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

REPLY BRIEF

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REPLY BRIEF

District court review of patent interferences has been a mainstay of the patent system since 1836. Pet. 1. Respondents agree that the Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 284 (2011), continues district court jurisdiction over interferences declared before September 16, 2012. Opp. 6. The AIA likewise grants district courts jurisdiction over derivation proceedings, the successors to interferences. *Id.* at 5 n.2. Yet respondents contend that the AIA eliminated district court jurisdiction solely over interferences declared on or after September 16, 2012. *Id.* at 6.

That makes no sense, and respondents advance no policy rationale for such a bizarre result. No statutory text permits, much less compels, it. Since 1952, district court jurisdiction over interferences has been codified in 35 U.S.C. § 146. While the AIA amends § 146 to replace "interferences" with "derivation proceedings," § 3(j), that amendment "shall apply" only to patents and applications filed on or after March 16, 2013, § 3(n)(1). Because the applications here were filed in 1980, they remain subject to the pre-AIA, unamended § 146.

Relying on silence in one provision and negative inferences drawn from two others, respondents ironically assert that the AIA "*expressly*" divests district courts of jurisdiction over interferences. Opp. 15. The Federal Circuit recognized that there was no express divestiture, instead pointing to "silence" and inferences to hold that the AIA eliminated § 146 review. Pet. App. 12a, 14a. That holding conflicts with this Court's precedents requiring clear and explicit language to withdraw jurisdiction otherwise conferred by statute. The Federal Circuit also badly

misread the AIA, which preserved district court jurisdiction over both interferences and derivations.

The question presented is jurisprudentially too important, and the patent rights affected too valuable, to look the other way. *Amici* Merck and Sarepta Therapeutics, which together own thousands of patents, explain the importance of the issue to the everyday administration of the patent system. This case alone involves valuable patent protection for a crucial treatment for multiple sclerosis. Other cases respondents cite to show the "very low" stakes (Opp. 10) involves a life-saving antiviral drug and innovative treatments for diabetes and serious neurological conditions. Much is at stake, both financially and for the public health. Exclusive Federal Circuit review forecloses civil discovery and live testimony; it is no substitute for district court actions. Only this Court should determine the propriety of such a fundamental shift in the administration of the patent system.

I. THE QUESTION PRESENTED IS IMPORTANT AND RECURRING

A. This Court regularly grants review to address important "transitional issue[s]" (Opp. 2) involving the interpretation of amended or repealed statutory provisions, even though the number of cases affected will decrease over time. For instance, *Atlantic Mutual Insurance Co. v. Commissioner of Internal Revenue*, 523 U.S. 382 (1998), addressed a transitional rule that affected the tax calculation for the property and casualty industry for only the 1987 tax year. *Id.* at 384–85; *see also United States v. Hemme*, 476 U.S. 558 (1986) (transitional rule governing taxation of gifts made during four months in 1976).

Likewise, this Court often addresses whether a federal law is retroactive, even though the question inherently affects only a subset of cases that will diminish over time. In *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997), the Court granted certiorari to consider whether a 1986 amendment to the False Claims Act applied to pre-1986 false claims. Similar to respondents' argument here, the respondent in *Hughes* opposed certiorari on the ground that "[b]y the time this Court could render a decision . . . all pre-Amendments false claims would be more than ten years old, and any new FCA suit based on such claims would be time barred." Brief for Respondent in Opposition to Certiorari at 5, *Hughes Aircraft*, 520 U.S. 939 (No. 95-1340); *see also* Merck Br. 19 (additional examples of cases involving transitional issues); Sarepta Br. 14 (same).

Respondents do not dispute that the question presented will recur for many years. Because a patent's term is 20 years from filing, 35 U.S.C. § 154, "interferences will . . . likely persist until roughly 2033." Sarepta Br. 8–9. "[T]he transition period at issue is not months or years but *decades*." Merck Br. 4. "[F]or many years there will be two operative standards of priority," interferences and derivations. 3A-10 Chisum on Patents § 10.01.

B. Citing the "small number" of interference actions, Opp. 1, respondents assert that "the stakes are very low," Opp. 10. But they do not say how many actions would be enough. Even accepting respondents' statistics, the decision below will deny district court review to scores of interference parties.

Respondents also ignore the exceedingly large stakes in any one interference action. This case involves one of the only effective therapies for multiple

sclerosis. The decision below also affects Sarepta Therapeutics' new treatment for muscular dystrophy. Sarepta Br. 1, 3.

Respondents list sixteen district court interference actions in the past five years. Opp. 10 & n.4. That is more than enough to matter, especially when one case concerns a miracle drug for treating Hepatitis C. *Idenix Pharm. Inc. v. Gilead Pharmasset LLC*, No. 14-cv-109 (D. Del. Jan. 29, 2014). Another involves an innovative method of treating serious neurological conditions. *TACT IP LLC v. Janssen Biotech, Inc.*, No. 12-cv-909 (E.D. Va. Aug. 15, 2012). Another involves cell replacement therapies for diabetes. *Asterias Biotherapeutics, Inc. v. Viacyte, Inc.*, No. 12-cv-4813 (N.D. Cal. Sept. 13, 2012).

The question presented also goes to the integrity and stability of the patent system. Merck explains that companies have "relied upon the longstanding, traditional right of patent owners and applicants to present new evidence in district court §146 actions." Merck Br. 1–2. The decision below would upend those settled expectations. *Id.* at 2.

This Court recently reviewed the proper division of authority between the Federal Circuit and district courts to review agency decisions. In *Kloeckner v. Solis*, 133 S. Ct. 596 (2012), the Court reversed the Federal Circuit's erroneous decision that only the Federal Circuit may review certain agency decisions, thereby eliminating district court jurisdiction to do so. *Id.* at 600. The issue here is no less important.

C. Respondents' contentions (at 11, 21) that district court interference actions are wasteful and unnecessary ring hollow, especially when respondents concede that the AIA continues district court

jurisdiction over pre-September 16, 2012 interferences. Opp. 6. The AIA likewise confers district court jurisdiction over derivation actions. *Id.* at 5 n.2. Congress could not have rationally thought district court review was too "costly" and "time-consuming" or allowed improper "do overs," Opp. 21, for one set of interferences, but not for other interferences or for all derivations going forward.

Board proceedings and Federal Circuit review are no substitute for district court actions. Respondents do not dispute that, "[u]nlike a § 146 action, a direct appeal under § 141 is based solely on the agency record and . . . therefore more akin to a traditional appeal from a district court decision." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech Inc.*, 759 F.3d 1285, 1296 (Fed. Cir. 2014). Nor do respondents contest that Board proceedings lack the discovery available in district court. They concede that "live testimony is generally not permitted" before the Board. Opp. 13.

Amici confirm that district court review of interferences "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." Sarepta Br. 4; *accord* Merck Br. 21. "[W]hile 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." Sarepta Br. 11.

D. Respondents suggest this case is a poor vehicle because "Biogen has not challenged the Federal Circuit's merits decision" or detailed why district court

review would "chang[e] the outcome." Opp. 12. But if the Federal Circuit lacked jurisdiction, the merits decision is obviously null.

And respondents miss the point. The Federal Circuit's jurisdictional decision deprived Biogen of the opportunity to fully develop the merits in a district court action—an opportunity Biogen had every right to expect. That deprivation was highly material. Before the Board, there was no discovery under the Federal Rules. No live fact or expert witnesses. No depositions of the competing inventors. The Board had a single, second-hand deposition borrowed from a different, earlier proceeding. *See* Opp. 12.

That deposition illustrates the types of discovery Biogen could have pursued in district court. Sugano's co-inventor, Dr. Tadatsugu Taniguchi, testified that he was first to produce a functional hFIF protein only after working with leading researchers from Harvard and NYU. COA JA5246–63. With civil discovery, Biogen could have deposed all the researchers, obtained lab records, and presented expert testimony based on those materials to show that in the spring of 1980, a functional hFIF protein was patentably distinct (*i.e.*, not obvious) over a mere sequence of amino acids that could be deduced from Sugano's DNA sequence. Discovery also would have shown that Sugano's March 1980 Japanese patent application did not enable claims to the protein, because neither Sugano nor a person of ordinary skill could have prepared a functional hFIF protein based on Sugano's disclosure without undue experimentation. Such a showing would have resulted in Fiers being designated senior party in the interference, and Sugano's inability to prove priority of invention.

II. THE DECISION BELOW IS WRONG

A. The AIA Did Not Expressly Divest Jurisdiction

The Federal Circuit dramatically departed from this Court's precedents barring divestiture of jurisdiction by silence or implication. Respondents acknowledge that "silence or implication" is insufficient. Opp. 15. Only "a clear and explicit *withdrawal* of jurisdiction withdraws jurisdiction." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 468 (2007).

Respondents in vain contend that AIA § 3(j) "*expressly* amended Section 146 to remove district court jurisdiction over interferences" declared on or after September 16, 2012. Opp. 16. But they tellingly point to no such express language. One could search forever and not find it. Section 3 of the AIA replaced interferences with derivations. Section 3(j) amended § 146 by "striking 'an interference' and inserting 'a derivation proceeding.'" As respondents acknowledge, § 3(n)(1) specifies that *all* of § 3's amendments "shall apply to" patents and applications filed "on or after March 16, 2013." Opp. 17–18 (quoting AIA § 3(n)(1)) (brackets omitted). Respondents assert that the "natural" reading of § 3(n)(1) is that § 3(j) applies to *all* patents and applications, regardless of when they were filed. *Id.* at 18. "Natural" is hardly "express." Regardless, when § 3(n)(1) states that § 3's amendments apply to patents and applications filed "on or after" March 16, 2013, the only "natural" reading is that the amendments do not apply to patents and applications filed *before* March 16, 2013.

Nor did the Federal Circuit conclude, as respondents assert (at 16), that the AIA "*expressly*" divested district courts of § 146 jurisdiction. The

Federal Circuit said the opposite: it held that § 3(n)(1) "is *silent* as to whether . . . judicial review of [interference] proceedings continues with respect to patent applications filed prior to March 16, 2013." Pet. App. 14a (emphasis added). The court likewise noted that "the legislative history is silent" on the question. *Id.* at 17a.

To determine the meaning of Congress's "silence," *id.* at 14a, the Federal Circuit relied on negative inferences drawn from two provisions. The court stressed that AIA § 6(f)(3)(C) provides for Federal Circuit and district court "review of interferences declared before September 16, 2012," but "does not . . . explicitly provide for judicial review for interferences declared *after* September 15, 2012." *Id.* at 15a. The court then stated, "[f]or interferences declared after September 15, 2012, [TCA § 1(k)(3)] explicitly authorizes pre-AIA § 141 [Federal Circuit] review, but unlike AIA § 6(f)(3)(C), does not authorize pre-AIA § 146 review." *Id.* at 16a. Because neither § 6(f)(3)(C) nor § 1(k)(3) mentions § 146 jurisdiction over interferences declared after September 15, 2012, the court inferred that those provisions "eliminated" such jurisdiction, even though § 146 would not be amended until six months later. *Id.* The court thus found an implicit, not explicit, divestiture.

This case bears no similarity to the decisions respondents cite as "applying Congress's jurisdictional repeals based on their plain statutory language." Opp. 15. In *Bruner v. United States*, 343 U.S. 112 (1952), the statute was quintessentially express; it provided that "[t]he district courts shall not have jurisdiction" over certain claims. *Id.* at 113–14 & n.2. The statute in *Hallowell v. Commons*, 239 U.S. 506 (1916), provided that certain federal agency decisions were

"final and conclusive" and accordingly not subject to judicial review. *Id.* at 508.

The remaining cases respondents cite do not address divestiture of jurisdiction. *Republic of Austria v. Altmann*, 541 U.S. 677 (2004), held that the Foreign Sovereign Immunities Act, which "*grants* federal courts jurisdiction over civil actions against foreign states," applied retroactively. *Id.* at 691 (emphasis added). *Landgraf v. USI Film Products*, 511 U.S. 244 (1994), did not involve a jurisdictional statute, but rather held that the Civil Rights Act of 1991, which "create[d] a right to recover compensatory damages for certain violations of Title VII," did not apply retroactively. *Id.* at 247.

To distinguish this Court's precedents barring implied divestiture, respondents argue that they addressed whether "later-enacted statutes" repealed "a jurisdictional grant in a different statute that was not amended." Opp. 15. But this Court has never drawn such a distinction, and no principled basis exists to do so. Under the settled law against jurisdictional withdrawal by implication, the AIA cannot impliedly divest jurisdiction under § 146 any more than the AIA could impliedly divest jurisdiction under § 1331 or any other jurisdiction-conferring statute. Express means express. The AIA nowhere expressly divests district courts of jurisdiction that Congress has conferred for nearly 200 years.

B. The AIA Did Not Implicitly Divest Jurisdiction

Respondents offer "four reasons" to buttress the decision below. Opp. 18. None has merit.

First, respondents point to provisions in AIA § 6 and § 7 that "preserve the pre-AIA version of particular

statutory provisions," whereas "Congress provided no similar preservation with respect to Section 146." *Id.* But Congress *did* preserve pre-AIA district court jurisdiction: § 3(n)(1) provides that the amendment to § 146 applies only to patents and applications filed "on or after" March 16, 2013. Section 3(n)(1) therefore preserves § 146 jurisdiction over interferences involving patents and applications filed *before* March 16, 2013.

Second, respondents assert that Biogen's reading of § 3(n)(1) "would render entirely superfluous Section 6(f)(3)(C)." *Id.* Not so. Section 6(f)(3)(C) preserved § 146 jurisdiction over interferences by reconciling different effective dates in two provisions of the AIA. As the petition explains (at 17–18), while § 3(n)(1) preserved pre-AIA § 146 for patents and applications filed before March 16, 2013, pre-AIA § 146 permits district court actions following decisions of the "Board of Patent Appeals and Interferences." AIA § 7(a)(1) replaced that body with the Patent Trial and Appeal Board as of September 16, 2012. For the period *before* September 16, 2012, Congress needed to modify pre-AIA provisions referring to the old Board. Section 6(f)(3)(C) accomplished this by authorizing § 146 actions for interferences declared by the old Board "before" September 16, 2012.

Respondents are wrong that a different provision, AIA § 6(f)(3)(B), "fixed the nomenclature issue without any help from § 6(f)(3)(C)." Opp. 20 n.8. Section 6(f)(3)(B) does not mention § 146, but addresses only Board proceedings. It authorizes the PTO Director to "allow the Patent Trial and Appeal Board to conduct any further proceedings in [an] interference" declared by the old Board before September 16, 2012. Congress still needed to resolve the nomenclature issue in § 146

affecting district courts, and enacted § 6(f)(3)(C) to do so.

Third, respondents argue that AIA § 6(f)(3)(C) and TCA § 1(k)(3) are "specific" provisions that trump the "general" § 3(n)(1). Opp. 19. But the specific/general canon does not apply because those provisions complement, rather than conflict with, AIA § 3(n)(1). Moreover, the canon is not an "express" indication by Congress to depart from centuries of patent law. Anyway, § 146 and AIA § 3(n)(1) are more specific. Section 146 confers jurisdiction over interference actions, and § 3(n)(1) makes § 3(j)'s amendment to § 146 applicable only prospectively to patents and applications filed "on or after" March 16, 2013. By contrast, neither § 6(f)(3)(C) nor § 1(k)(3) mentions district courts' jurisdiction over interferences declared after September 15, 2012—either generally or specifically.

Finally, respondents dispute that "AIA § 3(n)(1) left in place the pre-AIA, unamended § 146 for interferences declared on or after September 16, 2012." Opp. 20 (quoting Pet. 18). In respondents' view, "[n]othing turns on whether an interference is declared before September 16, 2012," because "the only date provided for in that section is March 16, 2013, not September 16, 2012." *Id.* That argument ignores the nomenclature issue discussed above. As stated, AIA § 7 replaced the old Board with the new Board and deemed references to the old Board to refer to the new Board for interferences declared on or after September 16, 2012. Because pre-AIA § 146 conferred jurisdiction following a decision of the old Board, § 6(f)(3)(C) was needed to preserve district courts' jurisdiction over interferences declared before September 16, 2012.

The cornerstone of statutory interpretation is discerning Congress' intent. If Congress wanted to eliminate district court jurisdiction over interferences —while continuing district court jurisdiction for derivations—it easily could have said so. But Congress did not. And respondents have "offered no reason for Congress to have constructed such an obscure path to such a simple result." *Kloeckner*, 133 S. Ct. at 605.

CONCLUSION

The petition for a writ of certiorari should be granted, or alternatively, the decision below should be summarily reversed.

Respectfully submitted,

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