No. 17-1480

United States Court of Appeals
For the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LTD.,
AMGEN USA, INC.,

Plaintiffs-Appellees,

—v.—

SANOFI, AVENTISUB LLC, REGENERON
PHARMACEUTICALS INC., SANOFI-AVENTIS U.S., LLC,

Defendants-Appellants,

On Appeal from the United States District Court
for the District of Delaware, No.14-1317-SLR (Consolidated),
Judge Sue L. Robinson

BRIEF FOR AMICI CURIAE AARP AND AARP FOUNDATION IN SUPPORT OF DEFENDANTS-APPELLANTS AND ARGUING FOR REVERSAL OF PERMANENT INJUNCTION

BARBARA A. JONES
AARP FOUNDATION LITIGATION
200 So. Los Robles Avenue, Suite 400
Pasadena, CA 91101
Tel. (626)585-2628
bjones@aarp.org

Counsel of Record for Amici Curiae
AARP and AARP Foundation

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., et al. v. SANOFI, et al., No. 17-1480

CERTIFICATE OF INTEREST

Pursuant to Federal Rule of Appellate Procedure 26.1 and Federal Circuit Rule 47.4, counsel for Amici Curiae AARP and AARP FOUNDATION certify the following:

1. The full name of every party or amicus represented by me is: AARP and AARP Foundation.

2. The name of the real party in interest represented by me is: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None.

4. Amici Curiae AARP and AARP Foundation did not appear in the trial court. The names of all law firms and the partners or associates who will be appearing before this Court on behalf of amici curiae are:

BARBARA A. JONES
AARP FOUNDATION LITIGATION
200 SO. LOS ROBLES AVENUE
SUITE 400
PASADENA, CA 91101
(626) 585-2628

Date: February 23, 2017

/s/ *Barbara A. Jones*
Barbara A. Jones
AARP Foundation Litigation
200 So. Los Robles Avenue
Suite 400
Pasadena, CA 91101
Tel. (626) 585-2628

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DECLARATIONS

AARP and AARP Foundation (collectively "AARP") submit this brief as amici curiae pursuant to Federal Rule of Appellate Procedure 29(a) and Rule 29(c) of this Court. In accordance with those rules, AARP states that: (1) no counsel to a party authored this brief, in whole or in part, and (2) no person or entity, other than AARP, its members and its counsel, have made a monetary contribution to the preparation or submission of this brief.

Both the Plaintiffs-Appellees and the Defendants-Appellants have consented to the filing of this brief.

INTEREST OF AMICUS CURIAE

AARP is a nonpartisan, nonprofit organization dedicated to fulfilling the needs and representing the interests of people age fifty and older. AARP fights to protect older people's financial security, health, and well-being. AARP's charitable affiliate, AARP Foundation, creates and advances effective solutions that help low-income individuals fifty and older secure the essentials. Among other things, AARP and AARP Foundation work to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health care.

Access to safe and affordable prescription drugs is particularly important to older adults because they have the highest rates of prescription drug use and higher

rates of chronic health conditions. Nat'l Ctr. for Health Statistics, *Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities*, DHHS Publ'n No. 2016-1232 168-69, 272-73 (2016), http://bit.ly/1Tjr8T1 (tables 39 and 79). How the Court decides this case will have a significant impact on over 18,000 patients' access to health care. In light of the significance of the issues presented in this case, AARP respectfully submits this brief in support of Defendants-Appellants, Sanofi, et al. ("Appellants").

SUMMARY OF THE ARGUMENT

The decision in this case will impact thousands of patients whose elevated low-density cholesterol (LDL-C) is not controlled by statins. At a minimum, this Court should reverse the district court's permanent injunction enjoining the sale of Praluent, a medication currently prescribed to thousands of patients.[1] "An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010). From their inception, the ultimate objective of the patent laws has always been to benefit, not harm, the public. *Kendall v. Winsor*, 62 U.S. (21 How) 322,

[1] Since Praluent's launch, over 102,000 prescriptions, for over 18,000 patients, have been dispensed. Appellants' Mot. for Emergency Stay, Terifay Decl. Ex. S, ¶ 9, ECF No. 14. AARP urges this Court to vacate the district court's order granting a permanent injunction. Appellants' brief raises other grounds for reversal that are not repeated herein.

329 (1859). Taking a life-saving medication off the market does not benefit the public.

Even if this Court were to reject the Appellants' arguments that Amgen's patents are invalid, any harm suffered by Amgen is compensable in monetary damages. Seriously ill patients should not be denied life-saving medical care based on patent infringement. *See* Amicus Curiae Practitioners Who Currently Treat Patients with Praluent ("Amicus Curiae Practitioners") Mot. for Leave 2-3 (noting that patients' lives would be endangered if Praluent were taken off the market). In granting a permanent injunction, the district court erred in giving greater weight to Amgen's loss of market share, momentum, and risk of reputational harm, than to the endangerment of patients' lives. Denying members of the public access to a life-saving health care due to patent assertion is not in the public interest. The decision awarding Amgen permanent injunctive relief should be reversed.

ARGUMENT

I. THE PUBLIC INTEREST IN LIFE-SAVING HEALTH CARE MANDATES THAT THE GRANT OF PERMANENT INJUNCTIVE RELIEF BE REVERSED.

The Supreme Court has unanimously determined that an injunction should no longer be automatically issued after a finding of patent infringement, but that the traditional four-factor test applied by courts of equity applies. *eBay Inc. v.*

MercExchange, L.L.C., 547 U.S. 388 (2006). That test requires a plaintiff to demonstrate that it has suffered irreparable harm; that remedies available at law are inadequate; that considering the balance of hardships between the plaintiff and defendant relief is warranted; *and* that the public interest would not be disserved by an injunction. *Id.* at 391.

Physicians recognize that dyslipidemia caused by elevated low-density cholesterol (LDL-C) is a major risk factor for cardiovascular disease. *Amgen Inc. v. Sanofi*, No. 14-1317-SLR, 2017 U.S. Dist. LEXIS 192, at *7 (D. Del. Jan. 3, 2017). This case involves two different medications, Repatha and Praluent, which are composed of different molecules and available in different dosage strengths designed to treat high levels of LDL-C. *Id*. The active ingredient in Repatha is evolocumab, while the active ingredient in Praluent is alirocumab. *Id.* While doctors have long treated high LDL-C with statins; statins sometimes have adverse side effects or cannot reduce a patient's LDL-C to a healthy level, thus requiring alternative treatment. Defs.-Appellants' Br. 5. The medications, Praluent and Repatha, provide an alternative treatment for those patients for whom statins are insufficient.

Several practicing cardiologists have affirmatively stated that if Praluent is removed from the market, patients' lives will be endangered. Amicus Curiae

Practitioners 2-3. Amgen ignores the opinion of these cardiologists and argues that no patient will be harmed because, in their view, "Repatha is FDA approved to safely and effectively treat every indication and every patient for whom Praluent is approved." Amgen's Opp. to Defs.-Appellants' Emergency Mot. for Stay Pending Appeal 2. This argument ignores the fact that Repatha and Praluent are two different drugs composed of different chemical compositions.

Contrary to Amgen's argument that Repatha is the one drug that fits all, the U.S. Food and Drug Administration (FDA) recognizes that "[p]atients typically have variability in response to many drugs that are currently available" and that it is difficult to predict who will benefit from a medication and who will experience adverse effects. FDA, *Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development* 8 (2013), http://bit.ly/2kAyFaG ("FDA"). The actual safety and effectiveness of a medication varies from individual to individual as a result of not only its actual dosage and chemical composition, but also genetic and environmental factors, as well as the interaction of those factors. *Id.* at 12.

Individualized dosing of drugs is also important because certain patients have an increased response to a given dosage of a medication for a variety of reasons. *See, e.g.*, Ryan S. Funk & Jeffrey P. Krise, *Exposure of Cells to Hydrogen*

Peroxide Can Increase the Intracellular Accumulation of Drugs, 4 Molecular Pharm. 154, 159 (2006) (noting that patients experiencing oxidative stress (or an increase in H_20_2 levels) "may have an increased response to a given dosage of a drug relative to a patient with decreased oxidative stress"). In this case, the only medication that has been FDA-approved for a half-dose is Praluent.[2] An estimated 2.2 million adverse drug reactions occur each year in the United States, including more than 100,000 deaths. FDA, *supra,* at 12. The record simply does not support Amgen's broad assertion that no patient will be harmed by switching their prescription to a chemically different drug.

As one practitioner notes:

> PRALUENT® and its flexible titration options are very important to doctors and patients since the majority of doctors in this country treat a patient's LDL-C to a "target" – *i.e.*, a desired LDL-C value that is sought without going too far below that number. There is no particular LDL-C level that is widely accepted as being correct for patients. Instead, doctors evaluate patients on a case-by-case basis and, based on the available information and circumstances, identify a desired LDL-C level. Importantly, the majority of doctors (including me) do not treat a patient's LDL-C level to get it as low as it will go. This is because LDL-C levels that are "very low" (e.g., those under 225 mg/dL) are a concern for many doctors working in the cardiovascular area because it is unknown if there is

[2] Additionally, race, ethnicity and gender can make a difference. John J. Whyte, *FDA Drug Trial Snapshots and Diversity When Testing New Drugs*, FDA: FDA Voice (Feb. 13, 2107), http://bit.ly/2kGDT02 (*e.g.*, women are often prescribed only half the dose that men take of the sleep medication, Ambien (zolpidem)).

> an added benefit and/or any added safety risks to patients having such very low levels of LDL-C. Very low levels of LDL-C were a point of discussion between the FDA and each of Regeneron/Sanofi and Amgen during the pre-approval advisory committee meetings for their respective products. In fact, the FDA approved labels for both products state "the long-term effects of very low levels of LDL-C induced by [either product] are unknown."
>
> Importantly for many patients, the 75 mg dose is all that is necessary. That is, with the 75 mg dose, numerous PRALUENT® patients hit their LDL-C target number and don't go too low with their LDL-C….

Appellants' Mot. for Emergency Stay, Eckel Decl. Ex. O, ¶¶ 9-10, ECF No. 14.

The patients impacted by this case are patients whose high cholesterol levels are not controlled by statins, which places them at higher risk. It is not in the public interest to put Amgen's interest in market share above the 18,000 patients currently prescribed Praluent.

II. IT IS NOT IN THE PUBLIC INTEREST TO DENY PATIENTS ACCESS TO LIFE-SAVING MEDICAL CARE DUE TO PATENT ASSERTION.

The public's interest in access to life-saving medical treatment mandates the reversal of the district court's order granting the injunction. As the district court noted, there is a strong public interest in providing a broad choice of life-saving medical care to the public. *Amgen Inc. v. Sanofi*, No. 14-1317-SLR, 2017 U.S. Dist. LEXIS 1351, at *3 (D. Del. Jan. 5, 2017); *see also Advanced Cardiovascular*

Sys. v. Medtronic Vascular, Inc. 579 F. Supp. 2d 554, 561 (D. Del. 2008) (holding the public interest favored the denial of a permanent injunction because there was evidence of physician preference for the infringing companies' coronary stents). The ultimate objective of the patent laws has always been to benefit, not harm, the public. *Kendall*, 62 U.S. at 329.

This Court has held that, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of injunctive relief. *See Cordis Corp. v. Boston Sci. Corp.*, 99 Fed. Appx. 928, 935 (Fed. Cir. 2004) (holding that injunctive relief was properly denied when the public interest supports a broad choice of drug-eluting stents); *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988) (affirming that public interest is best served by keeping Abbott's cancer and hepatitis test kits available); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (holding that physician preference regarding choice of catheters supported a strong public interest in denying an injunction). The public interest is harmed when the assertion of a patent denies patients the medical treatments that they need. *See, e.g.*, *Cordis Corp.*, 99 Fed. Appx. at 935-36; *Datascope Corp.*, 786 F.2d at 401 (*citing Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 895 (D. Mass. 1985)).

Surprisingly, the district court acknowledged that, "[t]he public generally is better served by having a choice of available treatments," and even concluded "that the public interest of having a choice of drugs should prevail," but then found that loss of market share, momentum, and reputational harm outweighed the public interest in access to health care. *Amgen,* 2017 U.S. Dist. LEXIS 1351, at *6-8.

Reversing the district court's decision granting a permanent injunction is appropriate because of the serious, detrimental impact that such an order would have on public health. *See Rite-Hite Corp. v. Kelley Co.,* 56 F.3d 1538, 1547-48 (Fed. Cir. 1995) (citing cases denying injunctions to protect public health); *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.,* 146 F.2d 941, 944 (9th Cir. 1944) ("It is now well established that a patentee may not put his property in the patent to a use contra to the public interest . . . it is not the private use but '* * * the public interest which is dominant in the patent system.'") (citations omitted).

As the Supreme Court has noted an "injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course." *Monsanto,* 561 U.S. at 165. The extraordinary remedy of injunctive relief should not have been granted in this case. The equities weigh in favor of the public and the injunction should have been denied.

CONCLUSION

For the foregoing reasons, the grant of a permanent injunction should be reversed.

Date: February 23, 2017

/s/ Barbara A. Jones
Barbara A. Jones
AARP Foundation Litigation
200 So. Los Robles Ave. Suite 400
Pasadena, CA 91101
Tel. (626)585-2628
Counsel of Record for Amici Curiae
AARP and AARP Foundation

CERTIFICATE OF COMPLIANCE

1. This amici curiae brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and Federal Circuit Rule 32(a) because the brief contains 2,016 words, excluding the parts of the brief exempted by the Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Office Word in Times New Roman14 point font.

Dated: February 23, 2017

/s/ Barbara A. Jones
Barbara A. Jones
Counsel of Record for Amici Curiae
AARP and AARP Foundation

CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: February 23, 2017

/s/ Barbara A. Jones
Barbara A. Jones