IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GUARDANT HEALTH, INC. Plaintiff, v. FOUNDATION MEDICINE, INC. Defendant.	)	C.A. No. 17-1616-LPS-CJB
GUARDANT HEALTH, INC. Plaintiff, v. PERSONAL GENOME DIAGNOSTICS, INC. Defendant.	)	C.A. No. 17-1623-LPS-CJB

MEMORANDUM ORDER

WHEREAS, on September 11, 2019, Magistrate Judge Burke issued a Report and Recommendation (C.A. No. 17-1616 ("1616") D.I. 212; C.A. No. 17-1623 ("1623") D.I. 359) ("September Report") recommending that the Court adopt certain claim constructions for two disputed terms in United States Patent Nos. 9,598,731 (the "'731 patent"), 9,834,822 (the "'822 patent"), 9,840,743 (the "'743 patent") and 9,902,992 (the "'992 patent" and collectively with the other patents, "the asserted patents");

WHEREAS, on September 25, 2019, Defendants Foundation Medicine, Inc. ("FMI")

and Personal Genome Diagnostics, Inc. ("PGDx") (collectively, "Defendants") filed objections to the September Report (1616 D.I. 228; 1623 D.I. 378) ("Defs. Sept. Obj."), specifically objecting that (1) Judge Burke erred in not construing the terms "consensus sequence"[1] and "collapsing sequence reads in each family"[2] and (2) PDGx's proposed constructions of these terms should be adopted;

WHEREAS, on October 9, 2019, Plaintiff Guardant Health, Inc. ("Guardant" or "Plaintiff") filed a response to Defendants' Objections (1616 D.I. 237; 1623 D.I. 387) ("Pl. Sept. Resp.");

WHEREAS, on October 11, 2019, Judge Burke issued a Report and Recommendation (1616 D.I. 239; 1623 D.I. 389) ("October Report") recommending that the Court adopt certain claim constructions for two disputed term sets in the asserted patents;

WHEREAS, on October 25, 2019, Defendants filed objections to the October Report (1616 D.I. 251; 1623 D.I. 397) ("Defs. Oct. Obj."), specifically objecting that (1) the claim terms "detecting, at one or more loci, at least one single nucleotide variant, at least one gene fusion and at least one copy number variant"[3] and "detecting, at one or more genetic loci, a plurality of genetic aberrations, wherein the plurality of genetic aberrations comprises two or more different members selected from the group of members consisting of a single base substitution, a copy number variation (CNV), and insertion or deletion (indel), and a gene fusion"[4] (the "Detecting Terms") are indefinite; (2) Judge Burke failed to address

[1] This term appears in claim 1 of the '731 patent.

[2] This term appears in claim 1 of the '822 patent and claim 1 of the '992 patent.

[3] This term appears in claim 2 of the '822 patent.

[4] This term appears in claim 1 of the '992 patent.

Defendants' arguments about the scope of the Detecting Terms; and (3) the claim constructions proposed by Guardant and adopted by Judge Burke are indefinite;

WHEREAS, on November 8, 2019, Guardant filed a response to Defendants' Objections (1616 D.I. 264; 1623 D.I. 405) ("Pl. Oct. Resp.");

WHEREAS, on October 25, 2019, Guardant also filed objections to the October Report (1616 D.I. 255; 1623 D.I. 399), specifically objecting that Judge Burke erred in concluding that the claim terms "beginning" and "end" (the "Sequencing Terms")[5] are indefinite ("Pl. Oct. Obj.");

WHEREAS, on November 8, 2019, Defendants filed a response to Guardant's Objections (1616 D.I. 265; 1623 D.I. 406) ("Defs. Oct. Resp.");

WHEREAS, on November 1, 2019, Judge Burke issued a Report and Recommendation (1616 D.I. 260; 1623 D.I. 402) ("November Report"), recommending that the Court adopt certain claim constructions for four disputed terms in the asserted patents;

WHEREAS, on November 15, 2019, Defendants filed objections to the November Report (1616 D.I. 269; 1623 D.I. 411) ("Defs. Nov. Obj."), specifically objecting that the claim term "sequencing extracellular polynucleotides from a bodily sample from [a/the] subject"[6] should not encompass the sequencing of amplicons of extracellular polynucleotides;

WHEREAS, on December 2, 2019, Guardant filed a response to Defendants' Objections (1616 D.I. 283; 1623 D.I. 424) ("Pl. Nov. Resp.");

WHEREAS, on November 15, 2019, Guardant also filed objections to the November

[5] These terms appear in claim 1 of the '731 patent and claims 19-20 of the '992 patent.

[6] This term appears in claims 1 and 10 of the '743 patent.

Report (1616 D.I. 270; 1623 D.I. 412) ("Pl. Nov. Obj."), specifically objecting that (1) Judge Burke's construction of the claim term "each parent polynucleotide"[7] contradicted the intrinsic record and (2) Judge Burke's construction of the claim terms "grouping the plurality of sequence reads produced from each non-uniquely tagged parent polynucleotide into families," "grouping the sequence reads into families," and "grouping the sequence reads mapped in e) into families" (the "Grouping Terms")[8] improperly required that every generated sequence read into families;

WHEREAS, on December 2, 2019, Defendants filed a response to Guardant's Objections (1616 D.I. 282; 1623 D.I. 423);

WHEREAS, the Court has considered the parties' claim construction disputes addressed by the September Report, October Report, and November Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3);

WHEREAS, on January 7, 2020, Judge Burke issued a Report and Recommendation (1616 D.I. 343; 1623 D.I. 470) ("January Report") recommending that the Court deny Guardant's motions to dismiss (1616 D.I. 169; 1623 D.I. 285) the inequitable conduct counterclaims filed by FMI and PGDx;

WHEREAS, on January 21, 2020, Guardant filed Objections to the January Report (1616 D.I. 373; 1623 D.I. 505) ("Pl. Jan. Obj."), specifically objecting that the parties' summary judgment briefing mooted the January Report and that the evidence did not support Defendants' counterclaims;

[7] This term appears in claim 1 of the '731 patent.

[8] These terms appear in claim 1 of the '731 patent, claim 1 of the '822 patent, and claim 1 of the '992 patent, respectively.

WHEREAS, on February 4, 2020, Defendants filed a response to Guardant's Objections (1616 D.I. 385; 1623 D.I. 525) ("Def. Jan. Resp.");

WHEREAS, the Court has reviewed *de novo* the portions of the January Report relating to the dispositive issues of dismissal and adequacy of the pleadings, *see Brown v. Astrue*, 649 F.3d 193, 195 (3d Cir. 2011); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

A. the September Report is ADOPTED in full and Defendants' Objection to it is OVERRULED;

B. the October Report is ADOPTED in all respects EXCEPT with respect to the recommendation that the Sequencing Terms be found indefinite, Defendants' Objection to it is OVERRULED, and Plaintiff's Objection to it is SUSTAINED;

C. the November Report is ADOPTED in full and Defendants' and Plaintiff's Objections to it are OVERRULED; and

D. the January Report is ADOPTED in full, Plaintiff's Objection to it is OVERRULED, and Plaintiff's motions to dismiss (1616 D.I. 169; 1623 D.I. 285) are DENIED.

1. With respect to the September Report, Defendants argue that the Court should construe claim terms to which Judge Burke accorded "plain and ordinary" meaning because the parties' purported disputes over these terms are "now ripe." (1616 D.I. 228 at 6; 1623 D.I. 378 at 6) At least in the context of the instant case, this is not a meritorious basis to object to the September Report. The Report persuasively explains why, based on the arguments made to Judge Burke and the evidence before him, the claim terms "consensus sequence" and "collapsing sequence reads in each family" should be given their plain and ordinary meaning to a person having ordinary skill in the art ("POSA"). For example, the

claims themselves explain that "consensus sequences" are determined by "comparing the sequence reads grouped within each family to each other" and that each one "corresponds to a unique polynucleotide," '731 patent at 62:37-42, and the process of "collapsing sequence reads in each family" will "yield a base call for each family at the genetic locus," '822 patent at 62:43-46. It appears that the parties' dispute as to whether a single base may be a "consensus sequence" (*compare, e.g.*, Defs. Sept. Obj. at 5 *with* Pl. Sept. Resp. at 9) is a fact question for the jury (i.e., a question of infringement and/or invalidity). However, if it ultimately appears to the Court that this is properly understood as a dispute of claim scope, the Court will undertake additional claim construction at some later date. *See generally Stryker Corp. v. Zimmer, Inc.*, 837 F.3d 1268, 1276 (Fed. Cir. 2016) (contemplating "rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves"); *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.").

2. With respect to the October Report, Defendants argue that the Detecting Terms are indefinite because "the specification and the claims are at odds with one another, and thus a person of ordinary skill in the art would have found that the inventions set forth [in these claims] are not what the inventors regarded as their invention." (Defs. Oct. Obj. at 4) (internal quotation marks omitted) The Court, like Judge Burke, disagrees. The claim describes an invention that can "detect[], at one . . . genetic loci, a plurality of generic aberrations" while the specification, not inconsistently, provides that the invention can, at a single locus, identify and track individual molecules that exhibit multiple mutations. (*See,*

e.g., Pl. Oct. Resp. at 4-5) Defendants' expert acknowledged that a person of ordinary skill in the art could use the invention to detect several mutations at one locus. (*Id.* at 5) Further, in connection with their invalidity challenges, Defendants have been able to identify the "literal meaning" of the claim terms – that the invention "cover[s] the unexpected scenario of detecting multiple mutation types at a single locus," undermining the contention that a POSA would fail to have reasonable certainty as to claim scope. (Pl. Oct. Resp. at 5) (citing Defendants' expert stating POSA could use claimed invention to detect multiple mutations at one locus) Defendants have not shown by clear and convincing evidence that the Detecting Terms (nor the recommended constructions of them) are indefinite.

3. Guardant objects to the October Report's recommendation that the Sequencing Terms are indefinite, insisting that Defendants "did not show by clear and convincing evidence that these plain and ordinary words could not be understood by the skilled artisan with reasonable certainty." (Pl. Oct. Obj. at 1) The Court's *de novo* review leads it to conclude this is a fact dispute, not amenable here to resolution at the claim construction stage. The Court does not believe that, at the claim construction stage, Defendants produced evidence that would necessarily persuade all reasonable factfinders that a POSA would be unable to determine, with reasonable certainty, the scope of the disputed claims. For instance, Defendants' expert, Dr. Stacey Gabriel, provided testimony that could reasonably be interpreted as supporting a finding that the Sequencing Terms are ***not*** indefinite. (*See, e.g.*, Pls. Oct. Obj. at 6-8) (citing evidence) This portion of the October Report is NOT ADOPTED.[9]

[9] The Court is troubled that Plaintiff failed to provide the required certification that its objections do not raise new legal or factual arguments, or alternatively identifying the new arguments and showing good cause for failing to raise them with the Magistrate Judge. (*See* Standing Order (Oct. 9, 2013) ¶ 5; *see also* Defs. Oct. Resp. at 1-3) In the context of the instant

4. With respect to the November Report, Defendants argue that term "sequencing extracellular polynucleotides from a bodily sample from [a/the] subject" does not encompass amplicons because amplicons are created outside the body. However, the specification repeatedly suggests that the claimed invention can involve the sequencing of amplicons. *See, e.g.,* '743 patent at 33:39-40 ("Typically, polynucleotides in a tagged library are amplified and the resulting amplified molecules are sequenced."); *id*. at 33:65-66 (noting that "certain embodiments . . . provide[] sequence-tagged nucleotides, that [are] amplified and sequenced"). Excluding amplicons from the construction is improper also because dependent claims 3 and 12 of the '743 patent encompass the sequencing of amplicons. *See* '743 patent at 63:1-3, 64:3-5; *see also Trustees of Columbia Univ. in City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016) ("[W]here dependent claims have no meaningful difference other than an added limitation . . . construing the independent claim to exclude material covered by the dependent claim would be inconsistent."); *see also* Pl. Nov. Resp. at 5-7 (citing testimony of Defendants' non-infringement experts). Additionally, FMI argued in an IPR petition that this term was anticipated by prior art that discloses the sequencing of amplicons, further supporting the conclusion that this claim term does encompass amplicons. *See generally Research Frontiers, Inc. v. E Ink Corp.*, 2016 WL 1169580, at *3 n.4 (D. Del. Mar. 24, 2016), *report and recommendation adopted in* 2016 WL 7217217 (D. Del. Dec. 13, 2016).

---

case, however, the Court is not persuaded that the proper consequence of Plaintiff's procedural failing is the invalidation of a patent that this Court, on *de novo* review, believes could well be found to be not indefinite. The Court's conclusion in this regard is informed by the facts that (i) Plaintiff's "heav[y] reli[ance] on new portions of the specification that it has never previously cited," as Defendants attack Plaintiff for doing (Defs. Oct. Resp. at 3; *see also id.* at 6) is not the kind of abusive practice the Standing Order is principally directed to; and (ii) the Court would reach the same conclusion it has here even if it did not consider any of Plaintiff's new evidence or argument.

5. Turning to Plaintiff's objections to the November Report, the Court agrees with Judge Burke that the term "each parent polynucleotide" should be construed as "every one of the parent nucleotides from step (c)." The claim language itself, "each parent polynucleotide" plainly means "every one of the parent polynucleotides," an understanding the specification repeatedly confirms. *See, e.g.,* '731 patent at 5:36-41; *id.* at 42:32-36. While Guardant points to specification embodiments that may be outside of the claim as so construed, "the claims of the patent need not encompass all disclosed embodiments." *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008).[10] Guardant's emphasis on the claim term "comprising" does not alter the Court's conclusion, as "comprising" "permit[s] additional elements not required by a claim," but it "does not remove the limitations that are present." *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1409 (Fed. Cir. 2004). Even assuming (but not deciding) Guardant could show good cause for its reliance on expert depositions and reports it did not put before Judge Burke, the Court is not persuaded that any of this new material conflicts with the recommended construction. The Court also disagrees with Guardant's contention that Judge Burke construed the Grouping Terms "too narrowly." (Pl. Nov. Obj. at 7) Because definite articles such as "the" can be "anaphoric phrases, referring to the initial antecedent phrase," the Court (like Judge Burke) reads the claim terms "grouping the plurality of sequence reads" and "grouping the sequence reads" as referring to the set of sequence reads discussed in the prior step. *See Baldwin Graphic Sys., Inc. v.*

[10] In general, the Court agrees with Guardant that "[a] construction that renders infringement impossible using the very devices disclosed in the specification for use with the invention cannot be right." (Pl. Nov. Obj. at 1) However, here, Plaintiff has not persuaded the Court that this general principle provides a meritorious basis to reject the recommended construction, given the particular claim language being construed and Defendants' seeming agreement that "the Illumina system [disclosed in the specification] ***could*** carry out the claimed invention." (Defs. Nov. Resp. at 8 n.4)

Siebert, Inc., 512 F.3d 1338, 1342-43 (Fed. Cir. 2008). The Court is also not persuaded by Guardant's argument that dependent claim 5 of the '731 patent, which provides for "filtering out sequence reads," shows that "certain sequence reads will not be analyzed and not placed into groups." (Pl. Nov. Obj. at 8) The independent claims at issue here – none of which includes a filtering step – all require grouping every sequence described in the prior steps, and any additional step cannot eliminate this express limitation. *See Power Mosfet*, 378 F.3d at 1409. The deposition testimony cited by Guardant relates only to prior art and claim 5 of the '731 patent as well as claim 10 of the '822 patent; it does not address the independent claims at issue here nor undermine the express meaning of the claim limitations.

6. Finally, turning to the January Report, the Court disagrees with Guardant that the parties' summary judgment briefing necessarily renders that Report moot. The parties have a ripe dispute as to whether Defendants' counterclaims adequately allege inequitable conduct, and now also have a dispute as to whether Defendants can survive Guardant's summary judgment motion. Guardant fails in its objections to articulate how Judge Burke's recommendation that Defendants adequately state a plausible claim for inequitable conduct is wrong. (*See* Pl. Jan. Obj. at 1) (asserting, in conclusory manner, "[t]he facts pleaded by Defendants are not sufficient to show a plausible claim for relief") The Court has reviewed Judge Burke's thorough January Report *de novo* and agrees that Defendants have stated a plausible claim.

March 23, 2020
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE