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

SUPPLEMENTAL BRIEF FOR PETITIONER

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ARGUMENT

The government agrees with Ariosa that, where the disclosure in a provisional patent application is carried forward into a published patent application, the disclosure qualifies as prior art as of the provisional application's filing date. U.S. Br. 15. The government nonetheless advocates denying the petition because the government would reach that result from the opposite direction: Rather than saying the provisional application establishes the prior art date for the disclosures incorporated into the published application, the government would say that the provisional application itself is prior art because its disclosures were incorporated into the published application. The government's position that its alternative approach provides the exclusive path to reaching the same outcome, however, contradicts the plain text of the statute, casts aside decades of settled practice, and multiplies the confusion surrounding the fundamental and recurring question of when a disclosure qualifies as prior art. The government's brief thus powerfully reinforces the need for this Court's review. And, at minimum, it means that even if the petition is not granted as it should be, the case should be remanded to the agency to address the government's change in position.

I. THE GOVERNMENT'S NEW POSITION ON SECTIONS 119(e)(1) AND 120 UPENDS EXISTING LAW AND ON-LY REINFORCES THE NEED FOR REVIEW

The government's argument against review primarily rests on the proposition that the Federal Circuit's decision was indeed wrong—only for a different reason. Specifically, the government argues that the Federal Circuit erred in following the settled practice of using 35 U.S.C. \$\$ 119(e)(1) and 120 to establish the date on which disclosures in a published application or patent qualify as prior art under \$ 102(e). But that argument for avoiding the question presented is a bit like saying there is no need to settle a dispute of property law because the whole building should be burned down. The argument that \$\$ 119(e)(1) and 120 have no effect on the prior art date of a reference conflicts with the statutory text and the position the government has taken for decades. Indeed, the cloud of uncertainty created by the government's new position provides yet another reason to grant review.

Section 102(e) states that a patent or published patent application qualifies as prior art as of when it was "filed in the United States." 35 U.S.C. § 102(e) (2006). Sections 119(e)(1) and 120, in turn, determine when an application is entitled to an "earlier filing date." Id. 119(e)(1) & 120. They provide that an "application" for patent" for an invention disclosed in an earlier application "shall have the same effect, as to such invention, as though filed on the date of the [earlier] application." Id.¹ This language is not limited to situations in which a patent owner seeks to establish an earlier priority date for its claims in order to avoid intervening prior art. It declares more generally that the later application "shall have the same effect" as if filed earlier. One such "effect" is to put any unclaimed disclosures into the public domain under § 102(e), as of the filing

¹ Section 119(e), which applies in this case, carries back an application's effective filing date to its "provisional application." The parallel provision in § 120 carries the effective filing date back to a "prior application," meaning a non-provisional application. This supplemental brief discusses §§ 119(e) and 120 together because the government's argument applies equally to § 120.

date of the earlier application making those same disclosures. *Cf. Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390, 400-402 (1926).

The government has long shared the understanding that a § 102(e) reference claiming priority to a provisional application is prior art as of the provisional application's filing date under § 119(e)(1). For example, promulgating its first regulations implementing the statute that created provisional applications, the Patent and Trademark Office said:

As long as the requirements of 35 U.S.C. 119(e) are satisfied, a patent granted on a 35 U.S.C. 111(a) application which claimed the benefit of the filing date of a provisional application has a 35 U.S.C. 102(e) prior art effect as of the filing date of the provisional application ...

60 Fed. Reg. 20195, 20206 (Apr. 25, 1995). The PTO similarly said that "for purposes of 35 U.S.C. 102(e), the filing date of the reference patent which has issued on an application entitled to priority from a provisional application under 35 U.S.C. 119(e) is the filing date of the provisional application." Manual of Patent Examining Procedure § 706.02(a) (7th ed. 1998). The PTO also advocated in court for the interpretation it now criticizes, telling the Federal Circuit: "Given the plain language of § 102(e)(2), § 119(e)(1) and § 111(b)(8), in determining a reference's § 102(e) prior art date the USPTO is required to credit a patent reference with a proper claim to an earlier filed provisional application." Brief for the USPTO, In re Giacomini, No. 2009-1400, 2009 U.S. Fed. Cir. Briefs LEXIS 903, at *17 (Fed. Cir. Oct. 23, 2009).

Congress shared the same understanding when it expanded Section 102(e) to make published patent applications prior art. The House Report explained:

Section 405 amends \$102(e) of the Patent Act to treat an application published by the PTO in the same fashion as a patent published by the PTO. Accordingly, a published application is given prior art effect as of its earliest effective U.S. filing date against any subsequently filed U.S. applications.

H. Rep. No. 106-287, at 56 (1999) (emphasis added).

The government's sudden reversal in position upends this settled understanding. It implies that numerous cases were incorrectly decided. It creates asymmetry in the statute that is inconsistent with the principle "one really must be the first inventor in order to be entitled to a patent." *Milburn*, 270 U.S. at 400, 401-402. And it casts a shadow of uncertainty over the whole process of determining the fundamental question of what qualifies as prior art.

All of this strengthens the case for granting the petition. Federal Circuit precedent already rejects the government's view that §§ 119(e)(1) and 120 have no bearing on the effective prior art date of a reference. The government's argument thus depends on this Court concluding that the entire analytical framework applied by the Federal Circuit is wrong. That is not an argument for denying review, but a reason to grant the petition. Allowing the newly created conflict between the government's position and Federal Circuit precedent to fester will create tremendous uncertainty in PTO proceedings, litigation, and board rooms across the country. The better course is to grant and let the government present its theory on the merits, allowing this Court to address in a single case the original question presented and the intertwined issue the government has raised.

II. THE GOVERNMENT'S POSITION ON THE QUESTION PRESENTED IS CIRCULAR AND LARGELY IGNORES THE STATUTORY TEXT

The government's new position on §§ 119(e)(1) and 120 drives its apparent endorsement of the Wertheim and Dynamic Drinkware rule applied by the Federal Circuit in this case. Based on its flawed conclusion that 119(e)(1) and 120 serve only to allow a patent owner to backdate its *claims* and play no role in establishing the date on which unclaimed *disclosures* in the same patent or published application enter the public domain, the government declares that § 119(e)(1) must look exclusively to whether a provisional application provides support for the *claims* in a later-issued patent. U.S. Br. 13. The government then argues that \$119(e)(1)must have nothing to do with determining a \$102(e)reference's filing date because it would be inappropriate to impose "the stringent claim-based requirements set out in Section 119(e)" on the "questions of novelty and public disclosure" addressed by § 102(e). U.S. Br. 14 (emphasis omitted).

That is completely circular. The government is using a cramped conception of \$\$ 119(e)(1) and 120's purpose to artificially narrow those provisions, and then contending that the provisions must have the limited purpose the government supposed because it would make no sense to impose the *Wertheim* and *Dynamic Drinkware* rule on the question of when unclaimed disclosures in a reference qualify as prior art. The government is right on the last point: It makes no sense to require written description support for the *claims* in a patent when the operative question is whether the *disclosures* qualify as prior art as of when they first appeared in an earlier application. Pet. 24-25, 28-31. It makes even less sense to impose such a requirement on a published patent application where the draft claims are preliminary. Pet. 4. Fortunately, that is not what Congress did.

The government's position founders on the plain text of the statute. As discussed, §§ 119(e)(1) and 120's broad language "shall have the same effect" applies as readily to the "effect" of putting a disclosure into the public domain as it does to the "effect" of allowing a patent owner to backdate its claims. *See supra* pp. 2-3. The "earlier filing date" provisions in §§ 119(e)(1) and 120 thus apply to the question of when a reference is deemed "filed" within the meaning of § 102(e).

Other language, which the government ignores, reinforces §§ 119(e)(1) and 120's focus on the continuity of what was *disclosed* rather than simply what was *claimed*. See Pet. 22-24. For example, § 119(e)(1) looks to whether the same "invention" was "*disclosed* in the manner provided by the first paragraph of section 112 ... in a provisional application." 35 U.S.C. § 119(e)(1) (emphasis added). The cross-referenced provision asks whether the earlier application "contain[s] a written *description* of the invention," 35 U.S.C. § 112 (emphasis added). Similarly, § 102(e) focuses on whether "the invention was described"—not claimed—in a published patent application or patent.

Indeed, the government inadvertently reinforces the point when it argues that "as to such invention" in \$\$ 119(e)(1) and 120 "refers to the invention *described* in the provisional and later non-provisional application." U.S. Br. 15 (emphasis added). Exactly so. Consistent with *Milburn* and the plain text of the statute, the focus for purposes of determining the prior art date of a disclosure is on whether the same disclosure appeared in an earlier application, not on what the later application happens to claim.

The government clearly understood this point previously. Seeking rehearing in *Wertheim*, the government noted that the statute "reads 'An application for patent for an invention *disclosed* ...' It does not read 'An application for patent for a *claimed* [or *patented*, or *patentable*] invention disclosed ..." PTO Pet. for Reh'g, *In re Wertheim, reprinted in* 63 J. Patent Off. Soc'y 213, 219 (1981). The government thus criticized the Federal Circuit for "read[ing] into the patent laws limitations and conditions which the legislature has not expressed." *Id.* That is exactly Ariosa's point.

The government's newly minted arguments can be addressed on the merits, but do not eliminate the compelling need to address the question presented and bring clarity to this area of the law.

III. THE AMERICA INVENTS ACT DOES NOT DIMINISH THE URGENT NEED FOR REVIEW

The government's short discussion of the America Invents Act ("AIA") does not change the urgent need to get the law correct now. The government agrees that "the pre-AIA version of the Statute continues to govern a significant number of ongoing patent cases." U.S. Br. 19. Specifically, it governs millions of patents and will apply for at least another 15 years. Reply 7. That is a staggering amount of economic value. Reply 8. Further, although the government labels pre-AIA patents a "closed universe" (U.S. Br. 19), new patents governed by pre-AIA law continue to issue. As late as January 2017, a *majority* of newly issued patents were pre-AIA patents. Reply 7. The proper interpretation of pre-AIA law is thus immensely important.

That alone should be sufficient, but there is more. As explained previously, the AIA relies on \$ 119(e)(1)to determine when a provisional application can be used to establish the prior art date of a disclosure, and the AIA did not substantively change 119(e)(1). Reply 3.² This creates a serious risk that the incorrect interpretation challenged here will infect post-AIA law. Reply 3-7. The government never explains how that problem can be avoided. Moreover, this case arose because the Federal Circuit unthinkingly extended In re Wertheim. 646 F.2d 527 (C.C.P.A. 1981), notwithstanding an intervening statutory change and heavy criticism of the decision. Pet. 10-15. Leaving that rule untouched is an invitation for history to repeat itself. Properly interpreting pre-AIA law is thus not only important in its own right, but critical to ensuring that the flawed rule challenged here does not also skew interpretation of the AIA.

 $^{^2}$ The AIA's reliance on § 119(e)(1) to determine a patent or published application's prior art date rebuts the government's suggestion that conceptually § 102(e) and § 119(e)(1) involve "separate inquiries that serve distinct goals" or that § 119(e)'s language is somehow incompatible with determining the effective prior art date of the disclosures in a patent or published application. U.S. Br. 15.

IV. THE ALTERNATIVE PATH OFFERED BY THE GOVERN-MENT DOES NOT PROVIDE A BASIS FOR DENYING RE-VIEW

Finally, the government suggests there is no need to address the circumstances under which disclosures from a provisional application incorporated into a published patent application qualify as prior art because the "provisional application may *itself* qualify as prior art under Section 102(e)(1)." U.S. Br. 19. The government is talking about the *exact same disclosures* in the provisional application and published application that were the basis of Ariosa's challenge, and it is agreeing with Ariosa that those disclosures should be considered prior art because they predate Illumina's earliest application. The government merely suggests that Ariosa should have listed the provisional application as the prior art reference.

This purported difference is a bit like distinguishing between whether the first runner in a relay race gave the baton to the second runner or whether the second runner received the baton from the first. The substance of what was disclosed and carried forward to the next application is the same; the government is just looking at it from the opposite direction.

More importantly, the government's contention that treating a provisional application as a § 102(e) reference could deprive the question presented of "most if not all of its practical significance" (U.S. Br. 19) is highly speculative, and that is putting it mildly. Section 102(e)(1) refers to "an application for patent, *published under section* 122(b), by another filed in the United States before the invention by the applicant for patent." 35 U.S.C. § 102(e)(1) (emphasis added). Section 122(b) says "[a]n application *shall not be published* if that application is ... (iii) *a provisional application* filed under section 111(b)." *Id.* § 122(b)(2)(A) (emphasis added).

Ariosa appreciates the government's attempt to thread this needle by arguing that a provisional application nonetheless might qualify as being "published." U.S. Br. 15-17. The background principles articulated by this Court in *Milburn* dictate that—as the government and Ariosa are both arguing—the validity of Illumina's patents can be challenged based on the thirdparty disclosure filed in the Patent Office before Illumina's application. Pet. 18-21.

The path the government offers as an alternative, however, is not open in the way the government thinks. The Federal Circuit has treated it as settled that "provisional applications are not themselves prior art under 102(e)(1) because they are not applications published under § 122(b)." Amgen Inc. v. Sanofi, 872 F.3d 1367, 1380 n.5 (Fed. Cir. 2017), cert. denied, 139 S. Ct. 787 (2019); see also Mortgage Grader, Inc. v. Costco Wholesale Corp., 2014 WL 10763261, at *5-6 (C.D. Cal. Oct. 27, 2014) (similar). The PTO itself has also previously rejected the argument it offers here. Ex parte Mok, No. 2007-0841, 2007 WL 1378834, at *1 (B.P.A.I. May 10, 2007) ("The '121 provisional application cannot itself be the basis of the rejection since it was not published as § 102(e) requires."). Accordingly, this Court should not be swayed by the suggestion that parties can simply pursue a different path to reach the same result. Instead, the petition should be granted.

In the alternative, if the Court concludes that the government's alternative path remains viable, the proper course would not be to deny the petition, but to remand in light of the PTO's new position. Ariosa's petition for inter partes review emphasized that "[o]ne of the more relevant prior art references is U.S. Provisional Patent Application 60/180,810, filed Feb. 7, 2000"—i.e., the provisional application incorporated by reference into the published Fan application. C.A.J.A. 123. Ariosa's claim charts, providing a detailed explanation of where the elements of Illumina's claims appear in the prior art, quoted extensively and directly from the provisional application itself. C.A.J.A. 131-142. Although the PTO's view at the time was that a provisional application cannot qualify as a § 102(e) reference, *supra* p. 10, its new position in this Court indicates that the agency would treat the disclosures cited in Ariosa's petition as prior art.

Where an agency changes its position in this manner and then offers that change as a basis for denying review of agency action, basic fairness and sound principles of administrative law dictate that the case should be remanded for consideration under that new rule. See Schmidt v. Espy, 513 U.S. 801 (1994) (mem.) (GVR in light of administrative reinterpretation by agency that had prevailed below); see also Long Island Care at Home, Ltd. v. Coke, 546 U.S. 1147 (2006) (mem.) (GVR based on new Department of Labor advisory); Slekis v. Thomas, 525 U.S. 1098 (1999) (mem.) (GVR based on new Health Care Financing Administration guidance).

The petition should be granted to resolve the important question it presents, but if it is not, the Court should vacate and remand with instructions to return the case to the PTO for the agency to apply its new interpretation and decide whether Illumina's claims are anticipated or rendered obvious by the earlier disclosures in the prior art provisional application.

CONCLUSION

The petition for a writ of certiorari should be granted. If not, the case should be remanded.

Respectfully submitted.

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