No. 15-607

IN THE

Supreme Court of the United States

BIOGEN MA, INC.,
Petitioner,

v.

JAPANESE FOUNDATION FOR CANCER RESEARCH AND BAYER PHARMA AG,
Respondents.

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

BRIEF OF SAREPTA THERAPEUTICS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF SAREPTA THERAPEUTICS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Sarepta Therapeutics, Inc. ("Sarepta") respectfully submits this brief as *amicus curiae* in support of the petition for a writ of certiorari in this case.[1]

INTEREST OF *AMICUS CURIAE*

Sarepta is a biopharmaceutical company focused on developing RNA-targeted therapeutics to treat patients with significant unmet medical needs and improve the lives of people affected by rare and life-threatening diseases. Sarepta's diverse pipeline of investigational therapies includes potential treatments for Duchenne muscular dystrophy ("DMD").

Sarepta has an exclusive licensing agreement with the University of Western Australia ("UWA"), which grants Sarepta rights to UWA's extensive DMD-related patent portfolio to support Sarepta's efforts to develop drug candidates for the treatment of DMD. DMD is a rare, severe genetic disorder that affects boys and young men; there are currently no approved treatments. Patients with DMD lack functional dystrophin, and without dystrophin, normal

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[1] Pursuant to Rule 37.6, counsel for *amicus curiae* state that no counsel for a party authored 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 *amicus curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.2, counsel for all parties received notice of Sarepta's intent to file this brief at least ten days before the due date. The parties have consented to the filing of this brief, and copies of their letters of consent are on file with the Clerk's Office.

activity causes progressive muscle damage. DMD is caused by mutations in the dystrophin gene that prevent synthesis of fully functional dystrophin protein. Scientists have been investigating "exon skipping"—a molecular biology technique—as a means of generating a functional, though shorter, form of the dystrophin protein. As many as 80% of DMD patients may be candidates for exon-skipping treatments of various kinds.

In July 2014, the United States Patent and Trademark Office ("PTO") declared two interferences between UWA's exon-skipping patents and applications filed by Academisch Ziekenhuis Leiden ("AZL")—Interference Nos. 106,007 and 106,008. Shortly thereafter, the examiner allowed a related AZL application with method claims corresponding to the composition claims at issue in the '008 interference, despite AZL's admission, at the time it filed the application, that the application included claims based on a UWA patent. *See* Interference No. 106,013, Ex. 2097 (Preliminary Remarks filed on March 6, 2014, in the AZL U.S. Patent Application No. 14/198,992). Faced with the prospect that a patent with claims that interfere with one of its patents would issue, UWA had little choice but to request the declaration of an additional interference—Interference No. 106,013. Ironically, the burden then shifted to UWA to justify the '013 interference, and whether UWA could do so was the sole issue briefed in that proceeding. The '007 and '008 interferences are ongoing, and UWA's request for rehearing of the Patent Trial and Appeal Board (the "Board")'s decision to discontinue the '013 interference is pending.

Sarepta thus faces a real threat that one of UWA's exon-skipping patents—which are important to Sarepta's ongoing efforts to develop effective therapies for DMD patients—will be cancelled if it does not ultimately prevail in the '013 interference. The Federal Circuit's decision below, if left to stand, will preclude UWA from challenging the Board's decision by filing a district court action under 35 U.S.C. § 146, an option that has long been available to parties dissatisfied with the outcome of an interference proceeding before the Board. UWA would face the same restraint if the Board were to enter a judgment against it in the '007 and '008 interferences. Sarepta and its partners also own a number of additional patents related to the development of innovative therapies, and at least some of those patents could potentially become the subject of future interferences governed by the same rule. Sarepta accordingly has a substantial interest in the issues raised in this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Circuit below held that the Leahy–Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), eliminated district courts' jurisdiction over patent interference proceedings declared after September 15, 2012. Pet. App. 12a, 18a. The AIA, however, does not actually *say* that it withdraws district court jurisdiction. The Federal Circuit's decision accordingly cannot be reconciled with this Court's precedents holding that mere silence or implication cannot strip courts of jurisdiction. *E.g.*, *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 468 (2007) ("a clear and explicit withdraw-

al of jurisdiction withdraws jurisdiction" (emphasis omitted)); *Galveston, Harrisburg & San Antonio Ry. Co. v. Wallace*, 223 U.S. 481, 490 (1912) ("jurisdiction is not defeated by implication"); *see* Pet. 11-16. Making matters worse, the Federal Circuit also misconstrued the AIA, which, properly read, does not support even the *inference* that Congress intended to divest district courts of § 146 jurisdiction. *See* Pet. 17-20.

The magnitude of the Federal Circuit's legal errors alone suffices to warrant this Court's intervention. But the practical consequences that will follow from those errors make the case for review all the more compelling.

To begin, although the AIA did away with interference proceedings for patent applications with "effective filing dates" on or after March 16, 2013, there are several circumstances in which applications are afforded effective filing dates before—sometimes *years* before—the date on which they are filed in the patent office. New interferences will therefore continue to be declared for years to come, and the Federal Circuit's decision will preclude the parties to all of those interferences, as well as those currently pending, from seeking district court review of the Board's decisions.

The elimination of that option will substantially affect those parties. District court review affords several distinct benefits unavailable before the Board or on direct appeal to the Federal Circuit, including the opportunity to develop a robust factual record through full discovery and presentation of live testimony. That opportunity can be exceedingly im-

portant in interference proceedings, which often turn on fact-intensive questions of patentability and priority.

The fact that the AIA's amendments will eventually eliminate interferences entirely should not dissuade the Court from granting review to address the question presented. This Court regularly grants certiorari in cases that present issues of exceptional importance affecting a substantial set of ongoing and future cases that, because the issues involve an amendment or repeal, will necessarily diminish over time. The Court should do the same here.

ARGUMENT

I. THE EFFECTS OF THE FEDERAL CIRCUIT'S DECISION WILL BE FELT FOR YEARS TO COME AS NEW INTERFERENCES CONTINUE TO BE DECLARED

Historically, the United States patent system operated on a "first-to-invent" priority principle. *See Hyatt v. Boone*, 146 F.3d 1348, 1351 (Fed. Cir. 1998). An interference is a PTO proceeding to determine "who was the first to invent the common subject matter claimed in two or more applications or in one or more applications and an issued patent." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248-49 (Fed. Cir. 1993). In other words, it is a means of deciding who is entitled to a patent when multiple parties in a first-to-invent system claim rights to the same subject matter. Interference proceedings have been a feature of the U.S. patent system for nearly two hundred years. *See* 3A-10 Donald Chisum, Chisum on Patents § 10.09 (Matthew Bender 2015).

The PTO may declare an interference if the Director determines that "an application is made for a patent which . . . would interfere with any pending application, or with any unexpired patent." 35 U.S.C. § 135(a) (2006); *see Hitzeman v. Rutter*, 243 F.3d 1345, 1353 (Fed. Cir. 2001). A patent applicant may also request an interference, 37 C.F.R. § 1.607, and applicants in fact often "provoke" interferences by copying claims from another application or patent, *see Robertson v. Timmermans*, 603 F.3d 1309, 1312 (Fed. Cir. 2010). Once an interference is declared, the Board is empowered to decide both questions of priority and questions of patentability. 35 U.S.C. § 135(a) (2006); *see In re Gartside*, 203 F.3d 1305, 1317 (Fed. Cir. 2000).

The AIA, signed into law on September 16, 2011, shifted the United States from a "first-to-invent" to a "first-inventor-to-file" system. *Madstad Eng'g, Inc. v. U.S. Patent & Trademark Office*, 756 F.3d 1366, 1368 (Fed. Cir. 2014); *see* AIA § 3(o), (p). As a corollary, the AIA replaced interference proceedings with a new procedure, known as a "derivation proceeding," for patent applications with an effective filing date on or after March 16, 2013. *See* AIA § 3(i) (amending 35 U.S.C. § 135). Derivation proceedings are targeted to the distinct priority issues presented in a first-inventor-to-file system; they provide a means by which to establish that a patent applicant or patentee is not actually an "inventor," but derived the claimed invention from someone else. *See* 35 U.S.C. § 135(a) (2011). Interference proceedings, however, remain available for applications with an effective filing date prior to March 16, 2013, which

are still subject to the first-to-invent system. *See* AIA § 3(n)(2)(A).

While nearly two years have passed since the AIA's March 16, 2013 transition date, the PTO has continued to declare and conduct interferences,[2] and it will not stop doing so any time soon. *See* 3A-10 Chisum on Patents § 10.01 ("[F]or many years there will be two operative standards on priority."). In the first half of November 2015, only 20% of the new patents issued were "AIA" patents—i.e., none of the claims had an effective filing date before March 16, 2013. *See* Dennis Crouch, *AIA Patents: 20% of New Issued Patents*, PatentlyO.com (Nov. 20, 2015). That number naturally will rise as the PTO works through its backlog of applications and the percentage of new patents with applications filed on or after March 16, 2013 increases. *See* USPTO, Data Visualization Center, *Traditional Total Pendency*, http://www.uspto.gov/corda/dashboards/patents/kpis/kpiOverallPendency.kpixml (last visited Dec. 8, 2015) (reporting average of 26-27 months from date of filing to date of final disposition). But even so, new applications that can claim an effective filing date prior to March 16, 2013 will continue to be filed for many years.

There are several circumstances in which the effective filing date—or "priority date"—of the claims in a patent application is earlier than the date on which the application was filed at the patent office. *See* 35 U.S.C. § 100(i)(1). For instance, continuation

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[2] *See* USPTO, *PTAB/BPAI Statistics Archive Page*, http://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/ptabbpai-statistics-archive-page#toc-fy2015 (last visited Dec. 8, 2015).

and divisional applications by definition request the same priority date as their earlier-filed parents. *See id.* §§ 120, 121. Indeed, such applications can often claim priority to a *series* of earlier applications, in which case their effective filing date will be that of the first application in the series. *See* MPEP § 211 ¶ 2.11 ("There is no limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of prior copending applications."). In addition, U.S. domestic patent applications based on previous foreign or international filings typically request the earlier application's effective filing date, *see* 35 U.S.C. §§ 119(a), 365, 386, and applications based on a prior provisional application can claim the benefit of the original filing's priority date if certain conditions are met, *see id.* § 119(e)(1). Similarly, "the effective filing date for a claimed invention in an application for reissue or reissued patent" is "determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." *Id.* § 100(i)(2).

This case illustrates how far back the effective filing dates of claims involved in interferences still ongoing today can reach. The applications at issue here were filed in the mid-1990s, but their effective filing dates are as early as 1980. Pet. 21. Sarepta, too, has witnessed the phenomenon first-hand. In the UWA exon-skipping patent interferences declared in July and September of 2014, the PTO accorded the parties the benefit of filing dates of prior applications dating to 2003 and 2004. Under current law, patents are issued for a term of 20 years from the filing date, 35 U.S.C. § 154(a)(2), and interfer-

ences will therefore likely persist until roughly 2033. Thus, absent this Court's intervention, the effects of the Federal Circuit's decision in this case will be felt by patent owners and applicants for years to come.

II. THE DECISION BELOW WILL SUBSTANTIALLY IMPAIR PATENT OWNERS' ABILITY TO PROTECT THEIR INTELLECTUAL PROPERTY RIGHTS

Prior to the Federal Circuit's decision below, a party dissatisfied with the Board's decision in an interference had two options: It could appeal the Board's decision directly to the Federal Circuit, 35 U.S.C. § 141, or file a civil action in district court, *id.* § 146. The right to trial-court review of interference decisions, like interference proceedings themselves, has its roots in the Patent Act of 1836. *See Troy v. Samson Mfg. Corp.*, 758 F.3d 1322, 1327 (Fed. Cir. 2014) (citing Act of July 4, 1836, ch. 357, 5 Stat. 117).

The decision below fundamentally altered that long-standing system, holding that the AIA divested district courts of jurisdiction over § 146 actions—i.e., that the only option available to a party dissatisfied with the outcome of an interference is a direct appeal to the Federal Circuit. *See* Pet. App. 12a. For the reasons explained in Biogen's petition, the Federal Circuit's decision is wrong. And if left undisturbed, it will deprive parties to pending and future interferences of unique benefits available *only* in district court under § 146.

"[A] direct appeal under § 141 is based solely on the agency record and reviewed under the standard established by the Administrative Procedure Act."

AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1296 (Fed. Cir. 2014); *see In re Gartside*, 203 F.3d at 1315-16 (findings of fact are reviewed under the "substantial evidence" standard, and questions of law are reviewed de novo).

A § 146 action, by contrast, is "a hybrid of an appeal and a trial *de novo*," *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (quotation omitted), and it is governed by different standards than those that apply in a direct appeal under § 141, *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1190 (Fed. Cir. 2011). Significantly, the parties to a § 146 action are not limited to the evidentiary record before the Board. Indeed, "there are *no* limits on the admissibility of evidence [in a § 146 action] . . . except those in the Federal Rules of Evidence and Federal Rules of Civil Procedure." *Troy*, 758 F.3d at 1325 (emphasis added). Filing a district court action thus affords the parties to an interference the opportunity to "shor[e] up evidentiary gaps in the agency record." *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1380 (Fed. Cir. 2009). And when additional evidence is presented, the district court makes de novo factual findings, "treating the record before the Board when offered by a party as if it was originally taken and produced in the district court." *Winner*, 202 F.3d at 1347 (quotation omitted).

District court review provides not only a second chance to present evidence, but also a more complete set of tools with which to do so. *See Streck*, 659 F.3d at 1196 (§ 146 allows the parties to "bring to bear, upon the contested issues . . . the procedures and

rules of federal litigation"). To start, parties to a § 146 action are entitled to full discovery in conformity with the Federal Rules of Civil Procedure. Discovery before the Board, meanwhile, is far more limited. The applicable regulations provide for "automatic" discovery in only a specific, relatively narrow set of circumstances, and to obtain "additional discovery," "[t]he requesting party must show that such additional discovery is in the interests of justice." 37 C.F.R. § 41.150. Thus, while under the Federal Rules of Civil Procedure, it is generally the party *objecting* to discovery requests that bears the burden of convincing the court that they are inappropriate, before the Board it is the party *seeking* discovery that must justify its requests. As a result, the Board's procedures may deny parties discovery of information they would be able to obtain in district court.

Parties to a § 146 action also have the chance to present live testimony, *see Agilent*, 567 F.3d at 1380, while the Board "reviews testimony only in the form of affidavits and transcripts of depositions," *Winner*, 202 F.3d at 1347. As the Federal Circuit has recognized, the district court's ability to "observe witnesses under examination and cross-examination" can give it "a 'powerful advantage' over the Board which can never receive testimony in such a manner." *Id.* (quoting *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1582 (Fed. Cir. 1987)); *accord Streck*, 659 F.3d at 1191 (acknowledging "inherent limits to [the Board's] fact finding function that arise from the sterile nature of a proceeding that is limited to documentary and declaration or deposition evidence").

The opportunity to develop a more robust factual record—which exists only in § 146 actions—can be

essential, because the key contested issues in interferences are often fact-intensive. Priority—the motivating force behind interference proceedings—turns on questions of conception, reduction to practice, and diligence, *see Hitzeman*, 243 F.3d at 1353, all of which are decided based on underlying factual findings, *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed. Cir. 2011); *see In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002) (describing "conception" inquiry as "fact-intensive").

Interferences may also involve fact-driven patentability determinations. In the '007 and '008 exon-skipping patent interferences, for example, UWA has challenged AZL's applications for failure to comply with the written description requirement of 35 U.S.C. § 112(a). *E.g.*, Interference No. 106,008, Paper 213 (UWA Motion 1) (Nov. 18, 2014); *see GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014) ("Adequacy of the written description is a question of fact."). Because AZL's claims are directed to a broad genus, assessing the written description requires evaluation of whether the species disclosed in the applications would enable "ordinary artisans" to predict how the invention would work in *other* species. *In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004). That finding, of course, cannot be made absent an understanding of how the science underlying the claims operates. While the limited record before the Board may in some cases be all that is necessary to reach the right answer to such complex questions, it is not hard to imagine how the opportunity to fill evidentiary gaps identified by the Board or present live expert testi-

mony to explain the underlying concepts could have a substantial impact on the outcome.

The importance of reaching the correct result can hardly be overstated. The stakes for parties to interference proceedings are extraordinarily high. When a patent applicant loses an interference, its claims are refused and no patent will issue. *See* 35 U.S.C. § 135(a) (2006). The effects are even more severe for patent owners—when the final judgment is adverse to a patentee, the claims involved in its *existing* patent are cancelled. *See id.*; Interference No. 106,013, Paper 197 (Judgment) (Sept. 29, 2015) (ordering claims in UWA's involved patent cancelled). Pharmaceutical companies like Biogen and Sarepta rely heavily on patents to develop life-saving treatments for serious illnesses. And losing their patent rights often means losing the ability to compete effectively in the market with a product in which these companies have invested substantial amounts of time and money. District court review under § 146 helps to ensure that important determinations about who rightfully owns a patent are based on *all* of the relevant facts.

III. THIS COURT REGULARLY GRANTS CERTIORARI TO DECIDE IMPORTANT ISSUES INVOLVING AMENDED OR REPEALED PROVISIONS

The fact that interference proceedings will eventually disappear (and along with them any question about district court jurisdiction under § 146) does not render the question presented unworthy of the Court's attention. Indeed, this Court regularly grants certiorari to decide important retroactivity

issues and questions about the interpretation of amended or repealed provisions, even though the number of cases directly affected by the Court's decision will inevitably decrease with time.

In *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997), for example, the Court granted certiorari to decide whether a 1986 amendment to the False Claims Act's *qui tam* provision applied retroactively to suits involving false claims submitted prior to its enactment. *Id.* at 941-42. And in *Judulang v. Holder*, 132 S. Ct. 476 (2011), the Court granted certiorari to review the Board of Immigration Appeals' implementation of a repealed provision of the immigration laws, where the provision at issue continued to apply to individuals whose removal was based on a guilty plea entered before the repeal. *Id.* at 479, 480-81.

As these cases and others like them demonstrate, this Court has not hesitated to grant review simply because its decision will directly affect a declining number of cases covered by a rule or provision that will ultimately be phased out. The Court likewise should not hesitate to grant certiorari to answer the question presented here. Because the Federal Circuit has exclusive jurisdiction over appeals from § 146 actions, 28 U.S.C. § 1295(a)(4)(C), the decision below conclusively resolves the issue in the lower courts, leaving only this Court to intervene and correct the Federal Circuit's error. The Court should do exactly that.

CONCLUSION

For the foregoing reasons and those in the petition, the petition for a writ of certiorari should be granted, or alternatively, the decision below should be summarily reversed.

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