

No. 18-109

IN THE
Supreme Court of the United States

ARIOSA DIAGNOSTICS, INC.,
Petitioner,

v.

ILLUMINA, INC.,
Respondent.

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

REPLY BRIEF FOR PETITIONER

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ARGUMENT

This case presents an important question of law regarding the circumstances in which a patent can be invalidated based on someone else's prior disclosure of an invention to the Patent and Trademark Office. Respondent Illumina does not dispute that the Federal Circuit's predecessor created a circuit split when it adopted the rule at issue in this case, that the Federal Circuit's rule has been criticized by leading commentators and the PTO as inconsistent with the statute and this Court's precedent, and that the Federal Circuit extended its rule to published patent applications without any meaningful analysis.

Illumina nonetheless argues that this Court should disregard the Federal Circuit's legal error because Congress made certain changes to the statute in the America Invents Act ("AIA"). As Illumina acknowledges, however, the statutory provision at the center of the dispute—35 U.S.C. § 119(e)(1)—was not substantively changed by the AIA. The Federal Circuit's interpretation of § 119(e)(1) will therefore continue creating problems under the AIA.

But even if the Federal Circuit's rule were limited to pre-AIA patents, it would still warrant review. Millions of patents affecting large swaths of the economy continue to be governed by pre-AIA law. As late as January 2017, the majority of newly issued patents still qualified as pre-AIA patents due to their priority date. The monopolies created by those patents could last for another 15 years. Contrary to Illumina's position here, unless this Court acts, the binding national precedent set by the Federal Circuit—in conflict with the statute and the rulings of this Court—will perpetuate invalid patents and increase the complexity of proceedings for

years to come. Rather than let that problem fester, this Court should grant the petition and reverse.

I. THE FEDERAL CIRCUIT’S LEGAL ERROR PRESENTS AN IMPORTANT AND RECURRING QUESTION

A. The Key Statutory Provision At Issue Remains Substantively Unchanged In The America Invents Act

1. Illumina’s attempt to distinguish between pre-AIA and post-AIA law provides no basis for denying the petition. This case focuses on a question of timing: What is the effective prior art date of a disclosure in a reference patent or published patent application that is being used to challenge the validity of another patent? In particular, under what circumstances does the filing date of a provisional patent application to which the prior art reference claims priority establish the reference’s effective prior art date? Both before and after the AIA, the Patent Act answers that question by looking to 35 U.S.C. § 119(e)(1), which was not substantively changed by the AIA.

Section § 119(e)(1) provides in relevant part that a patent application “for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application [i.e., adequately described and enabled] ... shall have the same effect, as to such invention, as though filed on the date of the provisional application.” 35 U.S.C. § 119(e)(1) (2006).¹ In other words, when its requirements are met, “Sec-

¹ A minor wording change in the AIA reflects the restyling of § 112, ¶1 as § 112(a) and the elimination of the “best mode” requirement, which is not relevant here. Pub. L. No. 112-29, 125 Stat. 284, 328 (2011). Otherwise, the operative text of § 119(e)(1) remains the same. 35 U.S.C. § 119(e)(1) (2012).

tion 119(e) treats a nonprovisional application as though filed on the date of its corresponding provisional application.” *In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010).

It is undisputed that, before the AIA, a patent challenger could use § 119(e)(1) to establish that an invalidating disclosure in a reference patent or published application should be treated as prior art as of the date of an earlier provisional application. Opp. 20. Patent filings serve as a rich source of prior art disclosures, and the phrase “shall have the same effect” in § 119(e)(1) includes the “patent-defeating effect” of those disclosures against attempts by someone else to later patent the same invention. *Giacomini*, 612 F.3d at 1384 (quoting § 119(e)(1)).

The AIA likewise looks to § 119(e)(1) to determine when a provisional application can be used to establish the prior art date of a disclosure. Post-AIA § 102(d)(2) provides in relevant part that “[f]or purposes of determining whether a patent or application for patent is prior art to a claimed invention ... such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application ... as of the filing date of the earliest such application that describes the subject matter,” but only “*if the patent or application for patent is entitled to claim a right of priority under section 119.*” 35 U.S.C. § 102(d)(2) (2012) (emphasis added).

Because the AIA continues to rely on § 119(e)(1) to determine the effect of an invalidating disclosure in a provisional application, passage of the AIA does not diminish the urgent need to correct the erroneous interpretation of § 119(e)(1) challenged in this petition.

The Federal Circuit engrafted an improper requirement onto § 119(e)(1) when it held in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) that “[a] reference patent is only entitled to claim the benefit of the filing date of its provisional application if the disclosure of the provisional application provides support for the *claims* in the reference patent.” *Id.* at 1381 (emphasis added). The Federal Circuit clearly viewed this rule as an interpretation of § 119(e)(1). At the outset, it quoted § 119(e)(1) and then immediately declared: “In other words, the specification of the *provisional* must ... enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.” *Id.* at 1378 (quotation marks omitted).

Illumina likewise views the challenged Federal Circuit rule as an interpretation of § 119(e)(1). Illumina’s statutory argument (at 20-21) relies exclusively on a misinterpretation of § 119(e)(1)’s text. *See infra* p. 10. Illumina similarly focused on § 119(e)(1) throughout the Federal Circuit proceedings, arguing that “§ 119(e)(1) requires the patent challenger to establish that the claims of the § 102(e) reference are supported by the provisional application.” *Illumina C.A. Corrected Br. 9; see also id.* at 14-17.

Illumina’s concession (at 6) that the AIA did not substantively change § 119(e)(1) is thus fatal to its claim that the AIA provides a basis for denying review. The Federal Circuit’s decision rests on a flawed interpretation of § 119(e)(1), and that flawed interpretation

will continue to govern all patent cases unless and until it is reversed by this Court.²

2. The two changes to § 102 that Illumina cites do not alter the pressing need for review. AIA § 102(a)(2) establishes that patents and published patent applications can serve as prior art, just as was the case under pre-AIA § 102(e). The only difference Illumina notes is that, in describing the patent being challenged (but not the prior art reference), Congress exchanged the phrase “claimed invention” for the word “invention.” See 35 U.S.C. § 102(e) (2006) (“A person shall be entitled to a patent unless the *invention* was described in ... an application for patent[.]” (emphasis added)); see also 35 U.S.C. § 102(a)(2)(2012) (“A person shall be entitled to a patent unless the *claimed invention* was described ... in an application for patent[.]” (emphasis added)).³ This makes clear, as was already well established, that a patent’s validity is determined based on the validity of its claims. *E.g.*, *In re Hiniker Co.*, 150 F.3d 1362, 1368-1369 (Fed. Cir. 1998) (patent may have disclosed something “outstanding in its field,” but patent owner’s decision to pursue “broad claims” opened the door to a validity challenge that might not have succeeded had it sought narrower claims).

² Illumina criticizes (at 1, 11-12) Ariosa for citing pre-AIA provisions, but the petition explained (at 31) that “because the relevant portions of § 119 are unchanged by the AIA, [the Federal Circuit’s] narrow interpretation of § 119 ... would continue to apply when an invalidating disclosure is carried forward from an earlier application.”

³ Congress defined “claimed invention” as “the subject matter defined by a claim in a patent or an application for a patent.” 35 U.S.C. § 100(j) (2012).

To be sure, the AIA’s separate definition of “claimed invention” certainly supports Illumina’s argument that the plain meaning of “invention” is not, and never has been, inherently limited to inventions that are formally claimed. But the Court hardly needs to await an AIA case or to rely on the new wording in § 102(a)(2) to establish that fact. The Court has long made clear that a reference is prior art for all it teaches, and that the term “invention” encompasses an “invention made ... public property” through disclosure even if not “made the basis of a claim.” *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 400 (1926); *see also Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 62 n.10 (1998) (noting that a patent can be invalidated “because the invention had previously been disclosed in a prior patent application, although that application did not claim the invention”).

The only other change in the AIA that Illumina relies on is found in § 102(d), which addresses the prior art date of a reference patent or published application. As discussed, § 102(d) provides that a provisional application’s ability to establish an earlier prior art date for a reference depends on whether “the patent or application for patent is entitled to claim a right of priority under section 119.” 35 U.S.C. § 102(d)(2); *supra* p. 3. Illumina never explains how, in light of that language, the analysis would be any different under the AIA.

Finally, there is a certain irony in Illumina pointing to statutory changes as a basis for denying review. One of the flaws with the Federal Circuit’s rule is that it ignored the impact of the 1999 amendments to the statute and instead reached back and extended outdated precedent without any consideration of its original correctness or whether its logic still applied. Pet. 25-27. Allowing the Federal Circuit’s incorrect interpretation to

linger even longer is an invitation for history to repeat itself.

B. The Pre-AIA Patent Act Will Govern A Significant Number Of Cases For Years To Come

In any event, this Court need not decide the questions that Illumina raises under the AIA, because even if the AIA might ameliorate the harm caused by the Federal Circuit's rule in the future, the case would still warrant review. Pre-AIA law governs all patents with an effective filing date before March 16, 2013. AIA § 3(n), Pub. L. No. 112-29, 125 Stat. 284, 293 (2011). That includes not only patents issued before that date but also patents resulting from, or claiming priority to, an application filed before March 16, 2013. Even a new patent application filed today can result in a pre-AIA patent if it claims priority to an application filed before the AIA's effective date.

The Federal Circuit's rule thus governs a staggering number of patents. More than 2 million patents were issued in the 14 years before the AIA took effect. Pet. 31. Pre-AIA patents have continued to issue since then. As late as January 2017, a majority of newly issued patents were still pre-AIA patents. Crouch, *AIA Patents* (July 18, 2017), <https://patentlyo.com/patent/2017/07/patents-most-issued.html>. Patents last for 20 years from their priority date, 35 U.S.C. § 154(a)(2), or longer if they receive a term extension or adjustment, 35 U.S.C. § 154(b) & 156. The effect of pre-AIA patents will thus be felt for at least another 15 years. Indeed, far from counseling against review, Illumina's argument (at 14) that "no cases address[] the proper interpretation of the current version of the statute" reinforces the continued predominance of pre-AIA patents and the compelling need to get pre-AIA law right.

Illumina is mistaken, moreover, when it contends that the question presented rarely arises and is unimportant. The patent in this case resulted in a \$27 million infringement verdict after the Federal Circuit's ruling. Pet. 31.⁴ The product protected by the patents in *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), generated \$148 million in sales in the first half of 2018.⁵ The economic impact of the Federal Circuit's rule is immense.

Other examples illustrating the effect of the Federal Circuit's rule abound. Illumina does not dispute that the challenged rule was controlling in *SPTS Technologies Ltd. v. Plasma-Therm LLC*, 2018 WL 1638321, at *3 (PTAB Apr. 3, 2018), and *Cordelia Lighting, Inc. v. Cooper Lighting, LLC*, 2018 WL 922039, at *5 (PTAB Feb. 14, 2018). See Pet. 28. And those are hardly the only recent cases in which the challenged rule has controlled what was considered prior art. *E.g.*, *Ex parte Pi*, 2018 WL 3951584, at *8 (PTAB July 30, 2018); *Comcast Cable Commc'ns, LLC v. Promptu Sys. Corp.*, 2018 WL 3491787, at *7 (PTAB July 19, 2018);

⁴ Illumina's attempt (at 7-8) to argue the technical merits of Ariosa's validity challenge is premature. Ariosa's challenge was cut off at the threshold based on an error of law. Ariosa's *inter partes* review briefs explain why it is likely to prevail once that error is corrected, but that will be a question for remand, not for this Court. Moreover, any remand would include Ariosa's obviousness argument based on the Fan reference, which the PTO improperly declined to consider but would now have to address in light of *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). Pet. 33 n.4.

⁵ Press Release, *Amgen Reports Second Quarter 2018 Financial Results* (July 26, 2018), <https://www.amgen.com/media/news-releases/2018/07/amgen-reports-second-quarter-2018-financial-results/> (Repatha).

Ex parte Gurevich, 2018 WL 2383710, at *2-3 (PTAB May 16, 2018); *Huawei Techs. Co. v. Samsung Elecs. Co.*, 2018 WL 1124380, at *5-6 (PTAB Feb. 27, 2018).

Illumina is also wrong when it argues (at 15) that shifting the prior art date of a reference back by one year to the date of its provisional application will rarely matter. One need look no further than the first 10 days after the petition was filed to find at least three examples in which that timing question was the critical issue. *Ex parte Bridge*, 2018 WL 3741943, at *3 (PTAB July 19, 2018) (“The critical question, then, is whether the relied-upon subject matter in Sorden is entitled to the date of either of its provisional applications, for if it is not, then Sorden does not qualify as prior art[.]”); *Comcast*, 2018 WL 3491787, at *7; *Merck Sharp & Dohme Corp. v. Microspherix LLC*, 2018 WL 3374838, at *4-8 (PTAB July 9, 2018).

Illumina also overlooks that, even where the improper requirement that the Federal Circuit grafted onto the statute has been satisfied, the imposition of that requirement still burdens the parties and the tribunal. The Federal Circuit’s rule requires a trial-within-a-trial to determine if the unexamined claims of a published patent application are supported by an earlier application, even where it is clear that the relevant disclosure used to invalidate a challenged patent has been carried forward. Pet. 30-31. It also creates a prolonged period of uncertainty in which a disclosure that is not prior art at one point can later become prior art. Pet. 29. The Federal Circuit’s rule often is controlling, but even when it is not, it remains burdensome and disruptive.

II. THE FEDERAL CIRCUIT'S RULE IS WRONG

The petition discusses the flaws of the Federal Circuit's interpretation, and the criticism it has received, at length. Pet. 18-32. In response, Illumina offers (at 20-21) only a limited statutory argument based on the word "invention" in § 119(e)(1). The plain meaning of "invention," however, includes unclaimed discoveries put into the public domain through disclosure. Pet. 22-24; 35 U.S.C. § 100(a) (2006 & 2012) ("The term "invention" means invention or discovery."); *Milburn*, 270 U.S. at 400 ("The invention is made public property" "although not made the basis of a claim."). Nor does Illumina address the context in which the word "invention" appears. Pet. 23-24. Section 119(e)(1) refers to "an invention disclosed," not necessarily claimed. And rather than cross-referencing the portion of § 112 that controls "claims," § 119(e)(1) cross-references the portion of § 112 that relates to the "description of the invention." Compare 35 U.S.C. § 119(e)(1), *with id.* § 112.

Illumina's premise (at 21) that reversing the Federal Circuit would give "invention" two different meanings is incorrect. As explained in the petition (at 24-25), a patent owner seeking to establish the priority date of a claim it wishes to enforce against infringers will naturally focus on whether that *claimed* "invention"—as opposed to any unclaimed invention—is supported by an earlier application. When a patent is being challenged, however, the *disclosure* of any invention in the prior art is sufficient to put that "invention" into the public domain, regardless of what any prior art patent filings were themselves attempting to claim. That does not give the same word two meanings, but rather reflects the reality that even though "invention" is broad enough to encompass both situations, a patent owner

will likely focus only on the claimed invention it seeks to exclude others from practicing.

Finally, Illumina incorrectly dismisses (at 16) this Court’s decision in *Milburn* as “[i]rrelevant.” The statutory provisions here were built around the principles articulated in *Milburn. Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252, 255 (1965). Indeed, the challenged rule originated in part from the misinterpretation of *Milburn* in *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981). Pet. 11, 19-20. Nor does it matter that some other statutory provisions or doctrines do not strictly adhere to *Milburn*’s “first to invent” rule. Opp. 18. Specific exceptions in other areas of patent law that are grounded in policies not applicable here provide no basis for disregarding *Milburn*’s guidance on the very subject it addressed—the prior art status of disclosures to the PTO. The Federal Circuit’s rule has been widely criticized and is inconsistent with both the statute and *Milburn*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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