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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC., et al.,

Case No. <u>12-cv-05501-SI</u>

Plaintiffs,

v.

FINAL PRETRIAL SCHEDULING **ORDER**

ARIOSA DIAGNOSTICS, INC., et al.,

Defendants.

On December 20, 2017, the Court held a final pretrial conference in the above captioned matter, which is set for jury trial beginning January 8, 2018. All parties were represented by counsel. The following matters were resolved:

- 1. Number of jurors and challenges: There will be a jury of 8 members. Each side shall have 4 peremptory challenges.
- 2. Voir dire: The Court will conduct general voir dire, including various of the questions requested by counsel in their proposed additional voir dire filings. Counsel for each side shall have up to 30 minutes total to question the panel. The parties are directed to meet and confer concerning a neutral, non-argumentative statement of the case which can be read to the jury panel at the beginning of the voir dire process; this statement shall be provided to the Court no later than Friday, January 5, 2018 at 3:00 p.m.

3. Jury instructions: The Court received proposed jury instructions from the parties; substantial disagreements remain between the parties. The parties are directed to meet and confer to resolve as many disputes as possible. The parties are further directed to provide to the Court no later than Monday, January 8, 2018 a succinct statement of the fundamental disagreements in the substantive instructions, together with the (few) competing instructions reflecting those disagreements. The Court will review same and inform counsel prior to closing argument which substantive instructions will be given. In addition, if the parties provide the Court, by Friday, January 5, 2018, with an agreed-upon preliminary statement of the substantive law which will apply, the Court will read it to the jury.

- 4. Trial exhibits: No later than Friday, January 5, 2018, the parties shall submit their trial exhibits, in binders with numbered tabs separating and identifying each exhibit. The Court shall be provided with three sets (the originals for the file, one set for the Court and one set for the witnesses). The parties represented at the pretrial conference that they have stipulated to the admissibility of all such exhibits.
- 5. Timing of trial: The parties estimate that the trial can be completed in 10 days. Based on these estimates, the Court will set the matter for a 10 day trial, as follows: each side shall have up to 45 minutes to present opening statements; each side shall have 17 hours total for presentation of evidence, which includes direct and cross-examination and presentation of all exhibits; and each side shall have up to 1 hour for closing argument.
- **6. Trial schedule:** Jury selection will begin on January 8, 2018, at 8:30 a.m. The trial day runs from 8:30 a.m. until 3:30 p.m., with a 15 minute break at 10:00 a.m., a 30 minute break at noon and a 15 minute break at 2:00 p.m., all times approximate. The Court does not hear

trials on Fridays, although juries may continue to deliberate on Fridays.

7. Motions in limine: The parties filed approximately 19 motions in limine as follows:

Verinata/Illumina's Motions in Limine

- 1. <u>Exclude any reference to Illumina as an "arms dealer" (Dkt. No. 500)</u>: GRANTED in part, DENIED in part. Ariosa shall not refer to Illumina as an "arms dealer." To the extent the parties seek to use specific materials that contain the term, leave of Court must first be specifically received.
- 2. <u>Exclude evidence of Jay Flatley's personal investment in Tandem / Ariosa (Dkt. No. 502)</u>: GRANTED in part, DENIED in part. Ariosa may elicit testimony about the investment, but may not argue that it was a breach of a fiduciary duty or misconduct.
- 3. <u>Exclude any reference to Illumina as misusing Tandem / Ariosa's confidential information (Dkt. No. 503)</u>: GRANTED, without prejudice to Ariosa requesting that the Court allow specific evidence that may run afoul of this order.
- 4. Exclude any argument that Illumina has engaged in illegal or tortious anti-competitive activity (Dkt. No. 504): GRANTED in part, DENIED in part. Ariosa agrees not to refer to Illumina as a "monopoly," but may present evidence relevant to its contract counterclaims. Ariosa shall not argue any unpled claims, such as antitrust violations. As agreed to on the record, Ariosa may elicit information about plaintiffs' business dealings with third-party NIPT providers, but may not argue that those practices were improper or a form of misconduct.
- 5. Preclude trial evidence and argument regarding Ariosa's equitable defenses (Dkt. No. 505): DENIED. Equitable defenses will be decided by the Court after trial, and Ariosa may not argue same to the jury. However, predicate factual questions underlying these defenses will be submitted to the jury for advisory findings, and evidence directed to those questions will be admitted. Questions concerning determination of the availability of patent exhaustion and the

enforceability of the limitation of liability clause are deferred, subject to later briefing and argument.

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6. Exclude testimony of Nicolas Godici (Dkt. No. 506): DENIED without prejudice to objections to specific areas of testimony. "Given the complexity of patent litigation, courts have regularly permitted expert testimony . . . on a range of issues, including proceedings before the Patent and Trademark Office (PTO)." Szoka v. Woodle, No. C 02-5524 SI, 2004 U.S. Dist. LEXIS 30791, at *7 (N.D. Cal. June 7, 2004) (Illston, J.) (collecting cases). Godici's experience with patent prosecution procedures qualifies him to "assist the trier of fact to understand the evidence or to determine a fact in issue." FRE 702.

- 7. Preclude testimony of Dr. John Quackenbush, Ph.D., regarding whether the Golden Gate assay embodies the '794 patent (Dkt No. 507): DENIED without prejudice. A portion of Dr. Quackenbush's export report offers an opinion regarding whether Illumina's Golden Gate assay embodies the '794 patent. Plaintiffs argue that this opinion is unqualified, unreliable, and speculative. The Court defers decision on this question until Dr. Quackenbush's testimony at trial.
- 8. Preclude testimony of Dr. Brian Shaffer (Dkt. No. 508): DENIED without prejudice to specific objections. Plaintiffs assert that Dr. Shaffer's opinions are untimely, improperly offer claim construction argument, and are unqualified and unreliable in regards to infringement. The Court disagrees that Dr. Shaffer's opinion is untimely. Also, Dr. Shaffer is qualified to testify regarding physicians' use of NIPT technology, the Harmony test, and the NIPT market place. However, Dr. Shaffer shall not offer any claim construction arguments.
- 9. Exclude testimony of Dr. Ryan Sullivan (Dkt. No. 509): **DENIED** without prejudice to specific objections. Plaintiffs argue that Dr. Sullivan's opinions should be excluded as irrelevant, unreliable, and speculative, especially his stock market-based theories. arguments go to the weight, rather than admissibility of Dr. Sullivan's opinions. "Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." Primiano v. Cook, 598 F.3d 558, 564 (9th Cir. 2010).

10. Exclude invalidity arguments barred by IPR estoppel (Dkt. No. 510): DENIED. The Court declines to reverse its prior order on IPR estoppel because there has been no change in binding authority and the prior order was not clearly erroneous.

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- 11. Exclude Dr. Cantor's improper reliance on hearsay (Dkt. No. 511): without prejudice. Plaintiffs assert that Dr. Cantor's invalidity opinion improperly relies on hearsay of Drs. Fu, Oliphant and Stuelpnagel. However, "if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect. FRE 703. The Court finds that any potential prejudicial effect is low, and the probative value in explaining the full basis of Dr. Cantor's opinion outweighs the prejudicial effect.
- 12. Preclude Ariosa from relying upon advice of counsel (Dkt. No. 512): GRANTED in part, DENIED in part. Ariosa represents that it will not introduce a formal advice of counsel opinion to support its non-infringement or non-willfulness defense. However, in connection with its counter-claims, Ariosa plans to use a slide entitled "Freedom to Operate," which it provided to Illumina during an investment meeting with non-lawyer businesspersons. Plaintiffs argue that although the slide itself does not say whether the analysis was performed by a lawyer, the phrase "freedom to operate" necessarily implies that Ariosa obtained a lawyer's opinion. On the other hand, Ariosa asserts that a "freedom to operate" analysis may but does not necessarily involve counsel. Also, Ariosa asserts that the slide will not be used to argue advice of counsel, but rather provide context to its contract counterclaims.

The Court is not convinced that the "freedom to operate" title necessarily implies advice of counsel, and will not order it excluded or redacted. To the extent any testimony about the investment meeting suggests the Ariosa affirmatively injected advice of counsel issues into the discussion at the meeting (which Ariosa claims it did not), plaintiffs may raise specific objections at that time.

13. Preclude certain recurring prejudicial arguments and theories (Dkt. No. 513): GRANTED in part. Neither party shall suggest that employees will lose (or have lost) their jobs

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because of this litigation. The parties may discuss product pricing, but Ariosa may not suggest that if plaintiffs succeed on their infringement claims, prices will rise. Also, because Ariosa has not asserted an inequitable conduct defense, it should not suggest that Illumina misled or deceived the patent office.

Ariosa's Motions in Limine

Preclude reference to hearsay testimony from post-grant proceedings (Dkt. No. 490): GRANTED in part, DENIED in part. Ariosa moves to preclude Illumina's expert Dr. Cooper from relying on testimony of Drs. Cantor, Ward, and Fu given during post-grant proceedings, arguing that such testimony was hearsay. As a preliminary matter, the Court excludes any testimony from the post-grant proceedings (regardless of whether it is hearsay) if it relates solely to the order of steps (a) and (b). The Court already made its claim construction determination on this issue. To the extent the parties believe related testimony is relevant to another issue, they shall request specific relief prior to presenting such testimony.

The hearsay objections to Dr. Coopers's reliance on testimony from Drs. Cantor, Ward an Fu are DENIED without prejudice to specific objections to specific questions at trial. As noted above in plaintiffs' eleventh motion in limine, "if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." FRE 703. The Court finds that any potential prejudicial effect is low, and the probative value in explaining the full basis of Dr. Cooper's opinion outweighs any prejudicial effect.

2. Preclude reference to post-grant proceedings (Dkt. No. 492): Although the postgrant proceedings may be relevant and have some probative value, "this will be far outweighed by likely confusion to the jury" and the "significant amount of time and effort to adequately explain the relevance and limitations of the PTO proceedings to the jury." Finjan, Inc. v. Sophos, Inc., No. 14-cv-1197-WHO, 2016 U.S. Dist. LEXIS 189272, at *46 (N.D. Cal. Aug. 22, 2016). Therefore, the motion is GRANTED, with the following exceptions: (i) To provide context to the contract counterclaims, plaintiffs may present neutral evidence, not including outcomes, regarding "other patent proceedings" or "other patent challenges" that Ariosa referenced during the parties'

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negotiations. If plaintiffs seek to introduce the outcome of any proceeding, they must seek and obtain specific permission from the Court in advance. (ii) As to prior art included by Ariosa in its IPR petition but as to which the proceedings were not initiated, Ariosa in not precluded by estoppel from pursuing invalidity on such prior art. However, if Ariosa "either expressly or implicitly, leads the jury to believe that this is the first time the relevant references have been evaluated, the Court will permit [plaintiffs] to rebut this line of argument[.]" Rembrandt Wireless Techs., LP v. Samsung Elecs. Co., No. 13-cv-213, 2015 U.S. Dist. LEXIS 20306, at *19 (E.D. Tex. Jan. 31, 2015). (iii) Plaintiffs may request to introduce specific portions of the post-grant proceedings. To the extent necessary, a jury instruction explaining IPR proceedings will be given.

- 3. Preclude reference to Ariosa's decision not to rely on advice of counsel (Dkt. No. 494): GRANTED. However, if Ariosa or its witnesses testify or suggest that Ariosa relied advice of counsel, plaintiffs may seek leave to Court to inquire further.
- 4. Preclude reference to revenues, profits, or other business metrics of non-party Roche (Dkt. No. 497): DENIED as moot. At the hearing, the parties represented that this motion was resolved.
- 5. Preclude reference to revenues, profits, or other business metrics of non-party Roche (Dkt. No. 498): DENIED as moot. At the hearing, the parties represented that this motion was resolved.
- 6. Preclude argument and evidence on infringement under the doctrine of equivalents (Dkt. No. 499): Ariosa's request for an order precluding several of Illumina's doctrine of equivalents ("DOE") theories regarding the '794 patent is DENIED as follows:
- A. Steps (a) and (b): With respect to arguments regarding claim 1 steps (a) and (b), the motion is denied as moot in light of the Court's summary judgment order.
- B. Steps (f) and (g): Ariosa argues that DOE arguments under these steps are unavailable because of prosecution history estoppel and the "dedication-disclosure" rule. Plaintiffs oppose these grounds, and ask the Court to reconsider its ruling excluding a literal infringement theory for steps (f) and (g).

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Plaintiffs' arguments regarding their literal infringement theory are well-taken. particular, they point to parts of their infringement contentions for dependent claim 5, which states "enzymes are introduced to the amplicons, and the amplicons [are] dually cleaved to create a cleaved amplicon comprising the label binding regions and the capture regions." Dkt. No. 405, Appendix A at 17. This sufficiently disclosed the literal infringement theory. Any prejudice to Ariosa is minimal because, as noted during the pretrial conference, Ariosa's expert has already addressed this theory in a rebuttal report. Therefore, the Court's prior order (Dkt. No. 517) is amended to deny Ariosa's motion to strike the literal infringement theory that readout cassettes are amplicons as recited in steps (f) and (g).

In regards to the DOE theories for steps (f) and (g), the Court is unconvinced that such theories are barred by prosecution history estoppel or the "dedication-disclosure" rule. "Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733 (2002). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Id.* at 733-34.

Ariosa notes that step (g) originally stated "detecting said amplicons." In response to an obviousness rejection, a new limitation (step (f)) was added, which currently recites "immobilizing said different amplicons to a second solid support." Dkt. No. 499 at 6. Step (g) was amended to read "detecting said amplicons immobilized to said solid support, thereby detecting at least 100 target sequences." Id.. Ariosa contends that this was a narrowing amendment giving rise to the presumption that Illumina had surrendered the subject matter between the original claim and the amended limitation. Id. At the summary judgment stage, plaintiffs countered that the amended was only meant to clarify that the claimed invention used multiple solid supports. The Court is not convinced by Ariosa's argument; rather it appears that "the rationale underlying the

amendment may bear no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740-41.

Additionally, the disclosure-dedication rule "requires an inventor who discloses specific matter to claim it, and to submit the broader claim for examination." *PCS Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004); *see also Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) ("[W]hen a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right." (internal quotation marks omitted)). According to Ariosa, plaintiffs' expert asserts that readout cassettes are equivalents to "amplicons" because they are the same as "adapters" or "zip codes." However, Ariosa asserts that this subject matter was disclosed as embodiments in the '794 patent, but not claimed. The Court disagrees. Claims 5 through 8 of the '704 patent explicitly claim an "adapter sequence."

C. *Preamble*: Ariosa also asserts that plaintiffs' DOE theory regarding the preamble is barred by prosecution history estoppel. The preamble states, "A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising." However, the preamble originally stated, "A method of detecting target sequences in a sample comprising." Dkt. No. 499. Ariosa argues that Illumina cannot use a DOE theory for all subject matter between the original preamble and the current preamble. However, it fails to address whether any of the equivalents at issue relate to the amendment. Without such a showing, prosecution history estoppel does not apply.

D. *Ensnarement*: Ariosa argues that plaintiffs' DOE theories are barred by the ensnarement doctrine, and should be precluded. "A doctrine of equivalents theory cannot be asserted if it will encompass or 'ensnare' the prior art." *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). Ariosa argues that "any hypothetical claim presented by Plaintiffs at trial regarding either the '794 patent or '430 patent will ensnare the prior art" identified by Dr. Cantor.

However, without further explanation on how such claims will ensnare the prior art, the Court declines to preclude the DOE theories.

8. Other Matters: No formal bifurcation motion has been made, but defendant argued in its pretrial papers for a bifurcation of various legal and equitable issues. No bifurcation will be ordered, but the Court will work with counsel to provide verdict forms clearly defining the questions to be determined by the jury.

IT IS SO ORDERED.

Dated: December 22, 2017

SUSAN ILLSTON United States District Judge

Suran Illston