IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ARIA DIAGNOSTICS, INC.,

Plaintiff,

v.

SEQUENOM, INC.,

Defendant/Counterclaimant.
/

No. C 11-06391 SI

CLAIM CONSTRUCTION ORDER

NATERA, INC. and DNA DIAGNOSTICS CENTER, INC.,

Plaintiffs/Counterclaim-Defendants,

v.

SEQUENOM, INC. and ISIS INNOVATION LIMITED,

Defendants/Counterclaimants.
/

No. C 12-00132 SI

VERINATA HEALTH, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiffs,

v.

SEQUENOM, INC. and SEQUENOM CENTER FOR MOLECULAR MEDICINE, LLC,

Defendants/Counterclaimants.
/

No. C 12-00865 SI

VERINATA HEALTH, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiffs,

v.

ARIOSA DIAGNOSTICS, INC. and LABORATORY CORPORATION OF AMERICA HOLDINGS,

Defendants/Counterclaimants.
/

No. C 12-05501 SI

On September 12, 2013 and September 16, 2013, the Court held *Markman* hearings regarding the construction of disputed claim terms in six patents teaching techniques for non-invasive prenatal testing. Having considered the arguments of counsel and the papers submitted, the Court construes the disputed claim terms as follows.

BACKGROUND

1. Procedural Background

This dispute began in 2011, when Ariosa[1] filed a declaratory relief action against Sequenom, seeking a declaration that its "Harmony Test" does not infringe any claims of U.S. Patent No. 6,258,540 ("the '540 patent"). *Aria Diagnostics, Inc. v. Sequenom, Inc.*, C 11-6391-SI (filed Dec. 19, 2011). Sequenom filed a counterclaim against Ariosa, asserting infringement of the '540 patent. Subsequently, two other companies, Natera and Verinata, also filed declaratory judgment actions in this Court seeking judgments that their products do not infringe Sequenom's '540 patent and asserting that the '540 patent is invalid. *See Natera Inc. v. Sequenom, Inc.*, C 12-0132-SI (filed Jan. 6, 2012) (regarding the "Non-Invasive Paternity Test"); *Verinata Health, Inc. v. Sequenom, Inc. (Verinata I)*, C 12-0865-SI (filed Feb. 22, 2012) (regarding the "Verifi Prenatal Test"). Sequenom also filed counterclaims that Natera, DNA Diagnostics Center, Verinata, and Stanford are infringing the '540 patent. *See id.*

Additionally, in *Verinata I*, Verinata and Stanford allege that Sequenom is infringing U.S. Patent Nos. 7,888,017 ("the '017 patent"), 8,008,018 ("the '018 patent"), and 8,195,415 ("the '415 patent"). Finally, Verinata and Stanford also filed a case alleging that Ariosa and LabCorp are infringing U.S. Patent Nos. 8,296,076 ("the '076 patent") and 8,318,430 ("the '430 patent"). *See Verinata Health, Inc. v. Ariosa Diagnostics, Inc. (Verinata II)*, C 12-5501-SI (filed Oct. 25, 2012).

2. Factual Background

These patents all involve methods to conduct non-invasive prenatal DNA testing. Fetal DNA

[1] Formerly known as Aria Diagnostics, Inc.

testing can aid sex determination, blood typing and other genotyping, and detection of pre-eclampsia in the mother. It can also detect fetal aneuploidy, which is a disorder in which the fetus has an abnormal number of chromosomes, instead of the normal 23 pairs. Common aneuploidy disorders include Down syndrome (a third copy, or "trisomy," of chromosome 21), Edwards syndrome (a third copy of chromosome 18), and Patau syndrome (a third copy of chromosome 13).

Prior to these patents, testing fetal DNA required invasive techniques that took samples from the fetus or placenta. However, invasive prenatal testing presented risks to both the fetus and the mother. Scientists began researching various techniques to make these prenatal diagnoses non-invasively. Initially, non-invasive research had focused on detecting fetal cells that had passed through the amniotic sac into the mother's bloodstream. The fetal cells then had to be separated from the much more common maternal cells. This process of isolating intact fetal cells was labor-intensive and produced unreliable results.

The '540 patent followed the discovery in 1996-1997 by Drs. Lo and Wainscoat that fetal DNA is detectable in maternal serum or plasma samples in extra-cellular or cell-free form. According to Sequenom, prior non-invasive research had focused on detecting fetal cells because the presence of cell-free fetal DNA was not known. Evans Decl. ¶ 40. Therefore, the significance of the discovery by Drs. Lo and Wainscoat was that the process of isolating fetal cells was not necessary because fetal DNA was present outside of cells, as "extracellular" or "cell-free DNA" suspended together with the mother's DNA in the maternal bloodstream. This was a more efficient and reliable method then previous non-invasive techniques.

A decade later, Drs. Quake and Fan at Stanford further advanced the science in non-invasive prenatal testing using molecular counting techniques. Previously, researchers had believed that because aneuploidies do not present a mutational change in the DNA sequence (but are merely a change in the number of chromosomes), they would need to distinguish fetal DNA from maternal DNA in order to diagnose fetal aneuploidy non-invasively. The Stanford researchers used advanced DNA sequencing techniques, such as digital polymerase chain reaction ("PCR") and massive parallel sequencing. They discovered a method to diagnose fetal aneuploidy through their molecular counting techniques, without needing to distinguish the maternal DNA from the fetal DNA. Stanford and Verinata claim that these

techniques are much more efficient and effective than those utilized previously. They further refined their method by teaching how to correct for sequence tag density variances, how to selectively analyze specific DNA sequences, and how to generate a library from a pool of multiple samples. These advancements further increased the accuracy and the efficiency of the prenatal tests.

LEGAL STANDARD

Claim construction is a matter of law. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 372 (1996). Terms contained in claims are "generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312. In determining the proper construction of a claim, a court begins with the intrinsic evidence of record, consisting of the claim language, the patent specification, and, if in evidence, the prosecution history. *Id.* at 1313; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The appropriate starting point . . . is always with the language of the asserted claim itself." *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998); *see also Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed. Cir. 1997).

Accordingly, although claims speak to those skilled in the art, claim terms are construed in light of their ordinary and accustomed meaning, unless examination of the specification, prosecution history, and other claims indicates that the inventor intended otherwise. *See Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1053 (Fed. Cir. 1994). The written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format. *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001). In other words, the specification may define claim terms "by implication" such that the meaning may be "found in or ascertained by a reading of the patent documents." *Vitronics*, 90 F.3d at 1584 n.6.

In addition, the claims must be read in view of the specification. *Markman*, 52 F.3d at 978. Although claims are interpreted in light of the specification, this "does not mean that everything

expressed in the specification must be read into all the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983). For instance, limitations from a preferred embodiment described in the specification generally should not be read into the claim language. *See Comark*, 156 F.3d at 1187. However, it is a fundamental rule that "claims must be construed so as to be consistent with the specification." *Phillips*, 415 F.3d at 1316. Therefore, if the specification reveals an intentional disclaimer or disavowal of claim scope, the claims must be read consistently with that limitation. *Id.*

Finally, the Court may consider the prosecution history of the patent, if in evidence. *Markman*, 52 F.3d at 980. The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution. *See Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). In most situations, analysis of this intrinsic evidence alone will resolve claim construction disputes. *See Vitronics*, 90 F.3d at 1583. Courts should not rely on extrinsic evidence in claim construction to contradict the meaning of claims discernable from examination of the claims, the written description, and the prosecution history. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583). However, it is entirely appropriate "for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field." *Id.* Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. All extrinsic evidence should be evaluated in light of the intrinsic evidence. *Id.* at 1319.

DISCUSSION

1. Sequenom's '540 Patent

Sequenom is the exclusive licensee of the '540 patent, which Sequenom licensed from Isis Innovation Limited. The '540 patent is entitled "Non-Invasive Prenatal Diagnosis," and was issued to Drs. Yuk-Ming Dennis Lo and James Stephen Wainscoat on July 10, 2001. The patent "relates to a detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample." The '540

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