead to lower costs for those suffering from diabetes. Despite Respondent's tactics, there now exists a generic version that will, at some point, drive down the cost. The question for Petitioners is when it will see a return on its investment. But the question for consumers is whether they will see a continued commitment by the generic manufacturing industry to develop generic drugs. It is possible that rulings such as the Federal Circuit's will lead to a diminished interest by generic developers, as the risk of failing to capitalize on diligence may prove too costly to embark on the journey of creating the generic.

This Court is uniquely able to rectify this mistake. The FDA is powerless to change its approach, especially with the controlling authority of the Federal Circuit providing a myopic interpretation of the counterclaim provision. The FDA has long conceded that the courts are the most appropriate vehicle for interpreting the Hatch-Waxman Act, having explained a "fundamental assumption of the Hatch-Waxman [Act] is that the courts are the

appropriate mechanism for the resolution of disputes about the scope and validity of patents." 68 Fed. Reg. 36683 (2003). Reciprocally, federal courts have acknowledged that the FDA does not closely monitor compliance with the Orange Book, a fact that results in fraud and misrepresentation. 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).

Furthermore, Congress has already spoken on this issue. The enactment of the 2003 Amendments was a clear signal to the FDA and courts that the counterclaim provision was necessary to stop the abusive tactics of brand manufacturers. As current FDA Assistant Chief Counsel Julie Dohm once noted, "The FDA's *Orange Book* restriction conflicts with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." 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, 182 (2007). It is time to once and for all provide the judicial remedies conferred by Congress to generic manufacturers so that they can defend their rights under the Hatch-Waxman Act, and strike the balance that Congress initially envisioned nearly thirty years ago.

CONCLUSION

Because the Federal Circuit's opinion misreads the law, abrogates the legislative intent, impermissibly extends the scope of a patent, and threatens the wellbeing of consumers through artificially increased prices and limited choice, this Court should reverse the Federal Circuit.

Respectfully submitted,

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