

No.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926), this Court held that, regardless of whether a patent claims a particular invention, the description of that invention in the body of the patent creates prior art as soon as the application disclosing the invention is filed, meaning that the disclosure can be used to invalidate any later-filed patent seeking to claim the same invention.

Congress codified and later extended this rule in 35 U.S.C. § 102(e), which provides that an invention “described” in a patent or published patent application is prior art as of its filing date. Congress further provided that where an application claims priority to an even earlier application that “disclosed” the same invention, it “shall have the same effect, as to such invention, as though filed on” the earlier date. 35 U.S.C. §§ 119(e)(1), 120.

The question presented is:

Do unclaimed disclosures in a published patent application and an earlier application it relies on for priority enter the public domain and thus become prior art as of the earlier application’s filing date, or, as the Federal Circuit held, does the prior art date of the disclosures depend on whether the published application also claims subject matter from the earlier application?

CORPORATE DISCLOSURE STATEMENT

Ariosa Diagnostics, Inc. is a wholly-owned subsidiary of Roche Molecular Systems, Inc., which is a wholly-owned subsidiary of Roche Holdings, Inc. and an indirect subsidiary of Roche Holding Ltd. Novartis AG, a publicly held company, owns more than 10% of voting shares of Roche Holding Ltd.

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INTRODUCTION

This case presents a fundamental question of patent law on which the Federal Circuit's controlling precedent conflicts with this Court's decisions and the Patent Act. Almost a century ago, this Court was presented with a basic question: If a patent discloses but does not claim an invention, does that disclosure qualify as prior art as of the date of the application in which it was first made, such that no one else may patent the same invention based on a later-filed application? *See Alexander Milburn Co. v. Davis-Bourmonville Co.*, 270 U.S. 390 (1926). This Court answered in the affirmative, explaining that, in the absence of other evidence, the first applicant's filing with the Patent and Trade-

mark Office shows that the second applicant was “not the first inventor.” *Id.* at 400. This remains true even though claim “amendments might be required,” or the first applicant might file an entirely “new application and a claim ... based on the original description” before obtaining a patent. *Id.* at 401-402.

Congress codified the rule of *Milburn* in 1952, and after providing for the routine publication of patent applications, it extended the same rule to published applications. 35 U.S.C. § 102(e) (2006). It further provided that where such a reference results from a chain of earlier applications, its effective prior art date can be traced back to the earliest application in the chain that “disclosed” the invention. *Id.* §§ 119(e)(1), 120. That should have meant that whenever a patent or published patent application claims priority to an earlier application, any disclosures carried forward from that earlier application are treated as prior art as of the earlier application’s date.

The Federal Circuit and its predecessor, however, have tacked an improper requirement onto the statute and the simple rule announced in *Milburn*. Based on the incorrect premise that the *Milburn* principle applies only if the first-in-time application could have issued as a patent on the day it was filed, the Federal Circuit’s predecessor held that an invention disclosed in a first-in-time patent application is not prior art as of the application date against a later-in-time applicant unless the first application also supports the *claims* of whatever patent issues from the first-in-time application. See *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981).

The addition of this new requirement was wrong—and created a circuit split—on the day *Wertheim* was decided. It has only grown more untenable with time.

In particular, *Wertheim* was based on the rationale that a first-in-time application must provide support for later-issued claims in order to put all its disclosures into the prior art. But that rationale collapsed after Congress amended the statute in 1999 to include published patent applications as prior art—regardless of whether they contain any patentable claims.

Indeed, after 1999, the Patent and Trademark Office effectively stopped applying *Wertheim*. *E.g.*, *Ex parte Robbins*, 2009 WL 3490271 (BPAI Oct. 27, 2009). A leading treatise noted that *Wertheim* “is not correct, and that the decision’s prospects for future survival are not bright.” 2 *Moy’s Walker on Patents* § 8:149 (4th ed.). Senator Kyl likewise observed in 2011 that “*Wertheim* ... was already almost completely overruled.” *See* 157 Cong. Rec. 3422 (2011).

In *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), however, the Federal Circuit unexpectedly revived *Wertheim*. The Patent Trial and Appeal Board decision in this case subsequently extended *Dynamic Drinkware* and *Wertheim* for the first time to published patent applications. App. 18a-19a. This meant that, unless Petitioner showed adequate support for the *unissued and unexamined claims* in a published patent application, Petitioner could not challenge Respondent’s patent based on *disclosures* in that application that traced back to an application filed *before* Respondent’s own application. In other words, Respondent could keep its patent even though it was not the first inventor.

While Petitioner’s case was on appeal, the Federal Circuit endorsed this extension of *Wertheim* and *Dynamic Drinkware* to published patent applications in *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).

But in neither *Dynamic Drinkware* nor *Amgen* did the Federal Circuit ever discuss this Court's decision in *Milburn* or Congress's decision to amend the statute to make published patent applications prior art. The panel in this case thus found itself bound to apply a rule that, with minimal explanation, conflicts with this Court's precedent and both the letter and logic of the statute.

If left in place, the Federal Circuit's rule will shield patents from invalidation even where the same invention was already disclosed to the PTO. It will also create a minefield of uncertainty over what constitutes prior art and increase the complexity of proceedings. For example, it would mean that the effective prior art date of the public disclosure in a published application could shift over time, getting *earlier* as subsequent amendments correct any flaws in the initially published claims. It would also routinely require a trial-within-a-trial on whether collateral, unexamined claims in a published application that may never issue are supported.

There was no petition on this question in *Dynamic Drinkware* or *Amgen* due to other factors, and the Federal Circuit has proved unwilling to meaningfully engage with, let alone correct, the serious flaws in its interpretation. This petition thus provides the first and best opportunity for this Court to correct these substantial aberrations and bring the Federal Circuit's jurisprudence back in line with this Court's precedent and the Patent Act. Unless and until this Court acts, the Federal Circuit's new rule will continue to govern the fundamental question of what constitutes prior art in patent cases across the country. This Court should grant the petition and reverse.

OPINIONS BELOW

The court of appeals' opinion (App. 1a-2a) is unreported but available at 705 F. App'x 1002. The court of appeals' order denying rehearing en banc (App. 21a-22a) is unreported. The final written decision of the Patent Trial and Appeal Board (App. 3a-20a) is unreported but available at 2016 WL 354412.

JURISDICTION

The court of appeals entered judgment on December 11, 2017 (App. 1a-2a), and denied panel rehearing and rehearing en banc on April 12, 2018 (App. 21a-22a). This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

Unless otherwise noted, all references to Title 35 in this petition are to the version in effect prior to the passage of the America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). The appendix reproduces the versions of 35 U.S.C. §§ 102(e), 112, 119, 120, and 122(b) that apply to this case. App. 23a-28a.

STATEMENT

Patents and patent applications do much more than simply claim the subject matter that the inventor seeks to exclude others from practicing. They also serve a teaching function, providing a rich source of disclosures that often go beyond the claimed subject matter to provide relevant background and information on other variants or inventions. For example, a patent or application that includes claims covering a particular use for a particular machine might preface those claims with a lengthy written description that discloses far more, in-

cluding other solutions to the same problem, other ways of using the machine, ways to vary particular parts of the machine, and other details. Accordingly, parties challenging the validity of a patent regularly cite material disclosed in other patents and published applications as prior art to establish that the challenged patent was anticipated or obvious under 35 U.S.C. §§ 102 or 103.

The question in this case relates to the effective prior art date of the disclosures contained in such references. Patents and published applications frequently result from a chain of applications claiming priority to an original application's filing date. Challengers will thus trace material *disclosed* in a reference patent or published application back through the chain to show that an earlier application described the same invention. The dispute in this case centers on whether, as the Federal Circuit held, such a challenger must also trace back the potentially unrelated *claims* in the reference patent or published application being used as prior art to show support for those claims in the earlier applications.

A. Statutory Background

1. *Alexander Milburn*

In *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926), this Court examined whether a challenged patent could be invalidated for lack of novelty in light of the disclosures in a later-issued patent. The Court concluded that the later-issued patent could serve as a prior art reference if its filing date preceded the challenged patent's filing date. In other words, the filing date of the application leading to the reference patent established the effective prior art date of the

disclosures in the reference patent. Relying on the “fundamental rule ... that the patentee must be the first inventor,” *id.* at 402, the Court explained that “one is not the first inventor if ... somebody else has made a complete and adequate description of the thing claimed before the earliest moment to which the alleged inventor can carry his invention back,” *id.* at 400.

The Court concluded that the later-issued patent need not in fact claim the same invention as the challenged patent. All that matters is that the later-issued patent was filed earlier and disclosed the material claimed in the challenged patent. *Milburn*, 270 U.S. at 401. The Court explained that “[t]he question is not whether [the applicant for the prior art patent] showed himself by the description to be the first inventor” because “[i]t is not necessary to show who did invent the thing in order to show that [inventor of the challenged patent] did not.” *Id.* Thus, “[t]he disclosure would have had the same effect” if the reference patent applicant “had added to his description a statement that he did not claim the thing described.” *Id.*

The Court further explained that a person who tries to disclose an invention in an application should not be prevented from creating prior art by “[t]he delays of the patent office.” *Milburn*, 270 U.S. at 401. This did not mean, however, that a patent must be ready to issue on the date the application is filed. Rather, it is sufficient that the applicant “ha[s] taken steps that would make it public as soon as the Patent Office did its work, although, of course, amendments might be required of him before the end could be reached” or the applicant might file an entirely “new application and a claim ... based on the original description” before obtaining a patent. *Id.* at 401-402.

2. Patent Act of 1952

“[I]n 1952, Congress showed its approval of the holding in *Milburn* by adopting 35 U.S.C. § 102(e).” *Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252, 255 (1965); *see also* H.R. Rep. No. 82-1923, at 17 (1952) (“Paragraph (e) is new and enacts the rule of *Milburn*[.]”); Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1 (West 1954), *reprinted in* 75 J. Pat. & Trademark Off. Soc’y 161, 179 (1993) (“Paragraph (e) is new in the statute and enacts the rule of the decision of the Supreme Court in *Alexander Milburn ...*, under which a United States patent disclosing an invention dates from the filing of the application for the purpose of anticipating a later inventor, whether or not the invention is claimed in the patent.”).

The original version of § 102(e) stated that a person is not entitled to a patent if “(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent.” Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792, 797. The Patent Act also provided that, where a chain of earlier applications “described” an invention, a later application shall have “the same effect, as to such invention, as though filed on the date of the prior application.” 35 U.S.C. § 120.

3. *Hazeltine*

The Court reaffirmed and extended *Milburn* in 1965. Specifically, it held that reference patents are prior art as of their filing date not just for purposes of showing that an invention was anticipated under § 102(e) but also for purposes of showing that, in combination with another reference, the challenged patent

was obvious under § 103. *Hazeltine*, 382 U.S. at 254-256. The Court acknowledged that the disclosures in the first-filed application “were secret and not known to the public” at the time the challenged patent was filed. *Id.* at 253. But the Court found “no reason to depart from the plain holding and reasoning in the *Milburn* case” because the first-filer had “done what he could to add his disclosures to the prior art.” *Id.* at 256.

4. “Carried forward” test

Lower courts initially maintained *Milburn*’s focus on what a reference patent discloses—as opposed to what it claims—in determining the effective prior art date of a reference patent resulting from a chain of applications. The D.C. Circuit and the Federal Circuit’s predecessor, the Court of Custom and Patent Appeals (CCPA), applied a “carried forward” or “carried over” test that looked at whether subject matter was described in an application and a patent claiming priority to that application. If so, the disclosure in the patent qualified as prior art as of the date of the earlier application, regardless of whether the disclosure supported the claims of the reference patent.

For example, in *Goodyear Tire & Rubber Co. v. Ladd*, 349 F.2d 710 (D.C. Cir. 1965) (per curiam), the D.C. Circuit held that a reference patent was prior art as of the filing of an earlier application that disclosed the same invention. The D.C. Circuit explained that “as to all subject matter *carried over* into the continuing application from the parent application, the former is entitled to the filing date of the latter.” *Id.* at 711 (emphasis added). The court did not compare the claims of the reference patent to the earlier application.

Similarly, in *In re Klesper*, 397 F.2d 882 (C.C.P.A. 1968), the CCPA relied on the common disclosure in a parent and child application to set the prior art date of a reference patent. It held that because the relevant disclosure was present in both places “[i]t follows that it was carried forward and that the effective date of the patent as a prior art reference” is that of the earlier application. *Id.* at 888. Again, no showing of support for the claims in the reference patent was required.

The CCPA recited the same rule in *In re Lund*, 376 F.2d 982 (C.C.P.A. 1967). The court noted the “incontrovertible” proposition established in *Milburn* “that a *description* of an invention of another in an application filed before an applicant’s date of invention, upon which application a patent is issued, constitutes a bar to the issuance of a valid patent for the same invention.” *Id.* at 988 (emphasis added). The court further explained that “for purposes of ... utilizing the patent disclosure as evidence to defeat another’s right to a patent,” an “application is entitled to the filing date of the parent application as to *all subject matter carried over* into it from the parent application.” *Id.* (emphasis added).¹

5. *Wertheim*

The CCPA changed course—and created a circuit split—in *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981). The CCPA acknowledged that it had previously “embraced” as prior art disclosures that were “carried over” into an issued patent from an earlier application,

¹ Although *Lund* held on the facts before it that the reference patent “ha[d] not carried forward the disclosure” of its parent application, it made clear that if the disclosure relied on “were subject matter that was carried forward into the application that matured into the [reference] patent,” the result would have been different. 376 F.2d at 988, 991.

id. at 536, and that the “determinative question” had been “whether or not the subject matter ... was *disclosed* both in the [earlier] application and in the patent,” *id.* at 534 (emphasis added). But *Wertheim* announced a new rule: A reference patent could not be considered prior art as of an earlier application’s filing date unless that application also provided support for the *claims* of the later-issued patent.

To support its about-face, the *Wertheim* court interpreted this Court’s decision in *Milburn* narrowly and claimed that its earlier approach had “ignored the rationale behind” *Milburn*. 646 F.2d at 536. Citing this Court’s statement about an application issuing “‘but for’ the delays in the Patent Office,” the CCPA declared that “[i]f a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as ‘secret prior art.’” *Id.* at 536-537. *Wertheim* also cited 35 U.S.C. § 120 to argue that, for a reference patent to have been capable of issuing immediately, the invention *claimed* in that patent must have been adequately supported. If not, *Wertheim* reasoned, the application and reference patent might both disclose the invention in the challenged patent, but “the application could not have matured into a patent, within the *Milburn* § 102(e) rationale.” *Id.* at 539.

Wertheim did not address *Milburn*’s statement of the “fundamental rule” that “the patentee must be the first inventor,” *Milburn*, 270 U.S. at 402, or its holding that a reference patent need not claim a disclosed invention to put it into the public domain, *id.* at 401.

6. American Inventors Protection Act of 1999 and subsequent developments

The immediate impact of *Wertheim* was limited due to “several complicating circumstances” that “render[ed] its precedential value suspect.” 2 *Moy’s Walker on Patents* § 8:148 n.15 (4th ed.). In fact, before it was revived in 2015, *Wertheim* was “cited on only a few occasions” for the proposition that an application must support the claims of a reference patent. *Id.*

The American Inventors Protection Act of 1999 contributed to *Wertheim*’s sidelining. Before 1999, patent applications were “kept in confidence” by the PTO unless and until a patent actually issued. *Wertheim*’s concern regarding “secret prior art” thus arose at a time when patent applications could remain secret for years.

That concern was resolved in 1999 when Congress amended 35 U.S.C. § 122 to provide for routine publication of most patent applications “after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought.” Pub. L. No. 106-113, § 4502, 113 Stat. 1501, 1501 A-561 (1999) (codified as amended at 35 U.S.C. § 122(b)). Congress also modified 35 U.S.C. § 102(e) to add another form of prior art: “an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent.” Pub. L. No. 106-113, § 4505, 113 Stat. at 1501 A-565. This opened the door to using the disclosures in a patent application as prior art as of their filing date even if no patent ever issued.

After this legislative change, the PTO recognized that *Wertheim*’s logic had been eroded. For example, in a precedential opinion in *Ex parte Yamaguchi*, 2008 WL 4233306 (BPAI Aug. 29, 2008), the Board of Patent

Appeals and Interferences held that a reference patent was entitled to a prior art date reaching back to the filing date of its underlying provisional application because both documents disclosed the subject matter being used as prior art. *Id.* at *2. The Board noted that, in light of the automatic publication provided for in 35 U.S.C. § 122(b), “*Wertheim*’s ‘secret prior art’ rationale is inapplicable to determining whether the critical reference date of a U.S. Patent or U.S. application publication is the filing date of its underlying provisional application.” *Id.* at *6. Upon automatic publication of a utility patent, “its corresponding provisional application is likewise made available to the public,” *id.*, and this “authenticated disclosure[] constitutes prior art for all that it teaches,” *id.* at *8.

In *Ex parte Robbins*, 2009 WL 3490271 (BPAI Oct. 27, 2009), the Board similarly held that the “reasoning put forth in *Wertheim* is not applicable” because the case involved a published patent application instead of a patent. *Id.* at *4. The Board noted that the “‘but for’ legal fiction upon which *Wertheim* was based does not apply to a patent application which ... was required under 35 U.S.C. § 122(b) to be published after the expiration of a mandated period.” *Id.* “[U]nlike the circumstances in *Wertheim*,” the Board explained, “publication did not entail further action by the patent applicant or the PTO, and, significantly, a patentability determination was not a condition precedent to publication as was the case in *Wertheim*. Consequently, the framework that prevailed prior to enactment of the § 122(b) publication requirement is not logically extended to published patent applications.” *Id.* Because “the published application makes its disclosure and that of any parent applications, available to the public[,] [s]uch disclosure, which necessarily becomes available upon ful-

fillment of the § 122(b) publication requirement, is explicit evidence of the activity of another as of the earliest claimed filing date.” *Id.* Therefore, the Board held, a “published patent application which is statutorily destined to be published constitute[s] prior art for all that it discloses on its earliest filing date.” *Id.*

The legislative history of the Leahy-Smith America Invents Act reflected the same understanding that *Wertheim* was no longer viable. For example, Senator Kyl noted that, as a practical matter, “*Wertheim* ... was already almost completely overruled by the [American Inventors Protection Act] ... which, by making any published application prior art, effectively displaced *Wertheim*’s requirement that the application have been capable of becoming a patent on the day that it was filed.” *See* 157 Cong. Rec. 3422 (2011). He further stated that the PTO’s decisions “confirm this overruling, holding that any application that is ultimately published is prior art as of its filing date, and that provisional applications—which typically cannot become patents as filed—also are prior art.” *Id.*

7. *Dynamic Drinkware*

Notwithstanding these developments, the Federal Circuit revived *Wertheim* in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015). *Dynamic Drinkware* held that in determining the prior art date of a reference patent under 35 U.S.C. § 102(e)(2), such 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 [potential prior art] patent in compliance with § 112, ¶ 1.” *Id.* at 1381 (citing *Wertheim*, 646 F.2d at 537 (emphasis added)); *see also id.* at 1382 (“A provisional application’s effectiveness as

prior art depends on its written description support for the claims of the issued patent of which it was a provisional.”).

Neither party raised the possibility that *Wertheim* might not be good law, and the Federal Circuit never considered *Wertheim*'s viability. Nor did the losing party file a cert petition.

8. Extension of *Dynamic Drinkware*

The Federal Circuit extended *Dynamic Drinkware* and *Wertheim* to published patent applications in *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1380 (Fed. Cir. 2017). The Federal Circuit devoted only a few paragraphs to the issue, and did not discuss *Milburn*, the legislative change in 1999, the intervening PTO precedent, or the widespread criticism of *Wertheim*. *Id.* The losing party on the point, which prevailed on other issues, did not seek further review.

B. Procedural History

Respondent Illumina, Inc. is a life sciences company that concentrates on DNA sequencing and genome analysis. It owns U.S. Patent No. 7,955,794 (the “’794 patent”), which is directed to multiplex methods for determining whether a sample contains at least 100 different target sequences. C.A.J.A. 54-107. The ’794 patent issued on June 7, 2011, and claims priority to several provisional applications, the earliest of which was filed on September 21, 2000. C.A.J.A. 54.

Ariosa Diagnostics, Inc. is a molecular diagnostics company. The Harmony[®] prenatal test that it developed provides a non-invasive way to test for chromosomal abnormalities, reducing the need for invasive

procedures, such as amniocentesis, that can increase the risk of miscarriage.

On July 2, 2014, Ariosa filed a petition for *inter partes* review challenging the '794 patent's validity on three grounds. The Patent Trial and Appeal Board instituted on one of those grounds on January 8, 2015, finding "a reasonable likelihood that [Ariosa] would prevail" in showing that all claims of the '794 patent are anticipated. C.A.J.A. 266.

The prior art reference in the instituted ground was a published patent application, known as the "Fan reference." C.A.J.A. 262. It claimed priority to, and incorporated by reference the disclosure of, U.S. Provisional Application No. 60/180,810 (the "810 application"). C.A.J.A. 1219. A provisional application is an informal application without any claims that is used to establish an early disclosure date for an invention. The '810 application was filed on February 7, 2000, before the earliest possible priority date claimed by Illumina. C.A.J.A. 1460.

Consistent with the PTO's view at the time, Illumina did not initially argue that the '810 application had to provide written description support for the unexamined claims in the Fan reference. But it changed course after the oral hearing in the case when the Federal Circuit issued its opinion in *Dynamic Drinkware*. Ariosa countered that *Dynamic Drinkware* did not extend to published patent applications, such as the Fan reference. C.A.J.A. 714-726.

The Board issued its final written decision on January 7, 2016. App. 3a. In that decision, the Board did not reach the merits of Ariosa's invalidity arguments. Instead, the Board for the first time extended *Dynamic Drinkware* to published patent applications and ruled

that Ariosa “did not meet its burden of persuasion of demonstrating that Fan is prior art” because “it failed to demonstrate that the *claims* of Fan were supported by the disclosure of the ’810 provisional in compliance with 35 U.S.C. § 112, first paragraph.” App. 17a (emphasis added).

On appeal to the Federal Circuit, Ariosa argued that the Board had improperly extended *Dynamic Drinkware* and *Wertheim* to published patent applications. Ariosa C.A. Br. 29-39; Ariosa C.A. Reply Br. 1-10. Ariosa also argued that, to the extent *Dynamic Drinkware* and *Wertheim* were not distinguishable, they should be overruled. Ariosa C.A. Br. 39-41; Ariosa C.A. Reply Br. 10-11.

While Ariosa’s appeal was pending, the Federal Circuit expedited the appeal in *Amgen* and ruled that *Dynamic Drinkware* extends to published patent applications. Illumina told the Federal Circuit panel that “the *Amgen* decision conclusively resolves [Ariosa’s] primary argument on this appeal.” Illumina 28(j) Letter 1, Dkt. 79. On December 11, 2017, the Federal Circuit affirmed in a short opinion that stated, in relevant part, that “the Board did not err in determining that Fan is not prior art.” App. 2a. After the Federal Circuit’s decision, Respondent secured a \$27 million verdict against Petitioner for infringement of the ’794 patent. Dkt. 633, No. 3:12-cv-05501 (N.D. Cal.).

Ariosa petitioned for rehearing en banc, arguing that *Wertheim* and *Dynamic Drinkware* conflict with this Court’s precedent and the Patent Act and should be reversed, not extended to published patent applications. On April 12, 2018, the Federal Circuit denied Ariosa’s petition for rehearing en banc. App. 22a.

In June 2018, the district court held a hearing on Illumina’s motion to exclude Ariosa’s Harmony test from the market. Dkt. 703, No. 3:12-cv-05501 (N.D. Cal.).

REASONS FOR GRANTING THE PETITION

I. THE FEDERAL CIRCUIT’S RULE CONFLICTS WITH THIS COURT’S DECISION IN *MILBURN* AND THE PATENT ACT

A. The Federal Circuit’s Rule Conflicts With This Court’s Decision In *Milburn*

The Federal Circuit’s rule requiring that challengers establish support for the *claims* in a reference patent or published patent application when establishing an earlier prior art date for the material *disclosed* in the reference conflicts with this Court’s decision in *Milburn*.

In *Milburn*, this Court announced a straightforward rule: If a person files a patent application and does not abandon it, the disclosure in any patent that issues from that application qualifies as prior art as of the application’s filing date. 270 U.S. at 400-402. This rule protects the important principle that “one really must be the first inventor in order to be entitled to a patent.” *Id.* at 400.

This Court made clear that it does not matter in this context whether the first-filer ever *claimed* the invention as his or her own. The first-filed application in *Milburn* “did not claim” the subject matter claimed in the challenged patent, but because it “gave a complete and adequate description of the thing patented,” 270 U.S. at 399, the owner of the challenged patent was not free to remove that invention from the public domain. “The disclosure would have had the same effect,” this Court stressed, if the first-filer had added “a statement that he *did not claim* the thing described be-

cause he abandoned it or because he believed it to be old.” *Id.* at 401 (emphasis added). “It is not necessary to show who did invent the thing in order to show that [someone else] did not.” *Id.*

The rule announced in *Wertheim*, applied in *Dynamic Drinkware*, and extended in *Amgen* and this case conflicts with *Milburn*. This Court was explicit that the anticipation inquiry is not about what is claimed in the prior art, but what is disclosed. *Milburn*, 270 U.S. at 402. The focus should therefore remain on whether the prior art reference and the chain of applications leading up to it describe the invention at issue in the challenged patent, not on what the reference being used as prior art claim or fail to claim.

There are many reasons why the claims in a reference patent or published application might be unsupported. The applicant might have made a mistake in drafting the claims, or it might have tried to claim more broadly than it deserved. But the applicant’s failure to perfect its own claims does not diminish the scope of what the applicant’s disclosure teaches or open the door for the owner of the challenged patent to lay claim to that subject matter. *Milburn* stressed the “fundamental rule” that “the patentee must be the first inventor.” 270 U.S. at 402. Where the first filer discloses an invention in an application that later becomes public, the owner of a later-filed patent is not transformed into the first inventor merely because the first filer did not perfect its own claims.

Wertheim and its progeny ignored this central holding in *Milburn*. Worse, *Wertheim* misinterpreted another portion of this Court’s decision to imply that it had no choice but to do so. *Wertheim* declared that “the rationale behind the Supreme Court decisions in *Mil-*

burn and *Hazeltine*” had been that “‘but for’ the delays in the Patent Office, the patent would have issued earlier.” 646 F.2d at 536. *Wertheim* interpreted this to mean that “if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as ‘secret prior art,’ the rationale of *Milburn* being inapplicable.” *Id.* at 537. *Wertheim* then declared that it would “extend the ‘secret prior art’ doctrine of *Milburn* and *Hazeltine* only as far as ... required to do so by the logic of those cases.” *Id.*

Milburn’s discussion of patent office delay, however, focused on the first applicant’s effort “to make his *description* public.” 270 U.S. at 401 (emphasis added). It did not require, as *Wertheim* believed, that a patent theoretically be able to “issue[] the day the application was filed.” *Wertheim*, 646 F.2d at 537. To the contrary, this Court expressly noted that “amendments might be required of [the first applicant] before the end could be reached.” *Milburn*, 270 U.S. at 401. The Court added that there was “no reason” to let someone who filed later “make himself out to be the first inventor when he was not so in fact.” *Id.*

The tension between *Wertheim* and *Milburn* has not gone unnoticed. A leading patent treatise regularly cited by this Court has asked whether *Wertheim* is “consistent with the purposes of the *Milburn* doctrine as codified in Section 102(e)” given that “a major thrust of ... *Milburn* was to uncouple the prior art effect of a reference patent’s disclosure from what it claimed.” *Chisum on Patents* § 3.07. An administrative judge in the PTO put the matter somewhat more bluntly, remarking that “*Wertheim*’s but-for theory does actual violence to *Milburn*’s holding.” *Yamaguchi*, 2008 WL 4233306, at *13 (Torczon, J., concurring).

This is not the first time the Federal Circuit has failed to follow this Court's precedent. As before, the Court should not hesitate to grant a writ of certiorari and bring the Federal Circuit back in line with the principles this Court has articulated.

B. The Federal Circuit's Rule Conflicts With The Patent Act

The Federal Circuit's rule also conflicts with the plain text of the statute, which is no surprise given Congress's intent to codify the principles behind this Court's decision in *Milburn*.

1. Congress provided that a person is not "entitled to a patent" if "the invention was *described in (1) 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) (2006) (emphases added). Further, "[a]n application for patent ... for an *invention disclosed in the manner provided by the first paragraph of section 112 ... in a provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application,*" if the patent application "is filed not later than 12 months after the date on which the provisional application was filed," and the patent application "contains or is amended to contain a specific reference to the provisional application." 35 U.S.C. § 119(e)(1) (2006).²

² The operative language of 35 U.S.C. § 119(e)(1) was taken from § 120, which has long governed claims of priority to a non-provisional application. Section 119(e)(1) is cited here because the earliest priority application for the Fan reference in this case was a provisional application.

A plain reading of the statute’s text indicates that the *description* of an invention in a published patent application that claims priority to an earlier application containing the same disclosure is prior art as of the earlier application’s filing date, regardless of whether the earlier application supports the claims of the published patent application. Section 102(e)(1) provides that a published patent application serves as prior art as of its filing date for any “invention” “described” therein. Section 119(e)(1) then looks to whether the same “invention” was “disclosed in the manner provided by the first paragraph of section 112 in a provisional application”—i.e., whether the earlier application “contain[s] a written *description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same,” 35 U.S.C. § 112, ¶ 1 (2006) (emphasis added). If so, the later application claiming priority to the provisional application “shall have the same effect, as to such invention, as though filed on the date of the provisional application.” *Id.* § 119(e)(1).

The filing date of the provisional application thus establishes the effective prior art date of the disclosure in the reference serving as prior art under § 102(e)(1). Nothing in the plain text of the statute requires that the earlier application also support the unissued *claims* of the published patent application serving as prior art under § 102(e).

The Federal Circuit’s contrary rule requiring support for the claims in a reference patent or application misinterprets the statute. The problem began in *Wertheim* when the Federal Circuit’s predecessor declared that “questions of description, disclosure, ena-

blement, anticipation, and obviousness can only be discussed with reference to a specific claim which identifies ‘the invention’ referred to in the statutes.” 646 F.2d at 538. Respondent similarly argued below that the term “invention” must refer to the claims of a reference patent or application. *Illumina C.A. Br.* 14-19.

This interpretation improperly inserts words into the statute by reading the term “invention” in §§ 102(e)(1) and 119(e)(1) as if those provisions said “claimed invention.” But “invention” is a defined term that simply “means invention or discovery,” 35 U.S.C. § 100 (2006). Neither the definition nor §§ 102(e)(1) and 119(e)(1) uses the term “claimed.”³

Moreover, even if in some contexts “invention” serves as shorthand for a claimed invention, that is not the case when § 119(e)(1) is used to establish an earlier prior art date for a § 102(e) reference. “It is a fundamental canon of statutory construction that the words of a statute must be read in their context[.]” *Davis v. Michigan Dep’t of Treasury*, 489 U.S. 803, 809 (1989). Section 102(e) focuses on whether “the invention was described”—not claimed—in a published patent application or patent. Section 119(e)(1) similarly refers to “an invention disclosed,” not necessarily claimed. And § 119(e)(1) cross-references only paragraph 1 of § 112, which relates to the “description of the invention.” Notably, it does not cross-reference paragraph 2 of § 112, which indicates what must appear in the “claims.”

³ This distinction was later reinforced when the America Invents Act later added a separate definition of “claimed invention.” See 35 U.S.C. § 100(j) (“The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.”).

These repeated references to the disclosure of an invention—“described,” “disclosed,” “description”—are reinforced by this Court’s recognition that an “invention” can be disclosed but not claimed. As noted, one of *Milburn*’s central points was that a patent or application may contain more than one invention: the one “made the basis of a claim” and “[t]he invention made public property” through its disclosure. 270 U.S. at 400-401. This Court similarly noted in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 62 n.10 (1998), 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 confusion of the Federal Circuit and its predecessor appears to stem in part from the fact that § 119(e)(1) and the parallel provision in § 120 are often used by a patent applicant to establish priority for whatever invention is being claimed. For example, the sole authority cited in *Amgen* besides *Dynamic Drinkware* was a Federal Circuit case addressing whether a patent owner could find support for its claims in an earlier application. *See Amgen*, 872 F.3d at 1380 (citing *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)). In that context, if the claimed invention is not described in the earlier application, then the patent owner cannot show that its *claims* are entitled to the same filing date of the earlier application.

But that does not mean other inventions disclosed cannot be traced back to the earlier application and used as prior art. Determining the priority date of claims is fundamentally different from determining the priority date of a disclosure. For example, imagine that Patent 1 claims Invention A and, in the course of its specification, describes both Invention A and Invention

B. If an earlier application in Patent 1's chain of priority discloses only Invention B, the patent owner will not be able to use it to establish an earlier date for the *claims* directed to Invention A, since the earlier application fails to describe Invention A.

The situation is different, however, for someone relying on the disclosure of Invention B as prior art to challenge another patent. In that case, the fact that Invention B is *disclosed* in the earlier application is controlling and, per § 119(e)(1)'s plain words, the later disclosure “shall have the same effect, as to such invention”—i.e., putting the disclosure into the prior art—“as though filed on the date of the provisional application.”

The Federal Circuit's rule improperly engrafts an additional requirement onto this straightforward application of §§ 102(e) and 119(e)(1). Rather than focusing on the common invention “described” and “disclosed” as required by the plain text of the statute, it requires that the earlier application also support whatever invention is claimed in the reference patent or application, even if those claims have nothing to do with the relevant disclosure used to invalidate the challenged patent. Thus, in the hypothetical above, the Federal Circuit would find that, even though the earlier application disclosed Invention B, the reference patent cannot serve to invalidate a later-filed patent on Invention B because the reference patent claims only Invention A. Nothing in the plain language of the statute supports such a perverse result.

2. The conflict between the Federal Circuit's rule and the statute is further crystalized by the fact that Congress adopted § 102(e)(1) to make published patent applications prior art regardless of whether they claim

any patentable invention. This essentially eliminated concerns about “secret prior art” and demolished *Wertheim*’s reasoning that a patent must be capable of issuing to create prior art under § 102(e). One leading patent treatise explained:

There is no guarantee that these published applications will disclose any patentable inventions whatsoever; indeed, it is a statistical certainty that many will not. The fact that all will nevertheless qualify as potential anticipations under paragraph 102(e) suggests strongly that the rationale of ... *Wertheim* ... is not correct, and that the decision’s prospects for future survival are not bright.

2 *Moy’s Walker on Patents* § 8:149 (4th ed.); see also *id.* (“The view that ... *Wertheim II* is wrong ... received a significant boost with the passage of legislation calling for United States applications to be published prior to issuance.”).

The only institution that appears unwilling to acknowledge the impact of this statutory change on *Wertheim* is the Federal Circuit. Before *Dynamic Drinkware*, the PTO recognized that “*Wertheim*’s ‘secret prior art’ rationale is inapplicable ... under the statutory scheme of Title 35 as it exists today.” *Ex parte Yamaguchi*, 2008 WL 4233306, at *6. Similarly, in *Ex parte Robbins*, the PTO said that the “legal fiction upon which *Wertheim* was based does not apply to a [published] patent application.” 2009 WL 3490271, at *4. “[A] patentability determination was not a condition precedent to publication as was the case in *Wertheim*. Consequently, the framework that prevailed prior to enactment of the § 122(b) publication requirement is not logically extended to published patent

applications” and a “published patent application which is statutorily destined to be published constitutes prior art for all that it discloses on its earliest filing date.” *Id.*

Members of Congress have likewise recognized the impact of the statutory change on *Wertheim*. Senator Kyl noted that “*Wertheim* ... was already almost completely overruled” because “making any published application prior art ... effectively displaced *Wertheim*’s requirement that the application have been capable of becoming a patent on the day that it was filed.” See 157 Cong. Rec. 3422 (2011).

The Federal Circuit’s revival of *Wertheim* in *Dynamic Drinkware* and subsequent extension of the decision in both *Amgen* and this case swept aside these contrary views with little or no analysis and in a way that cannot be reconciled with the letter or logic of the statute. This Court has, with some regularity, been required to correct Federal Circuit rules that diverge from the plain text of the statute. The Federal Circuit’s transformation of a statute focused on what was “described” or “disclosed” into a rule focused on what was claimed likewise warrants review.

II. IF NOT REVERSED, THE FEDERAL CIRCUIT’S NEW RULE WILL HAVE SERIOUS NEGATIVE REPERCUSSIONS FOR PATENT LAW

This Court’s review is urgently needed to bring the Federal Circuit back in line with this Court’s precedent and the Patent Act. The Federal Circuit has nationwide jurisdiction over patent cases. Its mistaken revival and extension of *Wertheim* thus governs all proceedings in district court and the PTO, and will continue to do so unless this Court acts.

The question of whether a reference qualifies as prior art under the Federal Circuit’s test is a fundamental and recurring one. At the PTO, for example, the impact of *Dynamic Drinkware* has been felt in a broad range of circumstances, from appeals of examiner’s decisions, to decisions in *inter partes* reviews. *E.g.*, *SPTS Techs. Ltd. v. Plasma-Therm LLC*, 2018 WL 1638321, at *3 (PTAB Apr. 3, 2018); *Ex parte Budagavi*, 2018 WL 1621817, at *2-3 (PTAB Mar. 26, 2018); *Cordelia Lighting, Inc. v. Cooper Lighting, LLC*, 2018 WL 922039, at *5 (PTAB Feb. 14, 2018); *Ex parte Lee*, 2017 WL 1101681, at *4-6 (PTAB Mar. 20, 2017); *Ex parte Bullock*, 2017 WL 657375, at *3 (PTAB Jan. 31, 2017); *Ex parte Mann*, 2016 WL 7487271, at *4 (PTAB Dec. 21, 2016).

The Federal Circuit’s rule means that numerous patents that would otherwise be held invalid will now be allowed to stand even though an earlier application disclosed the same invention or an obvious variant. Such patents, on inventions actually made and disclosed earlier by someone else, unnecessarily stifle competition and innovation without any corresponding benefit to the public. *See Great Atlantic & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950) (“The function of a patent is to add to the sum of useful knowledge. Patents cannot be sustained when, on the contrary, their effect is to subtract from former resources freely available to skilled artisans.”).

The Federal Circuit’s rule also creates prolonged uncertainty about what constitutes prior art. By reviving and extending *Wertheim*, the Federal Circuit has “complicate[d] the task of determining the prior art effect of reference patents and therefore render[ed] even less certain the status of patent rights[.]” *Chisum on Patents* § 3.07 (discussing *Wertheim*). This is because,

under the Federal Circuit’s rule, the prior art status of a disclosure depends on the content of draft patent claims that are subject to amendment.

This creates a paradoxical situation in which public disclosure that is not considered prior art at one point in time can later become prior art as the claims in the reference are amended. Consider a published patent application that discloses Invention X and claims priority to an earlier application that also described Invention X. Under a straightforward reading of the statute, the prior art date of the disclosure of X could be ascertained on the day the application publishes. Under the Federal Circuit’s rule, however, the reference application might initially be denied an earlier prior art date due to some defect in its claims. But if those claims are amended over time until supported by the earlier application, the same disclosure of Invention X would retroactively become prior art as of the provisional application’s filing date. Another inventor who submitted a patent application and was issued a patent for Invention X after the provisional application was filed could thus have a valid patent one day and an invalid one the next.

A leading commentator has observed that “[a]nyone who works with prior art knows that this setup is an oddball way to address the situation. A patent’s disclosure for prior art purposes should not depend upon what was claimed or not but instead should focus on what was disclosed.” Crouch, *Federal Circuit Backtracks (A bit) on Prior Art Status of Provisional Applications and Gives us a Disturbing Result*, <https://patentlyo.com/patent/2015/09/provisional-applications-disturbing.html>; see also *id.* (“The result here is silly—and somewhat disturbing—that under the first-to-invent rule the second inventor gets a patent.”).

The Federal Circuit's rule also complicates patent proceedings by requiring a trial-within-a-trial. This is because even where an invalidating disclosure has clearly been carried forward from one application to the next, courts will now have to determine if the unexamined claims of a published patent application are supported by the earlier application. Worse, some of these proceedings would involve an entirely different invention than the one at issue in the litigation, as a patent is prior art for all inventions it discloses and not just the ones it claims. *See Milburn*, 270 U.S. at 401-402.

For example, imagine that a first-filer discloses both a new dosing regimen for a drug and a new method of manufacturing the drug. Suppose further that the first-filer later files a continuation application with claims directed to the method of manufacture, without purporting to claim the dosing regimen, but ultimately abandons even its manufacturing claims. Under the Federal Circuit's rule, whether the first-filer's disclosure of the dosing regimen serves as prior art to a later filer trying to claim that same dosing regimen would depend entirely on whether the initial application adequately supported the first-filer's unissued claims to the manufacturing method. A proceeding otherwise focused on the infringement and validity of the challenged patent's claims to the dosing regimen could thus morph into a proceeding about the manufacturing method. This could require the court to construe claims from a published application that never issued as a patent, and could require the factfinder to master a whole new set of difficult technical questions. Nothing in this expensive and time-consuming sideshow, however, would alter the fact that the second filer was trying to

establish a monopoly over a dosing regimen that the first filer had already disclosed.

Application of the America Invents Act (AIA) to patents filed on or after March 16, 2013 does not resolve these problems. The comments of Senator Kyl quoted above reflected the understanding, at the time Congress was working on the AIA, that *Wertheim* had been almost completely displaced. Thus, although Senator Kyl evidently thought that *Wertheim* would not apply to post-AIA patents, this was primarily because he thought *Wertheim* had already been displaced for the vast majority of pre-AIA patents as well. 157 Cong. Rec. 3422 (2011). Respondent has not taken a position on *Wertheim*'s application to post-AIA patents, but because the relevant portions of § 119 are unchanged by the AIA, its narrow interpretation of § 119 implies that the *Wertheim* rule would continue to apply when an invalidating disclosure is carried forward from an earlier application.

More importantly, regardless of whether the Federal Circuit's rule applies to post-AIA patents, its impact on the large number of pre-AIA patents that will remain in effect for years to come is significant and warrants review. The PTO issued more than 2 million patents in the 14 years before the AIA took effect. *See* <https://www.uspto.gov/learning-and-resources/ip-motion/millions-patents>. The Federal Circuit's rule governs all of those patents and, at minimum, will continue to shape patent litigation and the economy for a long time. *See supra* p. 28 (citing decisions applying the Federal Circuit's rule years after passage of the AIA). Indeed, in January 2018, Respondent secured a \$27 million verdict against Petitioner for infringement of the '794 patent, and it is now seeking an injunction to force Petitioner's product off the market—all based on a patent

that was shielded from invalidation by the Federal Circuit's erroneous interpretation.

With so much at stake, this Court should not countenance the Federal Circuit's departure from the simple rule it articulated in *Milburn* and that Congress wrote into the Patent Act.

III. THIS CASE IS A GOOD VEHICLE TO REVIEW THE QUESTION PRESENTED

This case is an ideal vehicle to resolve the question presented. This question was fully briefed by the parties before the Board and the Federal Circuit, both at the panel and rehearing stages. For example, the Board acknowledged but rejected Petitioner's argument. App. 18a. On appeal, Petitioner again challenged *Wertheim* and its extension to published patent applications as its lead argument. Ariosa C.A. Br. 29-41; Ariosa C.A. Reply Br. 1-11. In seeking rehearing en banc, Petitioner likewise urged the Federal Circuit to reconsider its "rule that is (1) manifestly inconsistent with *Alexander Milburn* and the Patent Act, and (2) based on decisions that did not even discuss the relevant Supreme Court precedent or the 1999 statutory changes." Ariosa Pet. for Rehearing En Banc 15.

The Federal Circuit's conclusion that the Fan reference is not prior art with respect to the '794 patent was dictated by the precedents that Petitioner challenges, including the *Amgen* case decided shortly before the Federal Circuit heard argument in this case. This would not be the first time this Court has reviewed a short, unpublished opinion by the Federal Circuit that provides an opportunity to address the underlying precedent being applied. See *Icon Health & Fitness, Inc. v. Octane Fitness, LLC*, 496 F. App'x 57

(Fed. Cir. 2012), *rev'd*, 134 S. Ct. 1749 (2014); *Teleflex Inc. v. KSR Int'l Co.*, 119 F. App'x 282 (Fed. Cir. 2005), *rev'd*, 550 U.S. 398 (2007). Indeed, the brevity of the panel's decision only reinforces the extent to which the Federal Circuit is unwilling to revisit its own decisions.

Neither the Board nor the Federal Circuit accepted Petitioner's invitation to resolve the clear conflict between the Federal Circuit's rule and this Court's precedent, the codification of that precedent by Congress, and subsequent changes to the Patent Act that further undermine the rationale of the Federal Circuit's current rule. It therefore falls to this Court to ensure that the law is interpreted correctly. This Court should act promptly before more harm is done. This important issue is ripe for review and warrants this Court's immediate attention.

CONCLUSION

The petition for a writ of certiorari should be granted.⁴

⁴ If the Court remands for application of the correct legal rule, the Board should issue a final written decision on all grounds raised in Ariosa's petition for *inter partes* review. As explained in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018), the statutory "text says only that the Director can decide 'whether' to institute ... not 'whether *and to what extent*' review should proceed." Here, the PTO instituted only one of three grounds presented. For example, it instituted on Ariosa's argument that the Fan reference anticipated Illumina's patent, but not on Ariosa's argument that the Fan reference rendered Illumina's patent obvious. In similar circumstances, the PTO has been expanding the scope of existing proceedings to address all challenged grounds. See https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf. The Federal Circuit has likewise remanded cases to address all grounds raised. *Adidas AG v. Nike, Inc.*, 2018 WL 3213007, at *2 (Fed. Cir. July 2, 2018) (collecting cases).

Respectfully submitted.

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APPENDICES