No. 18-916

In the Supreme Court of the United States

THRYV, INC., FORMERLY KNOWN AS DEX MEDIA, INC.,
Petitioner,
v.

CLICK-TO-CALL, LP, and

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR AARP AND AARP FOUNDATION AS AMICI CURIAE IN SUPPORT OF PETITIONER

BARBARA A. JONES
COUNSEL OF RECORD
WILLIAM ALVARADO RIVERA
DEAN GRAYBILL
AARP FOUNDATION
601 E Street, NW
Washington, DC 20049
Tel. (202) 434-6091
bjones@aarp.org

Counsel for Amici Curiae
AARP and AARP FOUNDATION

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INTEREST OF AMICI CURIAE[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans age fifty and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness. Among other things, AARP and AARP Foundation fight for access to affordable healthcare, including access to lower-cost prescription drugs.

In light of the impact that the cost of drugs in particular has on healthcare expenditures, AARP's Public Policy Institute (PPI) has been tracking the cost of widely used prescription drugs since 2004 and publishes the Rx Price Watch series, reporting on changes in the cost of

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[1] In accordance with Supreme Court Rule 37.6, Amici state 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 Petitioner and the Respondent have filed notice of their consent to the filing of amici briefs with the Clerk of the Supreme Court.

drugs widely used by older Americans.[2] In recent years, the cost of specialty drugs—drugs that typically treat chronic, complex, or rare conditions—are so high that their average cost exceeds the median U.S. household income.[3] The Congressional Budget Office has determined that "[n]et spending on specialty drugs in Medicare Part D rose from $8.7 billion in 2010 to $32.8 billion in 2015."[4] In addition, Medicaid net spending on specialty drugs was approximately $9.9 billion in 2015.[5]

AARP and AARP Foundation have filed several amici curiae briefs before this Court in cases that impact the cost of healthcare and have also supported the use of inter partes review (IPR) to expedite the removal of invalid patents and thus enable faster drug

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[2] The latest reports on trends in the retail prices of generic, brand name, and specialty drugs are available at https://www.aarp.org/ppi/info-2019/trends-in-retail-prices-of-drugs.html.

[3] Leigh Purvis & Dr. Stephen Schondelmeyer, *Rx Price Watch Report: Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2017 Year-End Update*, AARP PUB. POL'Y INST. (June 2019), *https://www.aarp.org/ppi/info-2019/trends-in-retail-prices-of-drugs.html* (concluding that, "[i]n 2017, the average annual retail cost of prescription drug therapy for a single specialty drug was $78,781 per year. This average annual cost was almost $20,000 more than the median U.S. household income ($60,336).").

[4] *Cong. Budget Office (CBO), Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* 6 (Mar. 2019), https://www.cbo.gov/publication/54964.

[5] *Id.*

entry for the benefit of consumers and the U.S. healthcare system. *See, e.g., Oil States Energy Servs., L.L.C. v. Greene's Energy Grp., L.L.C.*, 138 S. Ct. 1365 (2018); *Cuozzo Speed Techs., L.L.C. v. Lee*, 136 S. Ct. 2131 (2016). Inasmuch as invalid patents have a direct impact on the cost of prescription drugs to the detriment of older individuals and the general public, AARP and AARP Foundation submit this brief in support of Petitioner urging the Court to reverse the decision below.

SUMMARY OF ARGUMENT

Congress passed the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), to improve patent quality and address a growing concern that patent litigation was negatively affecting the climate for investment and innovation. The clear intent of the AIA was to create a streamlined process to correct the errors of the Patent and Trademark Office (PTO) and allow "invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation." 157 Cong. Rec. 3, 3375 (2011) (statement of Sen. Sessions).

The cost of litigating patent claims that result from poor patent quality is exceedingly high to both businesses and consumers. *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIRCUIT B.J. 539, 600-01 (2012). Because of the high cost of patent litigation, Congress determined that the decision by the Patent Trial and Appeal Board whether to institute inter partes review

is "final and nonappealable." 35 U.S.C. § 314(d). As this Court recently concluded, "[w]e doubt that Congress would have granted the Patent Office this authority . . . if it had thought that the agency's final decision could be unwound after some minor technicality related to its preliminary decision to institute [IPR]." *Cuozzo Speed Techs.,* 136 S. Ct. at 2140.

As a result of the monopolies created by drug patents, healthcare consumers pay ever-increasing prices for prescription medications. In 2017, the average annual price of a specialty drug was $78,780.[6] Invalid patents can have a direct impact on the cost of pharmaceutical drugs to the detriment of all Americans, and the cost is of particular concern to older individuals, who disproportionately rely upon pharmaceuticals for their health. Through IPR, biosimilar drug companies, for example, can eliminate invalid patents before finalizing their products and quickly enter the market with life-saving drugs for patients. The availability of such drugs could be needlessly delayed for years if the Federal Circuit decision is affirmed.

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[6] Purvis & Schondelmeyer, *supra* note 3.

ARGUMENT

I. The Decision of the Patent Trial and Appeal Board to Institute IPR is Final and Nonappealable.

The clear language of 35 U.S.C. § 314(d) makes the "determination by the [Patent Office] whether to institute an inter partes review . . . *final and nonappealable.*" *Cuozzo*, 136 S. Ct. at 2139. "[A] contrary holding would undercut one important congressional objective, namely, giving the Patent Office significant power to revisit and revise earlier patent grants." *Id.* at 2139-40.

Section 314(d), along with all sections of the America Invests Act, must be interpreted to effectuate the overriding goal of the statute, which is to "allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation." 157 Cong. Rec. 3, 3375 (2011) (statement of Sen. Sessions); *accord* 157 Cong. Rec. 2, 2844 (2011) (statement of Sen. Klobuchar) ("The legislation also provides a modernized, streamlined mechanism for third parties who want to challenge recently issued, low-quality patents that should never have been issued in the first place.").

Congress passed the AIA to address a growing concern that patent litigation was negatively affecting the climate for investment and innovation. When patents are invalid, they undermine competition and increase healthcare and other consumer costs with no

offsetting benefit to consumers, taxpayers, or insurers. Thus, Congress created IPR, a time-limited review process, that allows the Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims in a patent only on the limited grounds set forth in 35 U.S.C. §§ 102 or 103. *See* 35 U.S.C. § 311(b). The IPR process is designed only to correct the issuance of invalid patents. The process provides no right to monetary damages; it affords only the relief of cancellation of a patent.

The PTAB's sound decision to institute the IPR process should have been deemed "final and nonappealable" as envisioned in 35 U.S.C. § 314(d), in the face of Respondent's claim that a prior court action voluntarily dismissed without prejudice invoked the time-bar provision in 35 U.S.C. § 315(b).[7] "[A]s numerous federal courts have made clear, a voluntary dismissal without prejudice . . . leaves the situation as if the action never had been filed." 9 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FED. PRAC. AND PROC. § 2367 (3d. ed. 2018); *see, e.g., Biomedical Patent Mgmt. Corp. v. Calif. Dep't of Health Servs.,* 505 F.3d 1328, 1334 (Fed. Cir. 2007); *Smith v. Dowden*, 47 F.3d 940, 943 (8th Cir. 1995). "The effect of a voluntary dismissal without prejudice pursuant to Rule 41(a) is to render the proceedings a nullity and leave the parties as if the action had never

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[7] Section 315(b) prevents the PTAB from instituting the IPR process "if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner . . . is served with a complaint alleging infringement of the patent." 35 U.S.C. § 315(b).

been brought." *In re Piper Aircraft Distrib. Sys. Antitrust Litig.*, 551 F.2d 213, 219 (8th Cir. 1977). Allowing a patent holder to challenge the PTAB's decision to institute IPR in court, when there is a prior dismissal of a court action without prejudice, would undermine the entire purpose of the Act and allow invalid patents to linger in a lengthy, expensive court challenge—a result Congress did not intend.

II. The IPR Process Gives Biosimilar Companies an Opportunity to Invalidate Wrongfully Issued Patents Early, Increasing Patient Access to Life-Saving Drugs.

The rise of biotechnology in the late 1980s and early 1990s led to new therapies, so-called biologic drugs. Biologic drugs, primarily therapeutic antibodies and recombinant proteins, are derived from natural, biological sources. Biologics are quickly emerging as a vital tool in the fight against many chronic and life-threatening conditions that acutely or disproportionately affect older adults, including arthritis and cancer. Steven Kozlowski et al., *Developing the Nation's Biosimilar Program*, 365 NEW ENG. J. MED. 385, 386 (2011).

Indeed, AbbVie's therapeutic antibody Humera (adalimumab), a biologic drug, is currently the top-

selling drug in the world.[8] Unfortunately, the potential of biologics to treat life-threatening conditions comes at a steep cost to consumers, taxpayers and insurers as the prices for these drugs can far exceed the cost of traditional prescription drugs. As an example, the biologic Revlimid is currently priced at $21,050.26 for 28 capsules.[9] "It used to be that pricing a drug at $100,000 per year raised eyebrows. Now that price [for specialty drugs] has become routine.")[10]

In 2009, Congress passed the Biologics Price Competition and Innovation Act (BPCIA), Pub. L. No. 111-148, 124 Stat. 119 (2009) to create competition for biologics. The BPCIA provides a mechanism for bringing "biosimilar" products to market, establishing an elective process for biosimilar companies and brand-name biologics companies to negotiate the scope and content of patent infringement actions relating to biologics prior to commercial launch by the

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[8] Michael T. Siekman & Oona M. Johnstone, *Impact of Post-Grant Proceedings on Biologics and Biosimilars*, BIOPROCESS INT'L (Jan. 19, 2017), https://goo.gl/iNd78o; Megan Brooks, *Cancer Drugs Dominate Top 10 Best-Selling Drugs in 2018*, MEDSCAPE (Mar. 19, 2019), https://www.medscape.com/viewarticle/910600.

[9] *Revlimid Prices, Coupons and Patient Assistance Program* DRUGS.COM, https://www.drugs.com/price-guide/revlimid (last visited Sept. 4, 2019).

[10] Matthew Herper, *The World's Most Expensive Drugs*, FORBES (Feb. 22, 2010).

biosimilar. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669-71 (2017). Although biosimilar programs in the United States are still new, biosimilar products have the potential to mitigate the costs of prescribed medication to patients, insurers and government payers.

A tactic that has been used by multiple drug companies to maintain control over drug pricing "is to establish a patent thicket, or shield around a product." Alex Brill, *Gamesmanship and Other Barriers to Drug Competition*, MATRIX GLOB. PROVIDERS (July 2019).[11] A "patent thicket" is a large group of secondary patents that cover more than the biologic compound or drug itself.[12] For example, these secondary patents may include not only several patents directed to the biotechnology that made a biologic, but also patents on the method of use and minor modifications to the chemical compound that occur later in the drug development process. Secondary patents include patents on every aspect of the compound, including the formulations, dosage forms and strengths, uses, delivery devices, and extensions including combination products with the same active ingredient. Whereas the primary patent is generally filed early in the development of a new drug, secondary patents are

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[11] Available at, http://www.affordableprescriptiondrugs.org/resource/gamesmanship-and-other-barriers-to-drug-competition/.

[12] *See* Shayna B. Kravetz & Rosemary Frei, *Patent Reform Proposals Raise the Stakes for Researchers, Manufacturers of Biologics*, 1(2) AM. HEALTH & DRUG BENEFITS 13, 15 (Mar. 2008).

frequently filed later. Each new patent attached to a brand or biologic drug has a twenty-year term, and one study found that these secondary patents have extended the patent protection of brand drugs by approximately seven years, on average. Brill, *supra* at 6. IPRs provide a mechanism to "thin the herd" of patents covering critical biologic products in order to streamline BPCIA-based district court litigation and bring greater certainty to biosimilar development.[13]

Importantly, the IPR procedure has allowed biosimilar competitors a chance to invalidate wrongfully granted biologics patents early, often before the FDA has even approved their biosimilar application. The advantage of this early invalidation is substantial savings in cost and time. Through IPR, biosimilar companies can eliminate invalid patents before finalizing their biosimilar, giving them a chance to get to the market (and to patients) earlier than with the BPCIA procedures. Biosimilar manufacturers have found that:

> IPRs provide a number of distinct advantages over litigating biologics cases in district court, including lower cost, lower burden of proof, and faster time to final judgment, as well as the enhanced technical expertise of the administrative patent judges. And for biosimilar applicants in particular, the relative

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[13] *See* Siekman & Johnstone, *supra* note 8.

> simplicity and speed of IPRs can be an attractive means to avoiding the complexity of litigation under the Biologics Price Competition and Innovation Act, including the high volume of patents often in play and the corresponding two waves of litigation provided for by the act.[14]

These advantages are precisely what Congress intended in passing the AIA and creating a biosimilar provision under the BPCIA.

III. IPR Can Limit Soaring Drug Prices by Overturning Patents that Never Should Have Been Granted in the First Place.

Soaring prices of prescription drugs unduly burden the entire U.S. economy. This issue is important not only for the quality and affordability of healthcare, but also because it has significant implications for our nation's fiscal future. The national deficit has climbed sharply in the past several years, currently sitting at $22 trillion.[15] Given the

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[14] John Molenda & Richard Praseuth, *Current Trends In Biologics-Related Inter Partes Reviews*, LAW360 (July 20, 2017), https://www.law360.com/articles/942459/current-trends-in-biologics-related-inter-partes-reviews (citations omitted).

[15] Emily Cochrane et al., *Federal Budget Would Raise Spending by $320 Billion*, N.Y. TIMES (July 22, 2019),

insurmountable costs accompanying Medicare benefits, it is likely that increased spending shouldered by the federal government would add to the deficit.[16] Ultimately, "[w]hen viewed from the perspective of the entire federal budget, as the number of beneficiaries and per capita health care costs continue to grow, total Medicare spending obligations . . . are expected to place increasing demands on federal budgetary resources."[17]

While many adults have health insurance to help defray the cost of prescription drugs, a significant number of adults, including twenty-three percent of Medicare eligible adults, have difficulty affording their medication. Among the groups that have the most difficulty affording prescription medication are "those who are spending $100 or more a month on their prescriptions (58 percent), those who report being in fair or poor health (49 percent), those who take four or more prescription drugs (35 percent), and

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https://www.nytimes.com/2019/07/22/us/politics/budget-deal.html.

[16] *See Id.*

[17] Patricia A. Davis, *Medicare: Insolvency Projections*, CONG. RESEARCH SERV. 8 (2019), https://fas.org/sgp/crs/misc/RS20946.pdf; Patricia A. Davis, *Medicare Financial Status: In Brief,* CONG. RESEARCH SERV. 8 (2019) (reporting that "[o]f the $1.6 trillion, about $610 billion is expected to be spent on Part A services, $775 billion on Part B services, and $201 billion on Part D services.").

those with incomes less than $40,000 annually (35 percent)."[18]

When consumers are unable to afford their medication, some attempt to mitigate the problem by not taking their medication as prescribed or forgoing the treatment, risking their health and sometimes their lives. As many as "three in ten of all adults (29 percent) report not taking their medicines as prescribed at some point in the past year because of the cost."[19] Consumers report that either they will not fill prescriptions, sometimes taking an over-the-counter drug instead, or they opt to cut pills in portions or skip a dose entirely.[20] Fifty-eight percent of individuals who report having difficulty affording their prescription drugs are more likely to take such dangerous measures, as opposed to seventeen percent of those who have easy access to prescription drugs.[21] When consumers take action to mitigate high

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[18] Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, HENRY J. KAISER FAMILY FOUND. (Mar. 1, 2019), https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/.

[19] *Id.*

[20] *Id.*

[21] *Id.*

prescription drug costs, they are at serious risk of their condition worsening.[22]

Consumers with chronic conditions who need specialty drugs are frequently faced with extremely high out-of-pocket costs.[23] As a specific example, a Medicare beneficiary with rheumatoid arthritis could pay as much as $29,390 in annual out-of-pocket expenses for a specialty drug when there is no generic alternative.[24] A Medicare beneficiary with chronic myelogenous leukemia (CML) could pay as much as $49,969 to treat their condition.[25] And these are consumers with insurance. Unfortunately, there are still millions of Americans who are uninsured and who have limited access to life-saving medication.

Congress did not intend 35 U.S.C. § 315(b) to exempt a patent plaintiff from IPR when that plaintiff has made the voluntary and strategic decision to dismiss its own complaint without prejudice.

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[22] *Id.*

[23] *Out-of-Pocket Costs & Specialty Medications*, PAN FOUND., Issue Br. 7, 2-3 (July 2018), https://panfoundation.org/files/PAN-Foundation-Issue-Brief-7.pdf .

[24] *Id.* at 3.

[25] *Id.*

CONCLUSION

The decision of the Court of Appeals should be reversed.

Respectfully submitted,

BARBARA A. JONES
COUNSEL OF RECORD
WILLIAM ALVARADO RIVERA
DEAN GRAYBILL
AARP FOUNDATION
601 E Street, NW
Washington, DC 20049
Tel. (202) 434-6091
bjones@aarp.org

Counsel for Amici Curiae
AARP and AARP FOUNDATION