Appeal Nos. 2018-2198, -2303, -2305, -2306, -2317

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

VERINATA HEALTH, INC., ILLUMINA, INC.,

Plaintiffs-Appellants,

v.

ARIOSA DIAGNOSTICS, INC., ROCHE MOLECULAR SYSTEMS, INC.,

Defendants – Cross-Appellants.

Appeal from the United States District Court for the Northern District of California, Case Nos. 3:12-cv-05501-SI, 3:14-cv-01921-SI, and 3:15-cv-02216-SI, Judge Susan Illston

ILLUMINA, INC.'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

NON-CONFIDENTIAL

Edward R. Reines
Derek C. Walter
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Zachary D. Tripp
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW
Washington, DC 20036
(202) 682-7220

Counsel for Illumina, Inc.

May 22, 2020

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Illumina, Inc. and Verinata Health, Inc. certify as follows:

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

   Illumina, Inc.
   Verinata Health, Inc.

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

   Illumina, Inc.
   Verinata Health, Inc.

3. All parent corporations and any public companies that own 10 percent or more of the stock of the parties represented by us are:

   Formerly known as Artemis, Health, Inc., Verinata Health, Inc., is a wholly owned subsidiary of Illumina, Inc. Illumina, Inc. is traded under the symbol "ILMN."

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or are expected to appear in this Court are:

   Weil, Gotshal & Manges LLP

   Edward R. Reines
   Derek C. Walter
   Zachary D. Tripp
   Christopher J. Cox*
   Christopher S. Lavin
   Hannah L. Jones*
   Michele A. Gauger*
   Aaron Y. Huang*
   Anant N. Pradhan*
   Sonal N. Mehta*

* No longer with firm

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. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary.)

Verinata Health, Inc. v. Ariosa Diagnostics Inc., No. 3:12-cv-05501-SI (N.D. Cal.)
Illumina, Inc. v. Ariosa Diagnostics Inc., No. 3:14-cv-01921-SI (N.D. Cal.)
Illumina, Inc. v. Ariosa Diagnostics Inc., No. 3:15-cv-02216-SI (N.D. Cal.)

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CONFIDENTIAL MATERIAL OMITTED

- The material deleted from pgs. 1, 3, 6, 7, 15 and 18 of this brief includes information regarding Roche's marketing strategy that Roche has designated as confidential.
- The material deleted from pgs. 13 and 14 of this brief includes information regarding Illumina's third-party customers and customer relationships that Illumina has designated as confidential.

TABLE OF AUTHORITIES

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FEDERAL CASES

STATUTES

TABLE OF ABBREVIATIONS AND CONVENTIONS

’794 Patent	U.S. Patent No. 7,955,794
AcfS	Ariosa Cell-Free DNA System
Ariosa	Ariosa Diagnostics, Inc.
DANSR	Digital Analysis of Selected Regions
DNA	deoxyribonucleic acid
Harmony V1	Harmony Version 1
Harmony V2	Harmony Version 2
Illumina	Illumina, Inc.
NIPT	non-invasive prenatal technology
Roche	Roche Molecular Systems, Inc. and Roche Sequencing Systems, Inc.
Verinata	Verinata Health, Inc.

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions: *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006); *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405 (1908).

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting questions of exceptional importance:

1. Whether it is a sufficient basis for denying a permanent injunction that the infringer directly competes with third parties that license completely different patents from the patentholder.

2. Whether the panel improperly affirmed the denial of a permanent injunction where uncontradicted evidence proves:

- the patentholder and infringer view each other as competitors;
- the infringer has never licensed the patent-at-suit;
- the infringer previously purchased from the patentholder before it created an infringing substitute;
- infringing competition decreases demand for the patentholder's products and has caused the patentholder's customers to negotiate lower [redacted]
- the infringer's marketing undercuts the patentholder's brand; and
- the infringer [redacted] to [redacted] a product that would further compete in the patentholder's primary market through infringement.

Dated: May 22, 2020

/s/ Edward R. Reines
Attorney of Record for Appellant Illumina, Inc.

CONFIDENTIAL MATERIAL HAS BEEN REDACTED

INTRODUCTION

This case is an excellent vehicle to correct a reflexive anti-injunction impulse by courts in the wake of *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006). Plaintiff-Appellant Illumina, Inc. respectfully asks this Court to grant en banc review to vindicate permanent injunctions as a critical tool to prevent irreparable harm caused by ongoing infringement of important patent rights.

Reflecting that a patent is a right to exclude, permanent injunctions issued in the vast majority of patent cases for nearly 200 years. *See Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405 (1908). In *eBay*, the Supreme Court made clear that this does not mean there is a general rule that injunctions *must* be granted every time infringement is found; each case requires application of the traditional four-factor test. But seven Justices found historical practice instructive, see *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring); *id.* (Kennedy, J., concurring), and the Supreme Court reaffirmed that injunctions cannot be denied based on simplistic shortcuts.

The pendulum has now swung too far back in the other direction, with courts taking shortcuts to deny injunctive relief—even in cases involving sophisticated, publicly-traded companies in the same sector (here, biotechnology). In a few quick paragraphs, the panel affirmed the denial of an injunction by determining that there is direct competition between the infringer and the patentholder's "licensees." But

that focus is myopic and misplaced. There is competition *both* between the infringer and the "licensees" *and* between the infringer and the patentholder—and the latter competition causes irreparable harm for which a per-test royalty is no substitute. Indeed, the so-called "licensees" do not even license the patent-at-suit. They purchased Illumina products bundled with rights to use them to perform specific fetal genetic *tests*. The patent here (U.S. Patent No. 7,955,794) is a general-purpose assay used in a testing *platform*. Illumina has never licensed the'794 Patent to allow another company to create a home-brew substitute for Illumina's products.

Without a misplaced focus, this case is easy. Illumina and the infringer (Ariosa Diagnostics Inc., now owned by Roche Molecular Systems, Inc.) are major practicing biotechnology companies that identify each other as competitors. And although the parties have somewhat different business models—Illumina primarily markets testing platforms whereas Ariosa/Roche primarily markets a send-away genetic test—they are still competitors and Roche's infringement irreparably harms Illumina: (1) Ariosa initially purchased Illumina's assays before creating a knockoff; (2) Ariosa/Roche's infringement has caused Illumina customers to negotiate lower prices, because Ariosa/Roche's send-away test is a market substitute for those same customers running a test in-house on an Illumina platform; (3) Roche's marketing is harming Illumina's brand position as a thought leader; and (4) Roche has [redacted] to [redacted] a new product ("AcfS") that

would further compete with Illumina by allowing purchasers to run the infringing test in-house. There is no sound basis for denying Illumina an injunction, and the panel's cursory ruling to the contrary warrants rehearing.

BACKGROUND

A. Illumina And The '794 Patent

Illumina develops and sells DNA sequencers, microarrays, and other platforms for genetic testing, as well as reagents and other products to support them. One use of those platforms is for non-invasive fetal genetic testing, known as non-invasive prenatal technology ("NIPT"). NIPT testing allows safe and accurate detection of fetal genetic abnormalities through a mere blood test. Once a sample from a pregnant woman is taken: (1) a clinical lab (like LabCorp) or a provider (like Kaiser) can test it in-house; or (2) the sample can be sent away to a NIPT company, which tests the sample then returns the results.

Because Illumina is a leader in testing platforms, the more NIPT testing that is done, the bigger the demand for Illumina products. There was a barrier to widespread adoption of NIPT testing, however: Early NIPT providers were in patent litigation with each other. Illumina Op. Br. 9-10. Illumina responded by investing $400 million in intellectual property, grouping NIPT testing patents into a package and enabling customers of Illumina products to practice those patents on the Illumina

platform. *Id.* That investment was wildly successful: at least 80 different companies now offer NIPT tests on Illumina's sequencers. *Id.* at 10.

B. Ariosa/Roche And The Infringement

Defendant Ariosa (now owned by Roche) markets a NIPT test called "Harmony V2," using the send-away test business model. Like every other NIPT test in evidence, Ariosa initially used Illumina sequencers to run the Harmony test. See Roche Op. Br. 73. When originally developing its Harmony product, Ariosa purchased "Golden Gate" assays from Illumina. Illumina Op. Br. 11-12. For its released product, however, Ariosa made a knock-off assay called "DANSR." *Id.*

The problem for Ariosa is that using DANSR to run the Harmony V2 test infringes Illumina's patents practiced by the Golden Gate assay. Op. 3. Specifically, the jury found infringement of the '794 Patent, which is for a method of "detection of DNA target sequences by introducing probes with complementary sequences into a sample and observing whether hybridization occurs." *Id.*

Notably, the '794 Patent is not a patent for a NIPT test and the right to use it is not included in Illumina's NIPT licensing package. It is a general-purpose method for DNA testing. Illumina has never granted a license to the '794 Patent to allow another company to create a home-brew version of the Golden Gate assay. Appx01457 [Trial Tr. (1/10/18)] at 457:15-20; *see* Appx10021 [Eidel Decl.] ¶ 4.

C. Procedural History

Illumina brought an infringement action against Ariosa. After a two-week trial, the jury found that Harmony V2 infringes the'794 Patent; that the patent was not invalid; and awarded $27 million in damages. Op. 10.[2] Illumina moved for a permanent injunction. Among other things, Illumina introduced evidence showing:

- Roche is continuing to infringe and has not announced plans for a design-around to halt infringement;
- Illumina and Roche identify each other as competitors, see Appx10363 [redacted] Appx10021 [Eidel Decl.] ¶¶ 4-5, and Roche seeks to "[redacted] [the] [redacted]," Appx10355-10356.
- Illumina has never licensed the '794 Patent to allow another company to make a home-grown substitute for Illumina's own products, Appx10021 [Eidel Decl.] ¶ 4.
- Ariosa purchased Golden Gate assays from Illumina until it developed the infringing DANSR assay as a substitute, *see* p.5, *supra*;
- Sales of Harmony V2 undercut Illumina's market by (1) reducing demand for clinical labs or providers to purchase Illumina's sequencers, because a low-price send-away test is a market substitute for purchasing Illumina equipment to run the test in house; and (2) unlike virtually all other send-away labs, which run on Illumina products, Roche's send-away lab avoids doing so by infringing Illumina's Patents, Appx10023 [Eidel Decl.] ¶ 9; *see also* Appx10024-10025 ¶ 12 (identifying customers that negotiated lower [redacted] in response).

[2] The jury also found that the first version ("Harmony V1") infringed U.S. Patent No. 8,318,430, owned by Verinata Health, Inc. ("Verinata"). That ruling is not at issue because Roche discontinued that version of the test. Verinata was an appellant but did not seek injunctive relief and does not seek rehearing.

- Roche's marketing touts Harmony V2 as superior because it runs on the "DANSR" assay, *see* Appx10271-10277 (promoting it as "significantly improv[ing] assay efficiency"), when, in fact, it infringes Illumina's intellectual property;
- Roche has [redacted] to [redacted] a product ("AcfS") that allows purchasers to run the infringing Harmony V2 test "in their own labs," Appx11498; *e.g.*, Appx10309.

The district court declined to enter a preliminary injunction. In assessing irreparable harm, the court looked exclusively to whether there was "direct competition." Appx0057-59. The court concluded that there was not because the companies had different business models: Ariosa (now Roche) markets a NIPT test that directly competes with Illumina's "licensees" (other NIPT testing companies), but Illumina primarily sells testing platforms. The court understood *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312 (Fed. Cir. 2012), to establish that "in cases such as this one where the licensees compete with the infringer, royalties are adequate forms of compensation." Appx0060. The court found that the balance of the equities and public interest factors were neutral, because Illumina discontinued the Golden Gate assay and "switching *from* [sic] Illumina sequencers would cost 'an enormous amount of resources, time, and dollars.'" Appx0062. In fact, Ariosa "switch[ed] from" Illumina sequencers years ago. See Roche Op. Br. 73.

A panel affirmed in a non-precedential opinion. The panel stated that "a lack of direct competition is a substantial basis for finding no irreparable harm," and that "where licensees compete with the infringer, royalties are adequate forms of compensation." Op. 20-21. The panel did not mention that the so-called "licensees" license *completely different patents* (not the '794 Patent), nor did it discuss any other evidence of irreparable harm or the other injunction factors.

SUMMARY OF ARGUMENT

En banc review is warranted to vindicate the importance of permanent injunctions as a remedy for patent infringement. As *eBay* makes clear, the availability of injunctive relief depends on case-by-case application of the four-factor test, not simplistic shortcuts. But the test the panel applied—looking only to whether the infringer directly competes with the patentholder's "licensees"—ignores the possibility that the infringer *also* competes with and irreparably harms the patentholder in other ways.

At a minimum, panel rehearing is warranted because the panel overlooked or misapprehended extensive record evidence of irreparable harm for which money damages are no substitute. Quite simply, this case cries out for an injunction. The panel's shortcut approach to denying an injunction—in an unpublished order with virtually no discussion of the facts beyond identifying the parties' business models—

marks a dramatic and unwarranted anti-injunction shift that deserves rehearing to restore the proper balance for this important remedy.

I. The Panel's Myopic Focus On "Direct Competition" And Licensees Undervalues Injunctive Relief And Conflicts With *eBay*

A. *eBay* Establishes That The Availability Of An Injunction Depends On Application Of The Four-Factor Test, Not Simple Shortcuts

The heart of a patent is the right to exclude. The Constitution gives Congress the power to grant "Inventors the exclusive Right to their … Discoveries" to "promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. Congress provided that a patent is a property right to "exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C. § 154(a)(1); *see* 35 U.S.C. § 261. Congress employed "the language of complete monopoly." *Continental Paper Bag*, 210 U.S. at 423. And "[f]rom at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases." *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring); *see id.* at 395-396 (Kennedy, J., concurring) (finding that tradition generally "instructive").

In *eBay*, the Supreme Court rejected a "categorical rule" that transformed a description of historical practice into a legal mandate that "a permanent injunction *will issue* once infringement and validity have been adjudged," absent exceptional circumstances. 547 U.S. at 394-395 (emphasis added). The Court reaffirmed that

an injunction "may" issue "in accordance with the principles of equity," namely, the traditional four-factor test. *eBay*, 547 U.S. at 392-394 (quoting 35 U.S.C. § 283).

Crucially, the Supreme Court also rejected the *eBay* district court's approach. The *eBay* district court had "recited the traditional four-factor test," but "appeared to adopt certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases." 547 U.S. at 393. The district court had determined that a "'plaintiff's willingness to license its patents' and 'its lack of commercial activity in practicing the patents' would be sufficient to establish" a lack of irreparable harm. *Id.* The Supreme Court held that "the District Court erred in its categorical denial of injunctive relief." *Id.* at 393-394. The Supreme Court thus rejected a categorical rule favoring injunctions *and* a simplistic two-factor test foreclosing them.

B. The Panel's Simplistic Test Conflicts With *eBay*

The panel's decision conflicts with *eBay*—and devalues the core patent right to exclude—by applying a simplistic two-factor test that is even more anti-injunction than the *eBay* district court's rule. 547 U.S. at 393. The panel treated "direct competition" not as a relevant factor but a *sine qua non*, stating that "a lack of direct competition is a substantial basis for finding no irreparable harm." Op. 20. The panel determined that an injunction is unavailable if the infringer directly competes with the patentholder's "licensees": "[T]he different sales models evidenced a lack of direct competition because defendants compete with Illumina's licensees," and

"where licensees compete with the infringer, royalties are adequate forms of compensation." Op. 21-22; *see* Op. 20 ("The district court concluded that defendants' losses would be quantifiable based at least on licensing fees per lost subscriber."). Accordingly, whereas the *eBay* district court's approach would have applied only to non-practicing entities, the panel's approach foreclosed injunctive relief even in a dispute between two sophisticated biotechnology companies.

More fundamentally, the court's blinkered focus on "direct competition" conflicts with *eBay* because, standing alone, it does not answer any part of four-factor test. Roche's send-away test competes with NIPT testing companies that have a license to use Illumina products to conduct NIPT tests—but that does not establish a *lack* of irreparable harm caused by Roche's creation of a knockoff of the '794 assay patent, which Illumina has never licensed.

First, the panel improperly discounted the harm of the ongoing violation of the right to exclude. Continuing infringement is not sufficient alone to justify an injunction, but it weighs in favor of one and is a reason why courts have historically granted injunctions in so many patent cases. *See, e.g.*, *Continental Paper Bag*, 210 U.S. at 430 ("It hardly needs to be pointed out that the right can only retain its attribute of exclusiveness by a prevention of its violation. Anything but prevention takes away the privilege which the law confers upon the patentee.").

Second, the panel's focus on "licensees" is utterly misplaced because they license completely different patents from Illumina, not the patent-at-suit: Those companies have a license to use Illumina products to conduct specific NIPT *tests*, whereas the '794 Patent is for a general-purpose assay used in a testing *platform*. Illumina has never licensed the '794 Patent. *See* p.6, *supra*. The fact that Roche is harming third parties that license *completely different patents* from Illumina sheds little or no light on whether Roche's infringement of the '794 Patent also causes irreparable harm to Illumina.

Relying on statements that Illumina wanted Roche to "take a license," the district court found that Illumina intended to license the '794 Patent. Appx0061. But those statements referred to Roche buying Illumina's products and obtaining licenses to *use* them—like virtually every other NIPT company—not a naked license to *create* a home-grown replacement for Illumina's products. Moreover, even if Illumina had been willing to grant such a license when Ariosa was running its test using Illumina assays, the per-user fee for using Illumina's NIPT patents would still be an inadequate substitute for ending market exclusivity as to the '794 Patent and allowing Ariosa to make a home-grown assay instead of buying from Illumina. That amount would be far higher and cannot be adequately measured because Illumina has never entered into a similar license.

Third, the panel's shortcut assumes that competition is an either/or proposition that exists on only one axis at a time—overlooking the possibility that the infringer *also* harms the patentholder by competing in other ways. As to the '794 Patent, Roche's only competitor is Illumina. Illumina has never licensed that patent. Roche was a customer of Illumina's Golden Gate assay that practiced it—until Roche developed the infringing DANSR assay as a replacement. *See* p.5, *supra*. It is hard to conceive of a more direct form of competition than creating an infringing knock-off rather than continue purchasing the original from the patentholder.[3]

The record also shows that Roche's infringement competes with Illumina for the same health-care dollars, driving down Illumina's prices: The Harmony V2 test reduces demand for labs or providers to purchase Illumina's platforms, because a low-price send-away test is a market substitute for purchasing Illumina equipment to run the same test in-house. *See* Appx10023 [Eidel Decl.] ¶ 9. Record evidence also shows that major Illumina customers ([redacted] and [redacted]) responded by negotiating lower [redacted] for Illumina products. Appx10025-10026 [Eidel Decl.] ¶

[3] In the shadow of Ariosa's decision to knock off Golden Gate rather than purchase it, Illumina discontinued its sale. Discontinuing sales is not a sufficient basis to deny an injunction. See *Continental Paper Bag*, 210 U.S. at 422-430.

12.[4] And unlike all or virtually all other send-away NIPT tests, which run on Illumina platforms, Roche's test is not powered by Illumina and instead uses an infringing assay. Appx10023 [Eidel Decl.] ¶ 9. Those harms are irreparable.

Fourth, the panel overlooked that "damage to brand recognition [can] provide a basis for concluding that monetary relief would be inadequate." *ActiveVideo*, 694 F.3d at 1340. Roche trumpets Harmony V2 as superior because it runs on the DANSR platform, which it claims "significantly improves assay efficiency." Appx10271-10277; *see* https://sequencing.roche.com/en/products-solutions/by-application/clinical/nipt/harmony-test-technology.html (last visited May 22, 2020) (Roche website still making similar claims). That is trumpeting infringement. It would surely be valuable to Illumina (in ways that are difficult to quantify) if Roche promoted Harmony V2 as superior because *Illumina's technology* "significantly improves assay efficiency." But Roche would never say that for a simple reason: Roche competes with Illumina.

[4] Roche has denied being in discussions with [redacted] or [redacted], and denied viewing them as potential customers. *See* Appx10590 (¶8). But Roche does not deny that those companies negotiated lower prices with Illumina, and they can do so without being in talks with Roche.

Finally, the panel overlooked evidence that Roche is threatening "direct competition"—even under the panel's narrow understanding of the phrase. Roche markets a platform ("AcfS") abroad that uses the DANSR assay to "enable[] customers who purchase it to run Harmony in their own labs." Appx11498, Appx11645. Roche has not denied its [redacted] to [redacted] AcfS [redacted]. An injunction is warranted to stop that harm before it starts.

C. The Panel's Decision Is In Tension With *ActiveVideo*

The panel relied on *ActiveVideo*, but the panel's simplistic approach marks a dramatic departure from that case-specific, nuanced decision. The *ActiveVideo* court avoided "suggesting that loss of market share cannot be a basis for irreparable harm or that there can be no irreparable harm absent direct competition." 694 F.3d at 1338. Yet the panel applied that very rule, stating that "a lack of direct competition is a substantial basis for finding no irreparable harm" and "where licensees compete with the infringer, royalties are adequate forms of compensation." Op. 20-21. And whereas *ActiveVideo* carefully analyzed all four injunction factors in considerable detail, *see* 694 F.3d at 1337-1341, the panel's analysis is a few short paragraphs, does not mention other evidence about irreparable harm or the inadequacy of damages, and does not assess the other injunction factors at all. *See* Op. 20-21.

The panel also did not mention glaring differences between the cases. First, the infringement in *ActiveVideo* involved the same patent as the license (for a video-

on-demand system). Here, the infringement and the "licenses" involve completely different patents (a general-purpose assay used in a testing *platform*, versus patents for specific DNA *tests*). Illumina has never licensed the patent-at-suit.

Second, ActiveVideo's only market was licensing the video-on-demand system to a cable company (Cablevision), and Verizon's infringement meant that it obtained for free something for which Cablevision paid a per-user fee. Forcing Verizon to pay the same per-user fee thus "readily" remedied the loss of licensing revenue. 694 F.3d at 1338. Here, no established royalty for the '794 Patent exists because Illumina has never licensed it. And whereas ActiveVideo's loss of license revenue was readily measured, Roche's infringement causes losses that are immeasurable, including (1) ending market exclusivity for a patent Illumina has never licensed and thereby enabling Roche to avoid purchasing directly from Illumina itself; and (2) enabling Illumina customers to negotiate lower prices for Illumina platforms, because Roche's send-away test is a market substitute.

Third, in *ActiveVideo*, "no evidence" showed harm to the patentholder's brand. 694 F.3d at 1338. Here, Roche's promotion of its infringing assay harms Illumina's position as a thought leader. *See* p.7, *supra*.

Fourth, the *ActiveVideo* court explained that "enforcing the right to exclude serves the public interest," but that the per-user fee exponentially increased ActiveVideo's revenues while an injunction would cause ordinary Verizon

subscribers to lose video-on-demand service. *Id.* at 1340-1341. Here, the panel did not even mention the right to exclude and no similar countervailing concerns exist. The only user of the infringing DANSR assay is Roche itself. *ActiveVideo* thus does not support the panel's decision, and if anything demonstrates its flaws.

II. At A Minimum, Panel Rehearing Is Warranted

As explained above, the panel's decision warrants en banc review because it departs dramatically from the case-specific analysis *eBay* and *ActiveVideo* demand. At a minimum, panel rehearing is warranted because the panel overlooked or misapprehended uncontradicted record evidence of irreparable harm, including:

- Roche is engaged in ongoing commercial infringement of Illumina's patents, violating its right to exclude;
- Roche and Illumina identify each other as competitors;
- the "licensees" that market NIPT tests do not license the general-purpose '794 Patent, and instead completely different patents for specific NIPT tests;
- Illumina has never licensed the '794 Patent to allow a competitor to create a knock-off assay;
- Ariosa previously purchased the Golden Gate assay until Ariosa created its infringing substitute, so the only company that has ever competed with Illumina with respect to the '794 assay patent is Ariosa/Roche;
- Roche's send-away NIPT test enabled Illumina customers to negotiate lower prices for Illumina's products, because they are market substitutes;
- Roche is marketing its infringing assay as superior, taking credit for Illumina's intellectual property and harming Illumina's brand; and

- Roche has [redacted] to [redacted] a product ("AcfS") [redacted] that allows customers to run Harmony V2 in-house, further competing in Illumina's primary market.

CONCLUSION

The court should grant rehearing en banc or, at a minimum, panel rehearing.

Respectfully submitted,

Dated: May 22, 2020

/s/ Edward R. Reines

Edward R. Reines
Derek C. Walter
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shoresw, CA 94065
Telephone: (650) 802-3000

Zachary D. Tripp
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW
Washington, DC 20036
(202) 682-7220

Counsel for Plaintiff-Appellant Illumina, Inc.

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

VERINATA HEALTH, INC., ILLUMINA, INC.,
Plaintiffs-Appellants

v.

ARIOSA DIAGNOSTICS, INC, ROCHE MOLECULAR SYSTEMS, INC.,
Defendants-Cross-Appellants

2018-2198, 2018-2303, 2018-2305, 2018-2306, 2018-2317

Appeals from the United States District Court for the Northern District of California in Nos. 3:12-cv-05501-SI, 3:14-cv-01921-SI, 3:15-cv-02216-SI, Senior Judge Susan Y. Illston.

Decided: April 24, 2020

EDWARD R. REINES, Weil, Gotshal & Manges LLP, Redwood Shores, CA, argued for plaintiffs-appellants. Also represented by CHRISTOPHER SHAWN LAVIN. Plaintiff-appellant Illumina, Inc. also represented by DEREK C. WALTER.

MARK CHRISTOPHER FLEMING, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for defendants-

cross-appellants. Also represented by TIMOTHY ANDREW COOK, KATHERINE P. KIECKHAFER; CHRISTOPHER ASTA, THOMAS SAUNDERS, Washington, DC; ROBERT J. GUNTHER, JR., OMAR KHAN, CHRISTOPHER R. NOYES, New York, NY; DAVID ISAAC GINDLER, ALAN J. HEINRICH, Irell & Manella LLP, Los Angeles, CA; LISA GLASSER, Newport Beach, CA.

Before REYNA, WALLACH, and HUGHES, *Circuit Judges.*

REYNA, *Circuit Judge.*

After trial on the merits, a jury found two U.S. patents valid and infringed. Ariosa Diagnostics, Inc., and Roche Molecular Systems, Inc., moved for judgment as a matter of law on invalidity and noninfringement. Verinata Health, Inc., and Illumina, Inc., moved for a permanent injunction, supplemental damages, an accounting, and pre- and post-judgment interest. The district court denied the parties' motions. Verinata and Illumina appeal the denial of the permanent injunction, supplemental damages, an accounting, and pre-judgment interest. Ariosa and Roche cross-appeal the denial of judgment as a matter of law on invalidity and noninfringement. We conclude that substantial evidence supports the district court's denial of Ariosa's motion for judgment as a matter of law on noninfringement and invalidity. We also conclude that the district court did not abuse its discretion by denying Verinata and Illumina's motion for a permanent injunction, supplemental damages, an accounting, and pre-judgment interest. We affirm.

BACKGROUND

A

Appellant Illumina, Inc., develops, manufactures, and markets integrated systems and tools for DNA analysis. Verinata Health, Inc., a wholly-owned subsidiary of Illumina (collectively "Illumina"), developed and offered a non-

invasive prenatal test ("NIPT") for the early identification of fetal chromosomal abnormalities. Appellee Ariosa Diagnostics, Inc., also conducts research and development in the field of NIPT for fetal chromosomal abnormalities. Roche Molecular Systems, Inc., acquired Ariosa in December 2014. In an effort to "streamline issues in the [l]itigation and avoid unnecessary discovery," the parties stipulated that "Ariosa will be deemed the Defendant responsible for the conduct that Illumina has accused of infringing the asserted claims" and that Roche would be dismissed from the litigation and subsequently "deemed a party to any judgment to the same extent as Ariosa." J.A. 11606-07.

Illumina owns U.S. Patent No. 7,955,794 (the "'794 patent"), which is directed to custom DNA assay optimization techniques. The '794 patent identifies seven inventors, including Dr. John Stuelpnagel and Dr. Arnold Oliphant. Dr. Stuelpnagel was a co-founder of Illumina, and Dr. Oliphant served as Illumina's executive vice president of scientific operations.

The '794 patent describes the detection of DNA target sequences by introducing probes with complementary sequences into a sample and observing whether hybridization occurs. An excerpt of claim 1 identifying the elements relevant to this appeal is set forth below:

> A multiplex for determining whether a sample contains at least 100 different target sequences, comprising:
>
> > a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;
> >
> > b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of

said more than 100 different probes comprises:

i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and

ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;

. . .

d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;

e) contacting said modified probes with:

i) at least a first primer that hybridizes to said universal priming site;

ii) NTPs; and

iii) an extension enzyme;

wherein said different modified probes are amplified and forming different amplicons;

f) immobilizing said different amplicons to a second solid support, and

g) detecting said different amplicons immobilized to said second solid support, thereby

> determining whether the sample contains at least 100 different target sequences.

'794 patent col. 68 ll. 46-67, col. 68 l. 65-col. 69 l. 12.

Verinata owns U.S. Patent No. 8,318,430 (the "'430 patent"), which is directed to methods for NIPT screening of fetal chromosomal abnormalities. An excerpt of claim 1 is appended below identifying the elements relevant to this appeal:

> 1. A method for determining a presence or absence of a fetal aneuploidy in a fetus for each of a plurality of maternal blood samples . . . comprising fetal and maternal cell-free genomic DNA, said method comprising:
>
> . . .
>
> (e) . . . enumerating sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences . . . ; and
>
> (f) . . . determining the presence or absence of a fetal aneuploidy comprising using a number of enumerated sequence reads corresponding to the first chromosome and a number of enumerated sequence reads corresponding to the reference chromosome of (e).

'430 patent at col. 63.

B

In 2008, both Dr. Stuelpnagel and Dr. Oliphant left Illumina. By late 2009, Dr. Stuelpnagel launched Ariosa. Dr. Oliphant rejoined Dr. Stuelpnagel at Ariosa shortly thereafter. They sought to develop a NIPT for the detection of fetal aneuploidies, which can lead to conditions such as Down Syndrome. Between 2010 and 2011, Ariosa provided

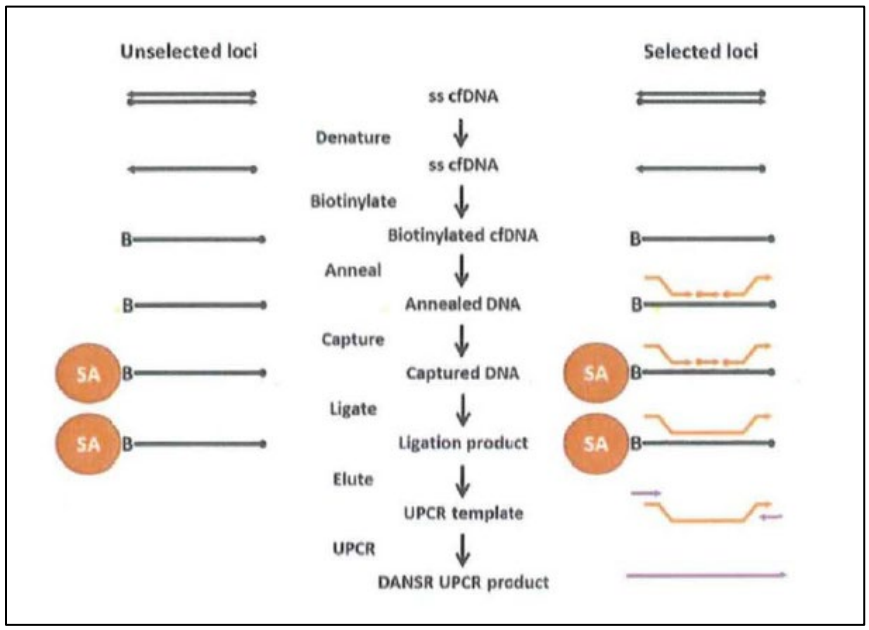
Illumina, as a prospective investor in Ariosa, technical information about its product proposals under development. In January 2012, seven months after the '794 patent issued, Ariosa entered into a three-year sale and supply agreement ("SSA") with Illumina. J.A. 4326, J.A. 4349-4350 (excerpts from SSA).

C

In March 2012, Ariosa launched a DNA-sequencing test called the Harmony Prenatal Test. The test consisted of materials supplied by Illumina. The Harmony Prenatal Test is a multiplex method that analyzes fetal cell-free DNA (or cfDNA). Ariosa designed two versions of the Harmony test—"Harmony V1" and "Harmony V2." For purposes of this appeal, we focus our discussion of the relevant technology on Harmony V2.

Harmony V2 tests a sample of isolated fetal cfDNA for the presence of about 6800 gene sequences by using a laboratory robot to perform the steps summarized below in Figure 1.

Figure 1



J.A. 3100-3101; J.A. 2067-2068. First, the sample's double-stranded fetal cfDNA is separated, or "denatured," into individual strands. Next, a molecule called biotin is added to the end of each cfDNA strand (represented by "B" in Figure 1). The robot then adds a solution containing a mixture of single-stranded oligonucleotides that are complementary to the 6800 sequences Harmony V2 detects (orange lines in Figure 1). The mixture contains three different oligonucleotides for each of the 6800 target sequences, corresponding to the beginning, middle, and end portions of the target sequence. The oligonucleotide for the beginning of each sequence contains a "readout cassette," which is a short, artificial DNA segment that is uniquely assigned to each of the 6800 sequences tested in Harmony V2. If the cfDNA sample contains one of the 6800 target sequences, each of the three oligonucleotides corresponding to that target sequence will hybridize to it, creating a section of double-stranded DNA with two gaps (between the first and

second and between the second and third oligonucleotides). If the cfDNA does not contain a certain target sequence, the oligonucleotides corresponding to that sequence will remain unbound in solution.

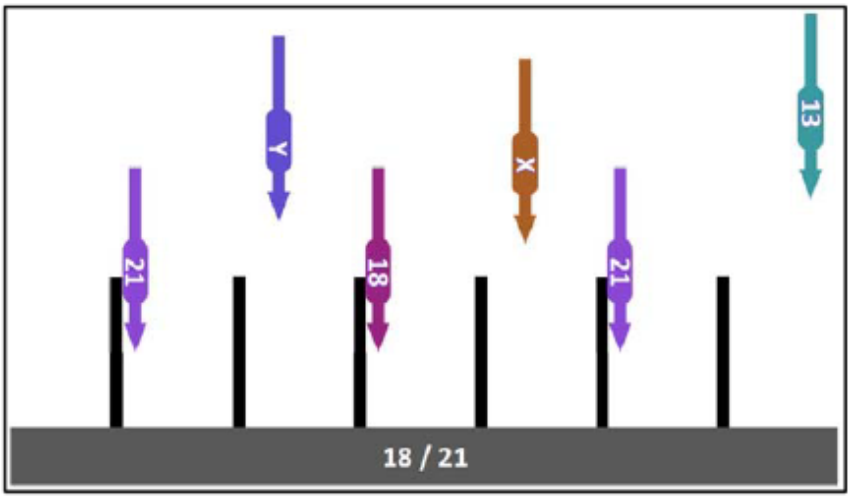
The test allows the oligonucleotides two hours to bind to target sequences. After the two hours elapse, the robot adds magnetic beads coated with a protein called streptavidin, which binds strongly with the biotin on the cfDNA and links it to the beads. The robot then immobilizes the magnetic beads (and therefore the sample DNA and any bound oligonucleotides) and washes away anything that is left in solution, including any unbound oligonucleotides.

Next, the robot adds an enzyme that ligates, i.e., connects, the three oligonucleotides, creating a single DNA strand. This only happens if all three oligonucleotides corresponding to the target sequence are bound to the sample cfDNA. The robot then denatures, i.e., separates, the newly-joined oligonucleotides from the sample cfDNA and amplifies the newly-joined oligonucleotides. Universal primer sequences on the first and third oligonucleotides enable this amplification.

During processing, the copies that result from the amplification step (termed "amplicons") are purified and added to a mixture that cuts ("digests") them into fragments. Then, detection begins by applying the digested reaction mixture, including the readout cassettes, to an array. An array is a chip (or device) containing thousands of short DNA sequences attached to a solid support. If a readout cassette corresponding to one of the 6800 target sequences is present, part of the readout cassette will bind to a DNA sequence on the array. The other part of the readout cassette remains unbound, hanging like a single-stranded tail off the double-stranded sequence attached to the solid support. Figure 2, below, shows how readout cassettes indicating target sequences on chromosomes 18 and

21 bind to the array while other readout cassettes remain unbound.

Figure 2



Any materials that do not bind to the array, e.g., chromosomes Y, X, and 13 in Figure 2, are washed away. Readout cassettes remain bound to the array. Fluorescently labeled oligonucleotides that are complementary to the readout cassettes' free single-stranded tails are then added. After the labeled oligonucleotides are given time to bind to the single-stranded tails on the readout cassettes, they are chemically joined or ligated to the DNA strand attached to the chip. The array is then heated up to separate the readout cassettes from the fluorescently tagged chip. The readout cassettes are then washed away, leaving only the labeled oligonucleotides attached to the DNA strands.

A machine then analyzes the array and detects the different colors of the fluorescent tags and their positions. From these data, and using algorithms and analyses, Ariosa can calculate the probability that each of the 6800 sequences was present in the cfDNA sample.

D

Starting late 2012, Illumina and Verinata filed several lawsuits against Ariosa and its parent company Roche accusing the Harmony V1 and V2 tests of infringing the '794 patent and the '430 patent. Verinata alleged Harmony V1 infringed the '430 patent, and Illumina alleged both Harmony versions infringed the '794 patent. Ariosa argued that the patents-in-suit were invalid and that it had an express license to the '794 patent. Ariosa also asserted a counterclaim for breach of contract.

During claim construction, the parties disputed the construction of two terms of the '794 patent: (a) "modified probes" and (b) "wherein said different modified probes are amplified and forming different amplicons." The district court construed those claims as follows:

- "modified probe" means "an enzymatically altered polynucleotide which contains a universal priming site and is capable of substantially hybridizing to a target sequence."

- "wherein said different modified probes are amplified and forming different amplicons" means "wherein the different modified probes are replicated, in whole or in part, to yield amplification products of each of the different modified probes."

The district court held a jury trial from January 8 to January 25, 2018. The jury returned a verdict finding the '430 patent not invalid and infringed by the Harmony V1 product and the '794 patent not invalid and infringed by both the Harmony V1 and Harmony V2 products; that Ariosa did not have an express license to the Harmony V1 product under the SSA; and that Illumina did not breach the SSA by suing Ariosa. The jury awarded plaintiffs approximately $27 million in damages. Thereafter, the parties filed post-trial motions.

Ariosa moved for judgment as a matter of law ("JMOL"), under Fed. R. Civ. P. 50(b), on the jury's various infringement and validity determinations. Illumina moved for a permanent injunction, a Fed. R. Civ. P. 52 conclusion of law that Ariosa was estopped as an assignor from challenging the validity of the '794 patent, and an accounting, supplemental damages, pre-judgment interest at the prime rate and post-judgment interest.

The district court denied Ariosa's motions for JMOL. The district court found that substantial evidence supported the jury's findings of no anticipation of the '794 patent by U.S. Patent Application No. 2003/0228599 A1 to Straus ("*Straus*"); that the Harmony V2 product infringes the '794 patent; that the '430 patent meets the enablement requirement; and that the Harmony V2 product infringes the '430 patent. The district court granted Illumina's motion for a Rule 52 conclusion of law and denied Illumina's motion for an accounting, and supplemental damages. The district court granted pre-judgment interest at the 52-week Treasury Bill rate and granted post-judgment interest at the statutory rate but deferred on calculating post-judgment interest until after appeal once the final amount of the judgment is known.

These appeals ensued. Illumina appeals the denial of a permanent injunction, supplemental damages, an accounting, and pre-judgment interest at the prime rate. Ariosa cross-appeals the denial of JMOL on validity of the '430 patent and the '794 patent and infringement of only the '794 patent by Ariosa's Harmony V2 product.

DISCUSSION

We address Ariosa's cross-appeal in §§ A, B, and C below. Then, in § D, we address Illumina's appeal.

A

We begin by addressing the district court's denial of Ariosa's motion for JMOL of noninfringement of the '794

patent. Ariosa argues that Harmony V2 does not literally infringe claim 1, steps (a) and (b). Ariosa also argues that Harmony V2 does not infringe claim 1, steps (f) and (g) literally or under the doctrine of equivalents. The district court's denial of Ariosa's motion for JMOL is supported by substantial evidence.

We review denials of JMOL under the law of the relevant regional circuit, in this case, the Ninth Circuit. *A TEN Int'l Co., Ltd. v. Uniclass Tech. Co., Ltd.*, 932 F.3d 1364, 1367 (Fed. Cir. 2019). The Ninth Circuit reviews a denial of JMOL de novo. *Harper v. City of Los Angeles*, 533 F.3d 1010, 1021 (9th Cir. 2008). JMOL is proper when the evidence permits only one reasonable conclusion that itself is contrary to the jury's verdict. *Id.* But the jury's verdict must be upheld if it is supported by substantial evidence. *Id.* Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (citation and quotation omitted).

A party asserting infringement under the doctrine of equivalents may prove its case by showing, on an element-by-element basis, that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product. *See, e.g.*, *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009).

Ariosa argues that its Harmony V2 does not literally infringe the step (a) "providing" and the step (b) "contacting" processes of the '794 patent. Cross-App. Br. 40-47. Ariosa argues that Dr. Cooper, Illumina's expert, offered no evidence that at least 100 different single-stranded target sequences remain completely unbound from any probe after the two-hour hybridization period. Ariosa further argued that Dr. Cooper presented no evidence that any unbound single-stranded target sequences would bind to

all three probes during the short period between the addition of the streptavidin beads and the washing-away of the probes.

Dr. Cooper detailed the reaction conditions in Ariosa's Harmony V2 that practice the method recited in step (a). J.A. 1965-1968. He explained that Harmony V2's annealing reaction is less than 99% complete following the two-hour incubation time. *Id.* He explained that Harmony V2's hybridization would occur after step (a) as a function of the relative rates of the slower "annealing reaction" compared to the faster "hybridization reaction." J.A. 1951-1952; J.A. 1955; J.A. 1964-1965; J.A. 2675-2676. Dr. Cooper concluded that, after annealing, at least 100,000 single-stranded target sequences attach to a solid support before hybridization takes place. J.A. 1967. Dr. Cooper testified that, given the reaction setup, the annealing reaction is "unlikely to complete or come close." *See* J.A. 2676.

Dr. Cooper also testified regarding how the solid support first attaches to 100 different single-stranded target sequences and how the target sequences hybridize to the probes as recited in step (b). According to Dr. Cooper, after two hours, the solid support is added and the process is "allow[ed] continued time to proceed." J.A. 1964-1965. Dr. Cooper explained that the solid support streptavidin beads quickly attach to the target sequences given the "extremely strong" covalent bond between streptavidin and biotin-coated cell-free DNA fragments. J.A. 1951-1952. Given the additional time and the strong bond between the solid support and the target sequences, Dr. Cooper testified that the reaction allows for the 100 single-stranded target sequences to "hybridize with their oligos." J.A. 1964-1965. Dr. Cooper concluded, therefore, that Ariosa's Harmony V2 practices steps (a) and (b) of claim 1. Dr. Cooper's testimony constitutes substantial evidence supporting the verdict of infringement.

Ariosa argues that the Harmony V2 does not literally infringe claim 1, steps (f) and (g) of the '794 patent because its readout cassettes do not meet claim 1's "amplicons" element. Cross-App. Op. Br. 28-31. Ariosa argues that after the amplification step performed in Harmony V2, the readout cassette is only a portion of each of the amplified DNA segments and not the complete "amplicon" that is required by the claims. Ariosa argues in the alternative that even if the readout cassettes are amplicons, Harmony V2 does not practice step (g)'s "detecting said different amplicons immobilized to said second solid support." '794 patent 69 ll. 10-12. Ariosa argues that because the readout cassettes are washed away from the array before the detection step takes place, the amplicons are not detected *while* attached to a second solid support.

Finally, Ariosa argues that Illumina failed to prove infringement of claim 1, steps (f) and (g) under the doctrine of equivalents. Cross-App. Br. at 31-35. Ariosa contends that the differences between the claimed amplicons and Ariosa's readout cassettes are substantial such that no evidence supports a doctrine of equivalents analysis. Ariosa further contends that Illumina failed to prove that immobilizing and detecting readout cassettes leads to insubstantially different results from immobilizing and detecting amplicons. We disagree.

Even were we to accept Ariosa's arguments for literal infringement, Ariosa fails to demonstrate that a reasonable jury could not find infringement under the doctrine of equivalents. Dr. Cooper testified that the readout cassettes and amplicons serve substantially the same function of "immobiliz[ing] onto a solid support"; in substantially the same way of "hybridization of [the] DNA molecule"; to achieve the same result of "detection of the target sequences that were in the original mixture." J.A. 2683-2684, J.A. 1979-1985. That testimony constitutes evidence that a reasonable mind could accept as proving infringement under the doctrine of equivalents.

B

Next, we address the district court's denial of JMOL of invalidity of the '794 patent. We conclude that the district court's denial of JMOL is supported by substantial evidence.

Ariosa appeals the district court's holding of assignor estoppel—that Ariosa is barred from challenging the validity of the '794 patent because Drs. Stuelpnagel and Oliphant are inventors of the '794 patent, they assigned their rights to the patent to Illumina, and they are in privity with Ariosa. *See Verinata Health, Inc. v. Ariosa Diagnostics, Inc.*, 329 F. Supp. 3d 1070, 1113-18 (N.D. Cal. 2018). Despite its finding of assignor estoppel, the district court analyzed anticipation of the '794 patent and found it invalid. Because we affirm the jury verdict of no invalidity, we need not reach the issue of assignor estoppel.

Ariosa contends that the district court improperly denied its motion for JMOL on anticipation of the '794 patent based on the *Straus* prior art reference. *Straus* discloses multiplex methods for detecting more than 250 nucleic-acid sequences, such as the signature sequences of pathogens in a blood sample using DNA probes. *See* J.A. 5395-5441.

Ariosa argues that a skilled artisan reading *Straus* and the method depicted in *Straus* Figure 5 would understand that it discloses "'numerous' pathogens includ[ing] using at least 100 different target sequences and over 100 different single-stranded probes" as claimed in claim 1 of the '794 patent. Ariosa further argues that *Straus's* disclosure of "a large number of distinct ID probes" anticipates the claimed universal priming sites because those probes disclose "substantial if not complete identity in the probes' priming sites." Finally, Ariosa argues that *Straus* need not disclose all the claimed limitations in a single disclosure or figure in order to anticipate.

Illumina disagrees, arguing that Dr. Cooper's testimony shows why *Straus* fails to anticipate the '794 patent. Dr. Cooper focused on *Straus's* failure to disclose claim 1, step (b)(i) ("a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites"). Dr. Cooper testified that *Straus* discloses only forty-eight probes in Figure 5, well below the "level of multiplexing" required by the '794 Patent, and that *Straus* is silent as to the actual number of primers that would be used. J.A. 2597-2598; *see also* J.A. 2602. Dr. Cooper further testified that *Straus's* references to ID probes confirms that there is no anticipation because ID probes "teach towards multiple different amplification sequences" and not a single universal primer as required by claim 1, step (b)(i). *See* J.A. 2600-2602. Dr. Cooper opined that even if some isolated disclosure in *Straus* did disclose or suggest a universal primer, that disclosure would fail to anticipate claim 1, step (b)(i), for it is unlinked to the disclosures on which Ariosa relies for anticipation, namely Figure 5. *See* J.A. 2654.

Ariosa's arguments are unavailing. Ariosa asks this court to reweigh the credibility of the parties' respective expert witnesses. This court does not engage in fact finding, nor does it weigh the credibility of expert testimony. *See Impax Labs. Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1382 (Fed. Cir. 2018). Our task is to review whether the jury's verdict is supported by substantial evidence.

Here, the jury heard conflicting expert testimony on whether *Straus* discloses a single universal primer. The jury was free to adopt Dr. Cooper's testimony over that of Dr. Cantor's in concluding that *Straus* did not disclose a single universal primer. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 848 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). We conclude that the jury verdict on invalidity is supported by substantial evidence.

We therefore affirm the jury's verdict of no invalidity and the district court's subsequent denial of Ariosa's motion for JMOL.

C

Next, we address whether substantial evidence supports the district court's denial of Ariosa's motion for JMOL of no enablement of the '430 patent. We conclude that the jury's finding and the district court's denial of JMOL are supported by substantial evidence.

Enablement is a question of law reviewed de novo. *Trustees of Bos. Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018). However, in the context of a jury trial, we review the factual underpinnings of enablement for substantial evidence. *Id.* The enablement requirement ensures that a patent contains a written description of the invention that enables "any person skilled in the art to which [the invention] pertains . . . to make and use the [invention]" without undue experimentation. 35 U.S.C. § 112(a); *Storer v. Clark*, 860 F.3d 1340, 1345 (Fed. Cir. 2017).

Ariosa argues that the '430 patent does not meet the enablement requirement because the patent fails to disclose an algorithm for determining the presence or absence of a fetal aneuploidy in the context of a targeted sequencing approach as claimed in claim 1, step (f). Cross-App. Br. 55-58. Ariosa agrees that the '430 patent incorporates by reference disclosures of "[m]ethods for determining fetal aneuploidy using random sequencing techniques." *Id.* at 56 (citing J.A. 268 (12:49-55)). Ariosa contends, however, that a skilled artisan would not be able to adapt those random sequencing techniques into non-random sequencing data without undue experimentation. Ariosa relies on the testimony of Dr. Rava, a named inventor of the '430 patent, and argues that Dr. Rava testified that a skilled artisan would be unable to use "random sequencing techniques . . . in a non-random method without modification." *Id.* (citing J.A.

1344-1345). Ariosa argues that the '430 patent discloses no such modification. Ariosa argues that even if the disclosures incorporated by reference could be modified for use in random sequencing techniques, their limited disclosure would not suffice to enable the full scope of the claimed invention.

In response, Illumina raises three main arguments. First, Illumina argues that Ariosa's expert, Dr. Cantor, testified that the Quake[1] and Craig[2] prior art references disclose the alleged missing enablement teachings of the '430 patent and that a skilled artisan is presumed to be aware of all pertinent prior art. Appellant Reply and Resp. Br. 62 (citing J.A. 2490). Illumina argues that these references disclose methods for analyzing targeted regions of DNA sequences as claimed in the '430 patent. Second, Illumina argues that Dr. Rava testified that "the algorithms for random . . . sequencing described in the publications referenced in the '430 [p]atent can be 'very similar to the ones that would be use[d] in a directed sequencing approach' but 'would have to be optimized.'" *Id.* at 64 (citing J.A. 1344-1345). Illumina further contends that Dr. Cooper confirmed that the references in the '430 patent disclose numerous enabling techniques to determine fetal aneuploidy. Third, Illumina argues that, according to Dr. Cooper, "the exact statistical methods the '430 Patent discloses based on Z-scores were in fact used by Roche scientists—and were 'quite effective' at determining fetal aneuploidy for the targeted approach." *Id.* (citing J.A. 2619-2621).

We conclude that a reasonable mind might accept Dr. Cooper's testimony that Roche scientists used the same

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[1] U.S. Patent App. Pub. No. 2007/0202525 (published August 30, 2007, filed February 2, 2007).

[2] Craig, et al., "Identification of genetic variants using bar-coded multiplexed sequencing," *Nature Methods*, 5(10):887-93 (2008).

statistical methods disclosed in the '430 patent to determine fetal aneuploidy in a targeted approach as evidence to support enablement of the '430 patent. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, (Fed. Cir. 1986) (finding specification was enabling where evidence showed the necessary screening and producing methods for making the monoclonal antibodies used in the claimed invention were known in the prior art). We therefore affirm the jury's verdict regarding enablement and the district court's subsequent denial of Ariosa's motion for JMOL.

D

Finally, we address whether the district court abused its discretion in denying Illumina's request for injunctive relief, supplemental damages, an accounting, and pre-judgment interest at the prime rate. We conclude that the district court did not abuse its discretion.

We review a district court's grant or denial of injunctive relief for abuse of discretion. *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1381 (Fed. Cir. 2017). A district court abuses its discretion if its ruling is based on an erroneous view of the law or on a clearly erroneous assessment of the evidence. *Id.* A plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). A plaintiff must demonstrate that: (1) it has suffered an irreparable injury; (2) remedies available at law are inadequate to compensate for that injury; (3) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. *Id.* Because we affirm the district court's conclusion on irreparable injury and adequacy of monetary damages, we need not reach the district court's conclusions on balance of harms and public

interest. *See Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1340 (Fed. Cir. 2017).

Regarding irreparable injury, Illumina argues that the district court failed to recognize that Roche and Illumina are direct competitors and that Roche's infringement causes irreparable injury because each sale made by Roche is a sale forever lost by Illumina. Appellant Op. Br. 22-23. Illumina argues that the district court's understanding of *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.*, 694 F.3d 1312 (Fed. Cir. 2012), was too broad and caused it to err in its conclusion of no direct competition. *Id.* at 26-30. We disagree.

In *ActiveVideo Networks,* we held a lack of direct competition is a substantial basis for finding no irreparable harm. 694 F.3d. at 1338. We reversed the injunction because the defendant (Verizon) competed with ActiveVideo's third-party licensees but not with the patentee (ActiveVideo). *Id.* The harm to ActiveVideo was therefore indirect, and ActiveVideo's loss was a "[s]traight-forward monetary harm" and "certainly not irreparable." *Id.* Here, the district court found that Illumina licenses its patents and products under the SSA, allowing third party laboratories to conduct their own tests. J.A. 58 (citing J.A. 2109:9-15). The district court also found that Ariosa does not utilize a licensing model but instead sells its Harmony V2 test directly. *Id.* Relying on *ActiveVideo*, the district court found that the different sales models evidenced a lack of direct competition because defendants compete with Illumina's licensees. *Id.* The district court concluded that defendants' losses would be quantifiable based at least on licensing fees per lost subscriber. J.A. 59. As we find no reason to disturb the district court's findings on irreparably injury, we turn to the next *eBay* factor, available remedies.

Illumina argues that the district court erred by finding that monetary relief would be adequate. Illumina reasserts that the district court erred in its reliance on

ActiveVideo and its reasoning that, where licensees compete with the infringer, royalties are adequate forms of compensation. *See* J.A. 60 (citing *ActiveVideo*, 694 F.3d at 1338). As noted above, the district court's reliance on *ActiveVideo* does not constitute an abuse of discretion. And Illumina does not challenge the district court's finding that third-party licensees compete with Ariosa. *See* J.A. 58-59. Because Illumina failed to establish irreparable injury and inadequacy of monetary relief, the district court did not abuse its discretion in denying Illumina's request for a permanent injunction.

Regarding Illumina's request for supplemental damages, and an accounting, Illumina argues that the district court's order deferring its request until after the resolution of this appeal created confusion regarding whether it is entitled to supplemental damages and an accounting. We decline to decide, in the first instance, whether Illumina is entitled to the supplemental damages it seeks. *See La Van v. United States*, 382 F.3d 1340, 1350 (Fed. Cir. 2004) (declining to award damages in the first instance on appeal). And we do not fault the district court's decision to defer this issue. *Cf.*, *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 748 F.3d 1354, 1357 (Fed. Cir. 2014) (explaining that district court's provision for an accounting of any additional damages that may accrue if the decision is affirmed on appeal did not negate finality of the judgment).

Regarding the district court's granting of pre-judgment interest at the 52-week Treasury Bill rate, Illumina requests we reverse and remand with an order to award prejudgment interest at the prime rate. Appellant Op. Br. 50-51. But Illumina articulates no reason in its opening brief for why a higher rate is appropriate. District courts have wide latitude in the selection of interest rates, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 939 F.2d 1540, 1545 (Fed. Cir. 1991), and prejudgment interest awards at the Treasury Bill rate are well within the court's discretion. *See Laitram v. NEC Corp.*, 115 F.3d 947, 955 (Fed. Cir. 1997). The

district court's decision does not constitute an abuse of discretion.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we conclude that substantial evidence supports the district court's denial of Ariosa's motion for JMOL of noninfringement and invalidity. We also conclude that substantial evidence supports the district court's denial of Ariosa's motion for JMOL of no enablement of the '430 patent.

We conclude that the district court did not abuse its discretion in denying Illumina's motion for a permanent injunction. We conclude that the district court did not abuse its discretion in denying Illumina's request for supplemental damages and an accounting. Finally, we conclude that the district court did not abuse its discretion in awarding pre-judgment interest at the 52-week Treasury Bill rate.

AFFIRMED

COSTS

The parties shall bear their own costs.

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2020, I filed or caused to be filed copies of the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system and served or caused to be served a copy on all counsel of record by CM/ECF system.

Dated: May 22, 2020

/s/ Edward R. Reines

Edward R. Reines
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Telephone: (650) 802-3000

CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type-volume limitation of Federal Circuit Rule 32(a) or Federal Rule of Federal Circuit Rule 28.1. This brief contains 3,880 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. The undersigned further certifies that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Federal Circuit Rule 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Federal Circuit Rule 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

Dated: May 22, 2020

/s/ Edward R. Reines

Edward R. Reines
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Telephone: (650) 802-3000