

Nos. 2016-2388, 2017-1020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

ARIOSIA DIAGNOSTICS, INC.,

Appellant,

v.

ILLUMINA, INC.,

Appellee,

ANDREI IANCU, Director, U.S. Patent and Trademark Office,

Intervenor.

Appeal from the United States Patent and Trademark Office, Patent Trial and
Appeal Board in No. IPR2014-01093

**APPELLANT ARIOSIA DIAGNOSTICS, INC.'S PETITION FOR
REHEARING EN BANC**

ROBERT J. GUNTHER, JR.
WILMER CUTLER PICKERING
HALE AND DORR LLP
250 Greenwich Street
New York, NY 10007
(212) 230-8800

THOMAS G. SAUNDERS
DAVID L. CAVANAUGH
HEATHER M. PETRUZZI
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000

THOMAS G. SPRANKLING
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304
(650) 858-6000

February 9, 2018

CERTIFICATE OF INTEREST

Counsel for Appellant Ariosa Diagnostics, Inc. certifies the following:

1. The full name of every party or *amicus* represented by us is:

Ariosa Diagnostics, Inc.

2. The names of the real party in interest represented by us is:

Ariosa Diagnostics, Inc., Roche Molecular Systems, Inc., Roche Holdings, Inc., Roche Holding Ltd., and F. Hoffman-LaRoche Ltd.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

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.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court (and have not or will not enter an appearance in this case) are:

WILMER CUTLER PICKERING HALE AND DORR LLP: Owen K. Allen, Steven J. Horn, William W. Kim

OBLON, MCCLELLAND, MAIER & NEUSTADT, LLP: Greg Gardella

CONVERGENT LAW GROUP LLP: Dianna L. DeVore

ARIOSIA DIAGNOSTICS, INC.: George Chih-Lun Yu

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

The following pending district court matters, which were consolidated, may be affected by this Court's decision: (1) *Verinata Health, Inc. v. Ariosa*

Diagnostics, Inc., No. 3:12-cv-05501 (N.D. Cal.); (2) *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:14-cv-01921 (N.D. Cal.); and (3) *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:15-cv-02216 (N.D. Cal.).

Dated: February 9, 2018

/s/ Thomas G. Saunders

THOMAS G. SAUNDERS

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decision of the Supreme Court of the United States: *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926).

Based on my professional judgment, I also believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

Where a published patent application carries forward a disclosure from a provisional application, is that disclosure treated as prior art as of the provisional application's filing date?

Dated: February 9, 2018

/s/ Thomas G. Saunders
THOMAS G. SAUNDERS

INTRODUCTION

A century ago, the Supreme 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-Bournonville Co.*, 270 U.S. 390 (1926). The Supreme Court answered in the affirmative, explaining that, in the absence of other evidence, the first applicant's filing with the Patent and Trademark 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 *Alexander Milburn* in 1952, and later applied it to published patent applications, in which there is often no claim which has been examined and is ready to issue. That should have meant that where a published patent application and an earlier application to which it claims priority both disclose an invention, the earlier application establishes the effective prior art date for that disclosure—irrespective of what the unexamined claims in the published application recite. Indeed, that is how the PTO itself understood the law before this case.

This Court and its predecessor, however, have tacked an improper requirement onto the statute and the simple rule announced in *Alexander Milburn*. Based on the incorrect premise that the *Alexander Milburn* principle applies only if the first application could have issued as a patent on the day it was filed, this Court’s predecessor held that an invention disclosed in an issued patent and an earlier application is not prior art as of the application date unless the application also supports the *claims* of the issued patent. *See In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981). In two recent cases, panels of this Court revived this requirement and extended it to published patent applications. Worse, they did so without any discussion of *Alexander Milburn*, Congress’s decision to amend the statute to make

published patent applications prior art, or even the fact that the unexamined claims of a published application are likely to change. The panel in this case thus found itself bound to apply a rule that, with minimal explanation, conflicts with Supreme Court precedent and both the letter and logic of the statute.

If left in place, the extended *Wertheim* rule will create a minefield of uncertainty over what constitutes prior art, increase the complexity of proceedings, and shield patents from invalidation even where the same invention was already disclosed to the PTO. 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 amendments corrected any flaws in the initially published claims. It also would routinely require a trial-within-a-trial on whether collateral, unexamined claims in a published application that may never issue are supported under 35 U.S.C. § 112.

This petition provides the first and best opportunity for this Court to revisit its decisions, correct these substantial aberrations, and bring its jurisprudence back in line with Supreme Court precedent and the Patent Act.

BACKGROUND

Appellant Ariosa Diagnostics, Inc. is a molecular diagnostics company, which creates non-invasive blood tests for pregnant women to inform them of the risk that their fetus has a genetic disorder. In July 2014, Ariosa filed a petition for

inter partes review challenging one of Appellee Illumina, Inc.’s patents related to genetic testing. *See* U.S. Patent No. 7,955,794 (“’794 Patent”).

Ariosa’s petition argued, *inter alia*, that the ’794 Patent’s claims were anticipated by U.S. Published Application 2002/0172946 (“Fan Reference”). The Fan Reference claimed priority to, and incorporated by reference the disclosure of, a provisional application filed on February 7, 2000, which was before the ’794 Patent’s earliest claimed priority date. Ariosa Opening Br. 17-20.

The Patent Trial and Appeal Board instituted proceedings, explaining that the disclosure in the Fan Reference and the underlying provisional application “established a reasonable likelihood that [Ariosa] would prevail” in showing all claims of the ’794 Patent were anticipated. Ariosa Opening Br. 21. After briefing was completed, this Court issued *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), which revived an anticipation rule announced over three decades earlier in *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981). Specifically, *Dynamic Drinkware* held that in determining the prior art date of the disclosures in a patent under 35 U.S.C. §§ 102(e)(2) and 120, 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’s written description requirement. 800 F.3d at 1381.

The Board’s final written decision in this case extended *Dynamic Drinkware* to published patent applications, and ruled that Ariosa had failed to demonstrate the Fan Reference was prior art because “it failed to demonstrate that the *claims* of Fan were supported by the disclosure of the ... provisional [application].” Ariosa Opening Br. 23-24 (emphasis added). While this appeal was pending, this Court adopted the same rule with minimal discussion in *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017). Bound by that precedent, the panel affirmed the Board’s decision in this case.¹

ARGUMENT

I. **WERTHEIM WAS FLAWED FROM THE OUTSET AND CONFLICTS WITH BINDING SUPREME COURT PRECEDENT**

In *Alexander Milburn*, the Supreme 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. It does not matter in this context whether the first-filer ever claimed the invention as his or her own, as “it is not necessary to show who did invent the thing in order to show that [someone else] did not.” 270 U.S. at 401. Nor does it matter that “amendments might be required” or that the applicant might later file an entirely “new application and a claim ... based on the original description.”

¹ The party that lost on the § 102(e) issue in *Amgen* prevailed on other points and did not petition for rehearing. This petition thus presents the first opportunity to review the new rule that *Amgen* adopted for published applications.

Id. at 401-402. As long as the invalidating disclosure was filed with the PTO and later became public, that disclosure is prior art for all that it teaches as of the date it was originally filed.

Congress codified *Alexander Milburn* in the Patent Act of 1952. H.R. Rep. No. 82-1923, at 17 (1952) (“Paragraph (e) is new and enacts the rule of *Milburn*[.]”); accord S. Rep. No. 82-1979, at 17 (1952). Under § 102(e), a person is not entitled to a patent if “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 (codified as 35 U.S.C. § 102(e)). In the years that followed, it was “well settled that where a patent purports on its face to be a ‘continuation-in-part’ of a prior application, the continuation-in-part application is entitled to the filing date of the parent application as *to all subject matter carried over* into it from the parent application.” *In re Klesper*, 397 F.2d 882, 885 (C.C.P.A. 1968) (emphasis added); see also *In re Lund*, 376 F.2d 982, 988 (C.C.P.A. 1967). This rule expressly applied when “utilizing the patent disclosure as evidence to defeat another’s right to a patent.” *Klesper*, 397 F.2d at 885.

This Court’s predecessor, however, took a doctrinal wrong turn *In re Wertheim*, 646 F.2d 527 (C.C.P.A. 1981). *Wertheim* engrafted a new rule, limiting the *Alexander Milburn* principle to situations in which a patent could “theoretically

have issued the day the application was filed.” *Id.* at 537; *id.* at 539 (application sets priority date only if the requested patent would have issued on the date filed “*but for the delays of*” the PTO” (emphasis added)). Under *Wertheim*, a reference patent is considered prior art as of the filing date of an unpublished patent application only if that application, in addition to disclosing the relevant invention being anticipated, provides written description support for the *claims* of the later-issued patent. *Id.* at 536.

Wertheim was wrong when it was decided. Its requirement that a patent theoretically be able to issue as soon as an application is filed conflicts with *Alexander Milburn*, which imposes no such rule. See, e.g., *Ex Parte Yamaguchi*, 2008 WL 4233306, at *13 (B.P.A.I. Aug. 29, 2008) (Torczon, A.P.J., concurring) (“*Wertheim*’s but-for theory does actual violence to *Milburn*’s holding.”); *supra* pp. 5-6. The Chisum treatise asks 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 (2017). Another leading patent treatise explains that *Wertheim* “has been criticized by commentators, and has not been applied broadly by later courts.” Moy, *Walker on Patents* § 8:148 (2017) (footnotes omitted).

In fact, *Wertheim* created a circuit split when it was decided, as it diverged from other courts' understanding of the *Alexander Milburn* rule. *See, e.g., Goodyear Tire & Rubber Co. v. Ladd*, 349 F.2d 710, 711 (D.C. Cir. 1964) (per curiam) (“[A]s 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.” (emphasis added)).²

Wertheim's deviation from *Alexander Milburn* cannot be justified as an interpretation of the Patent Act's priority provisions. *See* 35 U.S.C. §§ 119-120; *see also Wertheim*, 646 F.2d at 537. The logic of *Alexander Milburn* applies as readily to a chain of applications as to a single application. *See Alexander Milburn*, 270 U.S. at 401-402. Moreover, Illumina got the inquiry exactly backwards when it argued in its panel briefing that “nothing in *Alexander Milburn* ... preempts or nullifies” the Patent Act's provisions. Illumina Br. 22. The right

² More evidence that *Alexander Milburn*'s rule is intuitively correct comes from several of this Court's post-*Wertheim* decisions that have seemingly followed *Alexander Milburn*, albeit without significant discussion. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1367 (Fed. Cir. 2001) (noting that it is “logical ... to claim priority” to a parent application “even if the claims ... are not entitled to the earlier priority date” because “a claim to priority to an earlier patent strengthens the offensive value of a later patent, because, *for disclosures common to both documents*, the later patent will be effective as prior art as of the filing date of the earlier patent.” (emphasis added)); *see also Apple Inc. v. ITC*, 725 F.3d 1356, 1361 (Fed. Cir. 2013) (affirming finding that Perski '455 was prior art under § 102(e) because it claimed priority to a provisional application that “provides written description support for the *disclosure* in Perski '455” (emphasis added)).

question is whether the priority statute demonstrates a clear intent to deviate from the *Alexander Milburn* rule. *E.g.*, Scalia & Garner, *Reading Law* 318 (2012); *see also TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017) (“When Congress intends to effect a change of that kind, it ordinarily provides a relatively clear indication of its intent in the text of the amended provision.”); *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954, 963 (2017).

The language of § 119(e)(1) gives no such sign, and in fact points in the opposite direction. It states that an application “for an invention disclosed in the manner provided by section 112(a) ... in a provisional application ... shall have the same effect, as to such invention, as though filed on the date of the provisional application,” provided that the patent application includes specific reference to the provisional and is filed within a year after the provisional. This language is entirely consistent with *Alexander Milburn*. When a published patent application is being used *as prior art*, the relevant “effect, as to such invention” is to put an “[i]nvention”—i.e., a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” 35 U.S.C. § 101—into the public domain by disclosing it. *See generally* Reply Br. 2-5. The question under § 119(e)(1) in that circumstance is whether the invalidating *disclosure* in the published application—as opposed to whatever it claims—is

supported by the provisional application. If so, the published application puts the disclosed invention into the prior art (i.e., has “the same effect, as to such invention”) as of “the date of the provisional application.”

This contrasts with the situation in which a patent owner is trying to establish an earlier priority date of invention for a particular claim. To determine whether a *claimed* invention receives the benefit of an earlier priority date, it is, of course, necessary to compare the claim to the priority application. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). But no such showing is required when a published application or patent is being used as prior art and the invalidating disclosure is the relevant “invention” under § 119(e)(1). This does not give two different meanings to the word “invention.” It merely recognizes, as *Alexander Milburn* did, 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. *Wertheim*’s deviation from *Alexander Milburn* was unjustified.

II. PANELS OF THIS COURT COMPOUNDED THE ERROR BY REVIVING WERTHEIM AND EXTENDING IT TO PUBLISHED PATENT APPLICATIONS

A. *Wertheim*’s Rationale Did Not Survive The 1999 Amendments To The Patent Act

Even if *Wertheim* was not flawed at the outset, its rationale imploded in the wake of later amendments to the Patent Act. *Wertheim*’s “but for” rule arose from

a policy concern about “‘secret prior art.’” 646 F.2d at 537. Although *Wertheim* was still in tension with *Alexander Milburn*, this concern arguably might have made some sense in 1981, when patent applications were kept secret by the PTO unless a patent actually issued. But the law changed in 1999, when Congress altered the Patent Act to provide that (1) most patent applications would be published within 18 months of filing and (2) a published patent application would constitute prior art under § 102(e). See Pub. L. No. 106-113, §§ 4502, 4505, 113 Stat. 1501, 1501A-561, -565 (1999).

These changes obviated *Wertheim*'s rationale. At that point, there was no longer a realistic risk that would-be inventors might be unaware, for years at a time, of inventions already disclosed in pending applications. As the PTO later explained, “the ‘but for’ legal fiction upon which *Wertheim* was based does not apply to a patent application which ... was required ... to be published after the expiration of a mandated period.” *Ex Parte Robbins*, 2009 WL 3490271, at *4 (B.P.A.I. Oct. 27, 2009); see also 157 Cong. Rec. S1369 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (“*Wertheim* ... was already almost completely overruled by the [1999 amendments] ... 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.”).³ The same is true when a published application claims priority to a provisional application, since upon publication of a utility patent application, “its corresponding provisional application is likewise made available to the public.” *Yamaguchi*, 2008 WL 4233306, at *6 (majority op.). The “provisional application ... provides a self-authenticating instrument establishing a date of disclosure for the subject matter contained within” and shows that “the applicant was in possession of the subject matter disclosed in the provisional application when it was filed.” *Id.* at *7.

B. Panels Of This Court Revived and Extended *Wertheim* With Minimal Discussion

Without considering the erosion of *Wertheim*, this Court revived its dubious rule in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed.

³ Senator Kyl’s comment reflected the understanding, at the time Congress was working on the American Invents Act (“AIA”), that *Wertheim* had been almost completely displaced. Since reviving *Wertheim*, this Court has not decided whether the *Wertheim* rule applies to patents governed by the AIA. *E.g.*, *Dynamic Drinkware*, 800 F.3d at 1381 n.2. Although Senator Kyl evidently thought that *Wertheim* would not apply to such 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. S1369 (daily ed. Mar. 8, 2011). Illumina has not taken a position on *Wertheim*’s application to post-AIA patents, but its narrow interpretation of § 119 (the relevant portions of which are unchanged by the AIA) seems to imply that the *Wertheim* rule would continue to apply when an invalidating disclosure is carried forward from a provisional application to a non-provisional application. *See* Illumina Br. 26. In any event, regardless of whether *Wertheim* 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 en banc review.

Cir. 2015). No party in *Dynamic Drinkware* alerted this Court to the intervening change in the statute and its impact on *Wertheim*'s rationale.

The PTO decision in this case and the panel decision in *Amgen v. Sanofi* then compounded the problem by extending *Dynamic Drinkware* to published patent applications—with minimal discussion. Appx15-16; *Amgen*, 872 F.3d at 1380. Accordingly, even though the published application in this case carried forward and incorporated by reference an invalidating disclosure from the provisional application to which it claimed priority, that disclosure was not treated as prior art as of the provisional application's filing date because the showing of written description support for the unprosecuted *claims* in the published application was deemed insufficient. This result cannot be squared with the logic of the 1999 amendments to the statute, which “suggest[] strongly that ... *Wertheim* ... is not correct and that the decision's prospects for future survival are not bright.” Moy, *Walker on Patents* § 8:149.

III. THE RULE APPLIED IN THIS CASE WILL HAVE FAR-REACHING, NEGATIVE PRACTICAL CONSEQUENCES

The revival and extension of such a flawed rule has and will continue to have a substantial, detrimental impact on patent litigation across the country.

First, it creates prolonged uncertainty about what constitutes prior art. *See Chisum on Patents* § 3.07 (*Wertheim* “clearly complicates the task of determining the prior art effect of reference patents and therefore renders even less certain the

status of patent rights[.]”). For example, a provisional patent application that discloses invention X would not establish an effective prior art date—even if the inventor then filed a non-provisional application that carried forward the same disclosure—if the published claims in the non-provisional application were too broad to be fully supported by the provisional. If, however, the patent application was amended over time to the point that its claims were supported by the provisional application and became an issued patent, the 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.

Second, the *Wertheim* rule increases the complexity of proceedings. Even where an invalidating disclosure has clearly been carried forward, courts would be forced to hold a trial-within-a-trial to determine whether the unexamined claims of a published patent application are supported by a provisional 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 Alexander Milburn*, 270 U.S. at 401-402.

For example, imagine person A files a provisional application that claims invention X but also discloses invention Y, and the disclosure of both X and Y

becomes public when a non-provisional patent application that incorporates the provisional application by reference publishes. Now imagine that person B files an application for invention Y between person A's provisional application and the publication of person A's patent application. A court considering whether person B's later-filed patent application for invention Y was novel could not simply compare person A's disclosure of invention Y to person B's claim to invention Y. Instead, the court would first have to construe the claim to X in person A's patent application and then analyze whether X was adequately supported in the provisional application. This would greatly complicate proceedings and generate unnecessary appeals on collateral claim construction and § 112 questions.

* * *

This Court has inadvertently painted itself into a corner. Panels are now bound by a counterproductive 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. The en banc Court should grant review and conform its case law to Supreme Court precedent and the statute.

CONCLUSION

For the foregoing reasons, rehearing en banc should be granted.

Respectfully submitted,

ROBERT J. GUNTHER, JR.
WILMER CUTLER PICKERING
HALE AND DORR LLP
250 Greenwich Street
New York, NY 10007
(212) 230-8800

/s/ Thomas G. Saunders
THOMAS G. SAUNDERS
DAVID L. CAVANAUGH
HEATHER M. PETRUZZI
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000

THOMAS G. SPRANKLING
WILMER CUTLER PICKERING
HALE AND DORR LLP
950 Page Mill Road
Palo Alto, CA 94304
(650) 858-6000

*Attorneys for Appellant Ariosa
Diagnostics, Inc.*

February 9, 2018

ADDENDUM

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

ARIOSIA DIAGNOSTICS, INC.,
Appellant

v.

ILLUMINA, INC.,
Appellee

**JOSEPH MATAL, PERFORMING THE FUNCTIONS
AND DUTIES OF THE UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR, U.S. PATENT AND TRADEMARK
OFFICE,**
Intervenor

2016-2388, 2017-1020

Appeals from the United States Patent and Trade-
mark Office, Patent Trial and Appeal Board in No.
IPR2014-01093.

Decided: December 11, 2017

THOMAS SAUNDERS, Wilmer Cutler Pickering Hale and
Dorr LLP, Washington, DC, argued for appellant. Also
represented by JOSHUA LLOYD STERN, DAVID LANGDON

CAVANAUGH, JOSHUA KOPPEL, HEATHER M. PETRUZZI;
ROBERT J. GUNTHER, JR., New York, NY.

EDWARD R. REINES, Weil, Gotshal & Manges LLP,
Redwood Shores, CA, argued for appellee. Also repre-
sented by DEREK C. WALTER.

BENJAMIN T. HICKMAN, Office of the Solicitor, United
States Patent and Trademark Office, Alexandria, VA,
argued for intervenor. Also represented by NATHAN K.
KELLEY, MICHAEL SUMNER FORMAN, THOMAS W. KRAUSE,
SCOTT WEIDENFELLER.

Before MOORE, BRYSON, and HUGHES, *Circuit Judges*.

MOORE, *Circuit Judge*.

Ariosa appeals the Patent Trial and Appeal Board's ("Board") inter partes review decision holding claims 1–22 of U.S. Patent No. 7,955,794 were not anticipated by U.S. Patent Publication No. 2002/0172946 ("Fan") because Fan was not prior art. Because the Board did not err in determining that Fan is not prior art and did not abuse its discretion in denying Ariosa's request for rehearing, we *affirm* the Board's decision. Because we lack jurisdiction to review the termination of the ex parte reexamination proceedings, we *dismiss* the appeal of the termination of those proceedings.

AFFIRMED IN PART AND DISMISSED IN PART

COSTS

No costs.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Circuit Rule 32(a).

1. The petition complies with the type-volume limitations of F. R. App. P. 40(b) and 35(b), and the Rules of this Court applicable to cases docketed between April 1, 2016 and November 30, 2016, because the petition does not exceed 15 double-spaced pages.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Thomas G. Saunders
THOMAS G. SAUNDERS
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000

February 9, 2018

CERTIFICATE OF SERVICE

I hereby certify that, on this 9th day of February, 2018 I filed the foregoing document with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Thomas G. Saunders
THOMAS G. SAUNDERS
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000