IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

REPORT AND RECOMMENDATION

In these two related actions filed by Plaintiff Guardant Health, Inc. ("Guardant" or "Plaintiff") against Defendants Foundation Medicine, Inc. ("FMI") and Personal Genome Diagnostics, Inc. ("PGDx" and collectively with FMI, "Defendants"), Guardant alleges infringement of 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"). This Report and Recommendation addresses: (1) PGDx's motion for summary judgment of non-infringement of all patents-in-suit ("PGDx's MSJ of Non-Infringement") and invalidity of the '743 patent ("PGDx's MSJ of Invalidity"),[1] (Civil Action

[1] These and all other motions for summary judgment addressed in this Report and Recommendation were filed pursuant to Federal Rule of Civil Procedure 56.

No. 17-1623, D.I. 430); (2) FMI's motion for summary judgment of non-infringement ("FMI's MSJ of Non-Infringement"), (Civil Action No. 17-1616, D.I. 296); (3) Defendants' joint motion for summary judgment of invalidity ("Defendants' MSJ of Invalidity"), (Civil Action No. 17-1616, D.I. 290; Civil Action No. 17-1623, D.I. 436); (4) Guardant's motion for summary judgment on FMI's obviousness combinations, ("Guardant's MSJ Regarding FMI's Obviousness Combinations"), (Civil Action No. 17-1616, D.I. 291); (5) Guardant's motion to strike PGDx's prosecution history estoppel arguments ("Guardant's Motion to Strike"), (Civil Action No. 17-1623, D.I. 463); (6) PGDx's motion to strike certain of Guardant's literal infringement theories, ("PGDx's Motion to Strike"), (Civil Action No. 17-1623, D.I. 497); and (7) FMI's motion for leave authorizing the submission of the declaration of Dr. Gary Benson in support of FMI's MSJ of Non-Infringement, ("FMI's Motion for Leave,"), (Civil Action No. 17-1616, D.I. 318).

For the reasons that follow, the Court recommends that PGDx's MSJ of Non-Infringement be GRANTED-IN-PART and DENIED-IN-PART; FMI's MSJ of Non-Infringement be GRANTED-IN-PART and DENIED-IN-PART; Defendants' MSJ of Invalidity be DENIED; PGDx's MSJ of Invalidity be DENIED and Guardant's MSJ Regarding FMI's Obviousness Combinations be DENIED. Further, the Court DENIES Guardant's Motion to Strike, PGDx's Motion to Strike, and FMI's Motion for Leave.

I. BACKGROUND

The Court incorporates by reference the procedural background for these actions set out in its April 22, 2020 Report and Recommendation ("April 22, 2020 R&R"). (D.I. 550 at 2)[2]

In the currently-operative Third Amended Complaints, Guardant alleges that Defendants' liquid biopsy tests infringe claims of the asserted patents. (Civil Action No. 17-1616-LPS-CJB, D.I. 149 at ¶¶ 4, 14-24; Civil Action No. 17-1623-LPS-CJB, D.I. 280 at ¶¶ 6, 17-28) The asserted patents relate to methods for identifying genetic material harboring cancer-causing mutations from a patient's blood. (*See* D.I. 59 at 1) Each of the patents is titled "Systems and Methods to Detect Rare Mutations and Copy Number Variation." (D.I. 53, exs. C-F)[3] The '731 patent, '822 patent and the '743 patent share a common specification ("the specification"), and the '992 patent has a similar specification. (*See* D.I. 75, ex. 1 at Slide 4)

II. STANDARD OF REVIEW

A. Summary Judgment

The Court incorporates by reference its summary of the standard of review for summary judgment set out in the April 22, 2020 R&R. (D.I. 550 at 3)

B. Patent Infringement

The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning

[2] For simplicity's sake, the Court will refer to the "D.I." number in Civil Action No. 17-1623-LPS-CJB, unless otherwise indicated.

[3] The asserted patents appear on the docket in these actions more than once. Citations to the patents will simply be to the '731 patent, '822 patent, '743 patent and '992 patent.

and scope of the patent claims asserted to be infringed. *Id.* Claim construction is generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326-27 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing device. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between the claimed invention and the accused product are insubstantial. *See* *Warner–Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24, 40 (1997); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014).

The patent owner has the burden of proving infringement, and must do so by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). When an accused infringer moves for summary judgment of non-infringement, such relief is only appropriate if, viewing the facts in the light most favorable to the patentee, no reasonable jury could find that every limitation recited in the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) ("[S]ummary

judgment is proper only if no reasonable jury could return a verdict for the nonmoving party.") (internal quotation marks and citation omitted).

C. Invalidity[4]

A patent granted by the United States Patent and Trademark Office ("PTO") is presumed to be valid. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100-03 (2011). The rationale underlying this presumption of validity is that "the PTO, in its expertise, has approved the claim[.]" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). The burden of proving invalidity rests with the patent challenger at all times, who must establish a patent's invalidity by clear and convincing evidence in order to prevail. *Microsoft Corp.*, 564 U.S. at 100-14. Clear and convincing evidence places within the mind of the fact finder "an abiding conviction that the truth of [the] factual contentions are highly probable." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

III. DISCUSSION

A. Infringement

Defendants' respective MSJs of Non-Infringement raised several grounds, some of which were asserted by both PGDx and FMI. The Court will address these various grounds in turn (and will indicate in each sub-heading whether one or both Defendants asserted non-infringement with respect to the limitation at issue).

1. "Consensus Sequence" Limitation (PGDx only)

a. Literal Infringement

[4] The legal standards for the specific invalidity grounds asserted by Defendants will be set out in Section III below.

Claim 1 of the '731 patent recites, *inter alia*, the step of "comparing the sequence reads grouped within each family to each other to determine *consensus sequences* for each family, wherein each of the *consensus sequences* corresponds to a unique polynucleotide among the non-uniquely tagged parent polynucleotides[.]" ('731 patent, col. 62:37-42 (emphasis added)) At the *Markman* stage of these cases, the Court did not construe the term "consensus sequence" because the parties had not presented a ripe dispute with respect to the term's meaning. (D.I. 359 at 4-5; D.I. 541 at 5-6) In its MSJ of Non-Infringement, PGDx argues that: (1) there is now a ripe dispute regarding the meaning of "consensus sequence[;]" and (2) when the term is properly construed, the Accused Product[5] does not literally infringe the asserted claims of the '731 patent because it does not determine a "consensus sequence." (D.I. 431 at 4-7; D.I. 495 at 1-5; Tr. at 70-87)

The parties' dispute as to "consensus sequence" is this: PGDx asserts that it must be multiple bases (or nucleotides), while Guardant argues that it can be a single base (or nucleotide). (D.I. 431 at 4; D.I. 466 at 3-4; D.I. 495 at 1) In support of its position, PGDx posits that "consensus sequence" should be construed to mean "the string of nucleotides that represents a set of multiply aligned sequence reads derived from the same parent polynucleotide." (D.I. 495 at 1 (emphasis, internal quotation marks, citation and brackets omitted))[6] In PGDx's view, then,

[5] PGDx's Accused Product is the PlasmaSelect 64. (*See* D.I. 431 at 1)

[6] Guardant does not propose its own construction for the term, asserting that no construction is needed. (D.I. 466 at 2) It suggests that the parties' dispute with respect to "consensus sequence" is an infringement issue that should be decided by the factfinder, though its briefing does not really explain *why* the issue is one of infringement instead of claim construction. (*Id.* at 1) In the Court's view, the parties' dispute here presents an issue of claim scope (and thus an issue of claim construction) that the Court must resolve: i.e., when the claims refer to a "consensus sequence," can that encompass a single base or must it encompass more

the claims require comparing sequence reads to each other to create a "string of []nucleotides" that best represent the family. (*See* Tr. at 77, 79; PGDx's Summary Judgment Presentation, Slide 5)

For a number of reasons, the Court agrees with PGDx and will recommend that the term be construed as PGDx suggests. These reasons include the following:

- First, the term at issue is "consensus *sequence*." As a starting point, it seems uncontroversial to note that the word "sequence" is typically understood to refer to an order in which related things follow each other. (D.I. 431 at 6; Tr. 71, 97) Of course, the term's meaning within the *patent's context* is what ultimately matters here. The Court's point is just that its ultimate conclusion as to the meaning of the term is not divergent from how the term is used in most any other context.

- The claim at issue also explains that "*each* of the *consensus sequences corresponds* to a unique *poly*nucleotide[.]" ('731 patent, col. 62:39-40 (emphasis added); *see also* D.I. 59 at 13 (Guardant noting during claim construction that this language sets forth an "attribute[]" of a consensus sequence)) And so it seems consistent with this claim language that each consensus sequence represents multiple nucleotides (i.e., a *poly*nucleotide). (*See* D.I. 431 at 6; Tr. at 72-73)[7]

---

than one base? *See, e.g.*, *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008).

[7] Guardant contends that claim 1 of the '822 patent's recitation of "at each genetic locus of a plurality of genetic loci in the one or more reference sequences, collapsing sequence reads in each family to yield *a base call* for each family at the *genetic locus*" demonstrates that a consensus sequence can be a single base. (D.I. 466 at 2 (emphasis in original)) There is no dispute that the step of "collapsing sequence reads" creates a consensus sequence. (*Id.*; *see also* D.I. 378 at 9) Nor is there any dispute that a "base call" is a single position. (D.I. 433, ex. 9 at 220; D.I. 466 at 3; Tr. at 73) But the Court agrees with PGDx that the fact that collapsing sequence reads (to generate a consensus sequence) can yield a base call at a single position does not mean that the consensus sequence can be a single base. (Tr. at 73; D.I. 495 at 2 ("But making a 'base call' after 'collapsing sequence reads' does not define 'consensus sequence' or 'collapsing sequence reads'"); *see also* D.I. 431 at 11) It simply means that when a consensus sequence is generated, a base call has been made at each nucleotide position.

- That a "consensus sequence" contains more than one base is also consistent with the patent specification. (D.I. 74 at 9; PGDx's Summary Judgment Presentation, Slide 8) For example, the specification notes that "[b]y comparing sequences of progeny in a family, a *consensus sequence* of the original parent *poly*nucleotide can be deduced." ('731 patent, col. 43:33-35 (emphasis added)) And it describes "a base or *sequence of bases*[.]" (*Id*., col. 51:4-6 (emphasis added))[8]

- This understanding of the claim term also comports with the Court's constructions for other clam terms, such as the claim term "sequence read." (D.I. 431 at 6) The Court construed "sequence read" to mean "the *order* of the *bases* of a *poly*nucleotide determined by a sequencer." (D.I. 354 at 9 (emphasis added)) While this was not Guardant's proposed construction, Guardant had proposed that "sequence read" be construed to mean "[i]nformation obtained from a sequencer evidencing the *order of bases* in a nucleic acid molecule[,]" (*id.* at 7 (internal quotation marks omitted)), which associates a "sequence read" with more than one base, (*see* D.I. 432, ex. 1 at ¶ 96). The Court believes the construction for "sequence read" was correct, for the reasons set out in its Report and Recommendation regarding that issue. Guardant did not object to the Court's construction of that term, and the District Court has adopted it. (D.I. 403 at 2)

- The Court's conclusion even seems to be consistent with Guardant's previous understanding of the claim term "consensus sequence." (D.I. 1, ex. 6 at 11-12 ("The consensus sequence thus represents the *sequence* of the unique

[8] Guardant counters by citing to the specification's statement that "[t]he *sequence for each base* is aligned as the most dominant nucleotide read for that specific location." (D.I. 466 at 3 (quoting '731 patent, col. 50:5-7) (emphasis added)) The Court agrees with Guardant that this phraseology, at least at first blush, seems helpful to it, in that it can seem like the specification is aligning an (individual) "base" with the term "sequence." But considered in context, the Court concludes that this excerpt is not helpful to Guardant. (*See* Tr. at 74) The statement is found in a passage that is about determining read coverage for each mappable base position in a genome. The specification explains that when doing so using sequence reads with barcodes, all sequences with the same barcode can be collapsed into one consensus read since they are all derived from the sample parent molecule. ('731 patent, cols. 49:61-50:5) The next sentence is the one that Guardant relies on. And when that sentence is considered in light of what comes before it, it seems clear that the specification is there talking about *aligning sequence reads at each mappable base position*—not suggesting that a consensus sequence can be a single base. (*See* D.I. 495 at 2; Tr. at 74; PGDx's Markman Presentation, Slide 6)

*poly*nucleotide among the non-uniquely tagged parent polynucleotides[.]") (emphasis added); D.I. 85 at 50-52 (Guardant's counsel stating during the *Markman* hearing that "I think everyone gets the concept [of a 'consensus sequence'] which is you have a series of sequences, then you come out with something that you consider the best sequence" and answering in the negative when asked if it was disputed that a "consensus sequence involves *strings* that are derived from the same parent *poly*nucleotide") (emphasis added))

- The Court's position also aligns with a dictionary definition of "consensus sequence" cited by both parties. (D.I. 431 at 5; D.I. 466 at 3-4) The dictionary begins its discussion of the term by stating that "[a] consensus sequence is a *string of nucleotides* or amino acids which best represents a set of multiply aligned sequences." (D.I. 68, ex. 4 at 91 (emphasis added)) This statement is in harmony with PGDx's position that a "consensus sequence" must be more than one nucleotide. To support its contrary view, Guardant points to a subsequent statement in the dictionary's discussion that explains that "[t]he simplest form of a consensus sequence is created by picking the most frequent character at some position in a set of aligned DNA . . . sequences[.]" (D.I. 466 at 4 (quoting D.I. 68, ex. 4 at 91)) But the Court agrees with PGDx that this sentence simply seems to explain *how* a particular base ("in the set of aligned DNA . . . sequences") is selected within a consensus sequence, on a base-by-base level. (*See* D.I. 495 at 2; *see also* D.I. 432, ex. 1 at ¶ 96)

For these reasons, the Court recommends that "consensus sequence" be construed to mean "the string of nucleotides that represents a set of multiply aligned sequence reads derived from the same parent polynucleotide."

However, while the Court agrees with PGDx's construction for "consensus sequence," it agrees with Guardant that even under this construction, there are material fact disputes as to whether the Accused Product infringes this limitation. (D.I. 466 at 4-7; Tr. at 99-108) The Accused Product performs a "base-by-base analysis" in which it focuses on a single base at a particular position of interest. (D.I. 432, ex. 1 at ¶¶ 36, 85 (internal quotation marks and citation

omitted); *see also* D.I. 431 at 3-4; D.I. 495 at 2) [redacted] PGDx's position is that the Accused Product does not generate a "consensus sequence" since it examines only a particular position at a time, and thus does not "ever create such a representative or best consensus sequence" for any of the families of sequence reads. (*See* Tr. at 77-79; *see also* D.I. 495 at 3 ("PGDx's analysis [never] results in a string of nucleotides representing a polynucleotide"))

Yet Guardant and its expert opine that there is at least a dispute of fact as to whether the Accused Product's mode of analysis infringes. This is because, while the software may "break[] the analysis down into chunks that are a single base in size[,]" it "ultimately generate[s] a consensus sequence that includes multiple bases" since it ultimately does the analysis for all bases that map to the reference genome. (D.I. 466 at 5-7; *see also* Tr. at 100; D.I. 468, ex. 88 at

¶¶ 53-54, 60, 65) And it points to evidence that could demonstrate to a reasonable factfinder that the Accused Product meets the "consensus sequence" limitation.

For example, PGDx published its method in the journal *Science Translational Medicine* when it was launching its product (the "Phallen Publication" or "Phallen"). (D.I. 467, ex. 63 at 107-08, 112-13; *id.*, ex. 69 at PGDX0027513, PGDX0027516; *see also* D.I. 466 at 6; Tr. at 104) The Phallen Publication includes a figure depicting a "[s]equence reconciliation" step. (D.I. 468, ex. 79 at ¶ 156) Guardant contends that this step amounts to the generation of a consensus sequence since it depicts what appears to be a representative sequence for groups of sequences that "encompass not just a single base, but the entire stretch of DNA." (D.I. 466 at 7 (emphasis omitted); *see also* Tr. at 105; D.I. 468, ex. 79 at ¶¶ 215-26)[9] The Court agrees with Guardant that whether the Accused Product's mode of analysis is encompassed by the scope of the claims is a fact dispute that must be resolved by the jury. (D.I. 466 at 7; Tr. at 103)

b. Doctrine of Equivalents

[9] PGDx suggests the Phallen Publication cannot create a dispute of fact because it is not accurate. (Tr. at 85-87; *see also* D.I. 495 at 4) While Guardant's expert agreed that the "alignment" step depicted in the figure in Phallen should be moved up in the process, (D.I. 433, ex. 8 at 1018; *see also* D.I. 467, ex. 63 at 113), the Court is not persuaded that Phallen could not be evidence that the jury could consider with respect to this factual infringement dispute. It is, after all, a written description of PGDx's product, generated by PGDx, which PGDx published in a respected scientific journal. (*See* Tr. at 104-07)

PGDx also suggests that the Accused Product does not meet the "consensus sequence" limitation because [redacted] (D.I. 495 at 3; D.I. 432, ex. 1 at ¶ 42) Guardant's expert Dr. Gregory Cooper, however, pointed out that the limitation at issue only requires comparing the sequence reads grouped within each family to each other to determine consensus sequences—not that such reads be "stor[ed]" or "written out" all together in some way. (D.I. 496, ex. 19 at 1139) Disputes like these regarding whether there is infringement under the properly construed claims should be decided by the factfinder. (Tr. at 102-03)

PGDx next argues that the Court should grant summary judgment of no infringement of the '731 patent under the doctrine of equivalents ("DOE") for two reasons. (D.I. 431 at 7-10; D.I. 495 at 4-5) The Court will address these reasons in turn.[10]

First, PGDx asserts that claim amendments and arguments Guardant made during prosecution of the '731 patent preclude its DOE arguments. (D.I. 431 at 7-8) "[P]rosecution history estoppel ['PHE'] limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). PHE can occur during prosecution either through amendment or through argument to the patent examiner. *Id.* When a patentee makes a narrowing amendment to a claim during prosecution, that creates a presumption that the patentee surrendered "all subject matter between the broader and the narrower language." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 740 (2002). To overcome this presumption, the patentee must show that the alleged equivalent (1) "could not have reasonably been described at the time the amendment was made," (2) "was tangential to the purpose of the amendment," or (3) "was not foreseeable (and thus not claimable) at the time of the amendment." *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1298 (Fed. Cir. 2005). Argument-based estoppel occurs when an applicant "clearly and unmistakably surrenders subject matter by arguments made to an examiner." *AquaTex*

[10] In assessing application of DOE, the Court must examine "the fundamental question of whether there is a genuine factual issue that the accused device, while literally omitting a claim element, nonetheless incorporates an equivalent structure." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012).

Indus., Inc. v. Techniche Sols., 419 F.3d 1374, 1382 (Fed. Cir. 2005) (internal quotation marks and citation omitted).[11]

[11] Guardant has moved to strike PGDx's prosecution history estoppel ("PHE") arguments, including those in PGDx's summary judgment briefing. (D.I. 463) Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." To determine whether a failure to disclose was harmless, courts in the Third Circuit consider the *Pennypack* factors: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the possibility of curing the prejudice; (3) the potential disruption of an orderly and efficient trial; (4) the presence of bad faith or wilfulness in failing to disclose the evidence; and (5) the importance of the information withheld. *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977)). "[T]he exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Id.* (citations omitted).

PGDx served its supplemental interrogatory responses to explain its PHE contentions on July 17, 2019 (two months after the close of fact discovery and one week before the exchange of expert reports). (D.I. 464 at 1; D.I. 472 at 2) PGDx's experts did not reference the PHE arguments in their expert reports. (D.I. 464 at 1) Guardant asserts that this "effectively prevented Guardant's experts from opining on the issue, and now seeks to prevent Guardant from offering a rebuttal." (*Id.*; *see also* Tr. at 110) Guardant asserts that the Court should strike PGDx's PHE arguments from its summary judgment briefing, or short of that, allow Guardant to submit supplemental expert reports regarding PGDx's PHE contentions without having to present the experts for depositions and allow Guardant to update their summary judgment opposition. (D.I. 464 at 3; D.I. 489 at 2)

Even assuming *arguendo* that PHE arguments were untimely, the *Pennypack* factors do not warrant exclusion, and the Court thus orders that the Motion to Strike be denied. This is particularly so given that it should not have been a surprise that PGDx intended to rely on a PHE argument if Guardant argued infringement pursuant to the DOE, (D.I. 472, ex. 3 at 94), and because Guardant had been in possession of PGDx's PHE contentions (1) for nearly *six months* before filing its Motion to Strike; (2) before expert reports were due and (3) well before summary judgment opening briefs were due, (*see* D.I. 472 at 2-3). Under these circumstances, the Court agrees with PGDx that Guardant's claim to be surprised that PGDx would pursue its PHE defense rings hollow. Guardant could have asked its experts to provide opinions responsive to the PHE contentions long ago.

From the beginning, the claims recited "collapsing the set of sequencing reads to generate a set of consensus sequences[.]" (D.I. 467, ex. 71 at GD00000093; *see also* Tr. at 111) The Examiner had rejected the claims over prior art known as "Sparks," (D.I. 433, ex. 11 at PGDX0168505-20), and in response Guardant asserted that Sparks did not teach or disclose consensus sequences, (*id.* at PGDx0168124). The Examiner then rejected the claims as obvious over Sparks in view of prior art known as "Rava," asserting that Sparks did disclose a consensus sequence because it taught "comparison to expected sequence . . . . Each locus [of Sparks] corresponds to a family." (*Id.* at PGDX0168073-74) In response, Guardant then amended the claims to recite comparing the sequence reads grouped within each family "to each other" and "identifying consensus sequences that map to a given locus[.]" (*Id.* at PGDX0168031 (emphasis omitted)) And Guardant again argued that neither Sparks (nor Rava) teaches "the determination of *consensus sequences*, which represent the consensus of potentially different sequence reads generated from a single original polynucleotide during a process of amplification and subsequent sequencing of the amplified molecules." (*Id.* at PGDX0168038 (certain emphasis in original); *see also id.* at PGDX0168041 (elaborating that Sparks did not disclose comparing sequence reads within the family to each other to determine a consensus sequence, because it did not show grouping sequence reads into families, and because the sequence reads in Sparks were not compared with each other, but rather to an expected sequence))

PGDx asserts that these arguments "evidence a clear surrender of methods not involving the claimed collapsing method." (D.I. 431 at 8) Additionally, PGDx argues that these amendments establish a presumption that Guardant surrendered the entire territory between the original and the amended claims (including any equivalent that focuses on single base positions). (*Id.*) For its part, Guardant argues that the amendments are "tangential" to the equivalent in

question (i.e., a consensus sequence that utilizes a "base-by-base" analysis) since they had nothing to do with that issue. (D.I. 466 at 8; Tr. at 111)

The Court agrees with Guardant. The primary consideration in assessing whether an amendment bears only a tangential relation to the equivalent in question is "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Insituform Techs., Inc. v. CAT Contr., Inc.*, 385 F.3d 1360, 1370 (Fed. Cir. 2004) (internal quotation marks and citation omitted); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) ("[A]n amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim."). The focus of Guardant's arguments during prosecution was not on whether Sparks alone or in combination with Rava generated consensus sequences from examining a single base position at a time. And so it follows that the reasons for the amendment bore no more than a tangential relation to the equivalent in question. *See, e.g., Insituform Techs., Inc.*, 385 F.3d at 1370 (explaining that "[t]here is no indication in the prosecution history of any relationship between the narrowing amendment [reciting a single cup process] and a multiple cup process, which is the alleged equivalent in this case" and thus finding that "the amendment narrowing the claimed invention from multiple cups to a single cup was tangential"); *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, 322 F. Supp. 3d 537, 543 (D. Del. 2018) (noting that "[n]owhere in the Quake reference do I see the equivalent in question" and therefore concluding that the reasons for the amendment bore no more than a tangential relation to the equivalent at issue).

Second, PGDx argues that Guardant's DOE arguments are barred by claim vitiation, which applies when "the accused device contain[s] the antithesis of the claimed structure[,]" *Planet Bingo, LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006), and specific

exclusion, which assumes that a claim should not be interpreted to cover subject matter that the claim language specifically excludes, *Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) ("[T]he term 'mounted' can fairly be said to specifically exclude objects that are 'unmounted.'"). (D.I. 431 at 9-10) The application of these doctrines is ultimately a question of law. *See Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005); *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003).[12]

PGDx asserts that "[d]etermining one base . . . is the antithesis of determining more than one base." (D.I. 431 at 9) In support, PGDx cites only to one case: *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318 (Fed. Cir. 2011). (*Id.*) In *Am. Calcar, Inc.*, the United States Court of Appeals for the Federal Circuit concluded that "finding a signal from one source to be equivalent to 'signals from a plurality of sources' would vitiate that claim limitation by rendering it meaningless." 651 F.3d at 1339. However, the Federal Circuit explained that the plaintiff "was required to provide particularized testimony and linking argument to show the equivalence of the XM Programming Center and a plurality of broadcast sources[,]" yet had only proffered a declaration from the inventor in which he generally "stated that the XM Programming Center is, at most, insubstantially different from the claimed plurality of sources." *Id.*; *see also, e.g., Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015) ("'Vitiation' is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence *based on the evidence presented* and the theory of equivalence asserted.") (emphasis added).

[12] Throughout their briefing, Defendants treated their arguments as to these two doctrines as rising and falling together, (D.I. 431 at 9-10, 13, 17-18; Civil Action No. 17-1616, D.I. 299 at 5), and therefore the Court below will do the same.

Here, the record is much different. Guardant's expert provides a detailed explanation as to why the use of a base-by-base approach reflects an insubstantial difference to generating a consensus sequence for multiple bases, with citation to additional evidence in support of his view. (*See, e.g*, D.I. 468, ex. 79 at ¶¶ 227-40) The Court is thus not persuaded that the doctrines of vitiation or specific exclusion require grant of the motion. It is the factfinder's province to decide whether the Accused Product's process is insubstantially different from that recited in the claims.[13]

2. "Collapsing Sequence Reads" Limitation (PGDx only)

The asserted claims of the '822 and '992 patents recite "collapsing sequence reads in each family to yield a base call for each family at the genetic locus[.]" (*See, e.g.*, '822 patent, col. 62:44-46; '992 patent, col. 64:32-34) The parties' dispute with respect to "collapsing sequence reads" is the same dispute as above with respect to "consensus sequence." (D.I. 466 at 9; Tr. at 87-88) PGDx asserts that the term "collapsing sequence reads in each family" should be construed to mean "converting the polynucleotide sequence reads in each family into a single polynucleotide sequence that represents the sequence reads in the family[,]" (D.I. 431 at 10

[13] *See, e.g., Johnstech Int'l Corp. v. JF Microtech. SDN BHD*, 315 F. Supp. 3d 1130, 1137 (N.D. Cal. 2018) (finding that indirect engagement with a housing wall via a stiff elastomer is not the "antithesis" of direct contact described by the patent, where the plaintiff presented evidence that the size and composition of the elastomer allowed it to function similar to the patent's description of a housing wall that directly engages the contact); *Paone v. Microsoft Corp.*, 881 F. Supp. 2d 386, 405-07 (E.D.N.Y. 2012) (declining to apply the doctrine of vitiation and finding that the question of whether the DOE is applicable is properly left to the jury, where the plaintiff presented the court with sufficient evidence demonstrating at least a dispute of fact as to this issue); *cf. Int'l Designs Corp., LLC v. Hair Art Int'l, Inc.*, Case No. CV 17-8411-GW(PJWx), 2019 WL 1718680, at *7-8 (C.D. Cal. Mar. 1, 2019) (finding that the plaintiff failed to create a genuine dispute of material fact with respect to infringement under DOE where the plaintiff "failed to submit *any evidence*" to show that 5-6 hairs could be considered equivalent to a hair individually stitched through foil) (emphasis added).

(internal quotation marks omitted)), and that this process must result in a consensus sequence with multiple nucleotides, while Guardant asserts that it can result in a single base, (*id.* at 11; D.I. 466 at 9).

For the same reasons as described above with respect to "consensus sequence," the Court recommends that PGDx's construction for the "collapsing" term be adopted, but denies PGDx's MSJ of Non-Infringement, as fact issues remain as to whether the Accused Product's mode of operation meets this claim limitation for both literal infringement and DOE purposes. (D.I. 466 at 10-12; *see, e.g.*, D.I. 468, ex. 79 at ¶¶ 212-40)

3. "Determining Unique Sequence Reads" Limitation (PGDx only)

Claim 10 of the '743 patent requires, *inter alia*, "determining unique sequence reads corresponding to the extracellular polynucleotides from among the sequence reads[.]" ('743 patent, col. 63:36-38) According to PGDx, the base-by-base approach of the Accused Product does not even determine "sequence reads" (i.e., "the order of the bases of" multiple nucleotides), so it therefore cannot determine "unique sequence reads." (D.I. 431 at 13)

Guardant's expert provided a detailed opinion as to why the Accused Product satisfies this claim limitation, literally and under the DOE. (D.I. 433, ex. 4 at ¶¶ 382-89; *see also* D.I. 466 at 12; Tr. at 113)[14] There is therefore a dispute of fact with respect to whether the Accused Product infringes this limitation, and summary judgment is not warranted.

[14] Dr. Cooper explains that PGDx's Accused Product "groups sequence reads into families based on the combination of . . . barcodes" and that this process "of identifying sequence reads having the same grouping of barcodes allows one to distinguish sequence reads that are unique in that they correspond to different extracellular polynucleotides present within the sample." (D.I. 433, ex. 4 at ¶ 382) Dr. Cooper's analysis of what "unique sequence reads" are is consistent with the plural language of the claim term, (*see* D.I. 72 at 13), and also appears to comport with FMI's expert's interpretation of determining unique sequence reads, (*see* D.I. 466 at 13 (citing D.I. 467, ex. 64 at 188-89; *id.*, ex. 62 at 66-68)).

4. "Quantify Mapped/Unique Sequence Reads" Limitation (PGDx only)

Claim 1 of the '743 patent, which recites a "method for detecting copy number variation," requires, *inter alia*: (1) "mapping the plurality of sequence reads to a reference sequence[;]" and (2) "quantifying mapped reads or unique sequence reads in a plurality of predefined regions[.]" ('743 patent, col. 62:51-52, 62:54) The Court construed "sequence read" to mean "the order of the bases of a polynucleotide determined by a sequencer." (D.I. 354 at 9) PGDx asserts that the Accused Product does not practice the step of quantifying mapped reads or unique sequence reads since it examines single bases. (D.I. 431 at 16; *see also* D.I. 432, ex. 1 at ¶¶ 148-49)

In response, Guardant contends that dependent claim 20 of the '743 patent "make[s] clear" that the mapped reads or unique sequence reads do not need to consist of multiple bases. (D.I. 466 at 14) Claim 20, which depends on claim 1, recites "wherein each of the plurality of predefined regions is a single base." ('743 patent, col. 64:29-30) Guardant asserts that "[i]f the 'predefined regions' can consist of a single base, there is no reason that the reads in the 'plurality of predefined regions' should be required to consist of multiple bas[e]s." (D.I. 466 at 14)

The Court's claim construction of "sequence read," however, requires multiple bases. Even if a region can be a single base, that does not mean that a sequence read associated with that region is a single base. (D.I. 495 at 8)

Guardant does not attempt to show infringement under such a construction. (D.I. 466 at 14; *see also* D.I. 431 at 16; D.I. 495 at 7-8) The Court therefore recommends that PGDx's motion be granted with respect to claim 1 of the '743 patent and dependent claims.

5. "Produce a Plurality of Sequence Reads From Each Parent Polynucleotide" Limitation (the "Plurality Limitation") (Both Defendants)

Claim 1 of the '731 patent requires "sequencing the amplified non-uniquely tagged progeny polynucleotides to *produce a plurality of sequence reads from each parent polynucleotide*," ('731 patent, col. 62:21-23 (emphasis added)), which the Court construed to mean "produce two or more sequence reads for every one of the parent polynucleotides from step (c)," (D.I. 402 at 33; D.I. 541 at 9).[15] Claim 1 of the '992 patent requires "sequencing the amplified tagged progeny polynucleotides *to produce a plurality of sequence reads from each of the tagged parent polynucleotides*," ('992 patent, col. 64:16-18 (emphasis added)), which the

[15] Claim 1 and claim 10 of the '743 patent refer to "sequencing extracellular polynucleotides from a bodily sample from [a/the] subject, wherein *each* of the extracellular polynucleotides generates a *plurality* of sequence reads[.]" ('743 patent, cols. 62:45-48, 63:29-32 (emphasis added)) Defendants did not seek construction of this language from the '743 patent during the claim construction process, but now assert that it should be construed by the Court to require that every one of the extracellular polynucleotides *from the bodily sample* must generate two or more sequence reads (and that under such a construction, the Court should grant summary judgment of non-infringement). (Civil Action No. 17-1616, D.I. 299 at 9-10; D.I. 431 at 16-17; Tr. at 150-51; *see also* D.I. 466 at 19)

The Court is not persuaded. In the '743 patent, the "each" claim language at issue comes after a "predicate step," as even FMI acknowledges, (Tr. at 151)—"sequencing extracellular polynucleotides from a bodily sample[.]" And so it follows that the plain language of the claims would require each of the extracellular polynucleotides *that are being sequenced* to generate two or more sequence reads (like the Court's construction for the '992 patent). In contrast, the language of the '731 patent, for example, recites steps of: (1) amplifying the tagged parent polynucleotides; *and then* (2) sequencing the amplified tagged polynucleotides to produce a plurality of sequence reads from each of the tagged parent polynucleotides. ('731 patent, col. 62:18-25) FMI's non-infringement argument here is that the Accused Products do not infringe this claim limitation because they do not sequence every extracellular polynucleotide *from the bodily sample*, (Civil Action No. 17-1616, D.I. 299 at 10), and PGDx appears to make the same non-infringement argument here as it does for the '731 patent, (D.I. 495 at 9; PGDx's Summary Judgment Presentation, Slide 55; *see also* D.I. 466 at 21). The Court therefore recommends that Defendants' motions be denied with respect to this claim limitation of the '743 patent.

Court construed to mean "produce two or more sequence reads for every one of the parent polynucleotides that is sequenced," (D.I. 402 at 33; D.I. 541 at 5).[16]

With respect to the '731 patent, Guardant does not dispute that Defendants' Accused Products[17] do not literally infringe this limitation. (*See* Guardant's Summary Judgment Presentation, Slide 112; Civil Action No. 17-1616, D.I. 366 at 1-2; D.I. 495 at 8; Tr. at 136-37) Thus, the Court recommends that Defendants' MSJs of Non-Infringement be granted with respect to literal infringement of the "plurality" limitation in the asserted claims of the '731 patent.

With respect to the '992 patent, only PGDx moves for summary judgment of non-infringement with respect to literal infringement of the "plurality" limitation. (*See* D.I. 466 at 20 n.3; FMI's Summary Judgment Presentation, Slide DSJ 4; Tr. at 115) PGDx asserts that Guardant's expert did not opine that there is literal infringement with respect to this limitation of the '992 patent. (D.I. 431 at 17 (citing D.I. 433, ex. 4 at ¶ 166); D.I. 495 at 8-9) But the Court agrees with Guardant that its expert *did* opine on literal infringement regarding this limitation, asserting that PGDx's use of paired-end sequencing produces two sequence reads from each of the tagged parent polynucleotides. (D.I. 466 at 20; *see also, e.g.*, D.I. 468, ex. 79 at ¶ 157; D.I. 467, ex. 93 at 91-92; *id.*, ex. 94 at 531; Tr. at 115-16)[18] And there is thus a dispute of fact with

---

[16] The bulk of Guardant's answering brief with respect to this issue was spent arguing that the construction requiring two or more sequence reads to be produced "for every one of the parent polynucleotides" was erroneous, (D.I. 466 at 17-18), but the District Court has since adopted that construction, (D.I. 541 at 5, 9).

[17] FMI's Accused Products are the FoundationACT® and FoundationONE Liquid® assays. (Civil Action No. 17-1616, D.I. 299 at 1)

[18] PGDx has moved to strike this literal infringement theory (as well as Guardant's literal infringement theory with respect to the next limitation) on the basis that it was newly

respect to whether the Accused Product satisfies this limitation. The Court recommends that this portion of PGDx's motion be denied.

Guardant further asserts DOE infringement theories with respect to the '731 and '992 patents. (D.I. 466 at 21) PGDx moves for summary judgment of non-infringement with respect to both theories, (D.I. 431 at 17), and FMI moves for summary judgment with respect to Guardant's DOE theory for the '731 patent, (Civil Action No. 17-1616, D.I. 366 at 2; FMI's Summary Judgment Presentation, Slide DSJ 4). Summary judgment is not warranted.

Defendants argue that claim vitiation and specific exclusion bar Guardant's DOE theories with respect to the '731 and '992 patents.[19] (Civil Action No. 17-1616, D.I. 299 at 4-5; D.I. 431 at 17) By way of support, they cite largely to different cases in which courts have found such doctrines to bar a plaintiff's DOE theories. (Civil Action No. 17-1616, D.I. 299 at 4-5; D.I. 431 at 17) Focusing on the instant record before the Court here, however, Guardant's expert sets out numerous paragraphs explaining his opinion that to the extent there are some parent polynucleotides in the Accused Products that generate fewer than two sequence reads, the products nevertheless perform substantially the same function as the claim element at issue, and

raised for the first time in Guardant's answering brief. (D.I. 497; D.I. 498 at 1-2; D.I. 517 at 2) But Dr. Cooper had asserted in his expert report that PGDx's paired end sequencing process "'produces a plurality of sequence reads from each of the tagged parent polynucleotides[,]'" (D.I. 507 at 3-4 (quoting D.I. 468, ex. 79 at ¶ 157)), and thus this portion of PGDx's Motion to Strike is not well taken and will not be granted.

[19] PGDx argues that the Court should grant summary judgment of no infringement under the DOE with respect to the "plurality" limitations for the '731 patent and '992 patent in a single consolidated subsection. (D.I. 431 at 17-18; D.I. 495 at 9) With respect to the '992 patent, it is not clear to the Court whether PGDx has presented rebuttal to the application of the DOE that is specific to the Court's construction that requires two or more sequence reads from every one of the parent polynucleotides *that is sequenced.* (D.I. 466 at 23)

that the products' failure to meet the full scope of the claim language would be a result of "normal inefficiencies." (D.I. 468, ex. 79 at ¶ 168; *see also id.* at ¶¶ 167, 169-77, 458; *id.*, ex. 80 at ¶¶ 161-73) Furthermore, Guardant points to testimony of Defendants' experts suggesting that: (1) such normal inefficiencies "sometimes . . . happen" and would not be outside the scope of the claims, (D.I. 466 at 23-24 (citing D.I. 467, ex. 86 at 94, 101-02; *id.*, ex. 87 at 381-82)), and (2) the Illumina sequencing platform (which also suffers from these "inefficiencies") could be used to carry out the claimed invention, (*id.* at 24 (citing D.I. 467, ex. 60 at 146, 149-50)). Guardant notes that such testimony demonstrates that the person of skill in the art "see[s] no inconsistency between the claim language and a process that is not 100% efficient" (and that it follows that a reasonable jury therefore would not either). (*Id.*; *see also* Tr. at 159-64) On this record, the Court finds that vitiation or specific exclusion do not preclude application of the DOE, and it will be up to the factfinder to determine whether the alleged equivalence represents an insubstantial difference from the claims.

As for the '731 patent, Defendants further posit that the disclosure-dedication rule precludes Guardant's DOE theory. (D.I. 431 at 18; Civil Action No. 17-1616, D.I. 299 at 5-6) On this front, they assert that the patent specification discusses embodiments in which only a subset of polynucleotides produce sequence reads, and "[b]ecause Guardant disclosed, but did not claim, such embodiments, Guardant cannot recapture them through" DOE. (Civil Action No. 17-1616, D.I. 299 at 6; *see also* D.I. 431 at 18)

The disclosure-dedication rule precludes a finding of infringement that is based on subject matter disclosed in the written description but not claimed. *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019); *ViiV Healthcare Co. v. Gilead Scis., Inc.*, Civil Action No. 18-224-CFC, — F. Supp. 3d —, 2020 WL 567398, at *2 (D. Del. Feb. 5, 2020).

Such unclaimed subject matter is dedicated to the public. *Eli Lilly*, 933 F.3d at 1334; *ViiV Healthcare*, 2020 WL 567398, at *2. "The reason for the doctrine is that members of the public reading a disclosure of particular subject matter are entitled, absent a claim to it, to assume that it is not patented and therefore dedicated to the public (unless, for example, claimed in a continuation or other application based on the disclosure)." *Eli Lilly*, 933 F.3d at 1334.

The Court is not persuaded that the disclosure-dedication rule is a legal bar to Guardant's DOE infringement theories. This is so because, for example, claim 13 of the '992 patent (a continuation-in-part of the '731 patent) recites the elimination of some parent polynucleotides prior to the sequencing step. ('992 patent, col. 65:5-17; *see* D.I. 402 at 31) The disclosure-dedication rule is only triggered when the patentee "declines to claim subject matter" that is disclosed in the written description. *ViiV Healthcare*, 2020 WL 567398, at *3 (internal quotation marks and citation omitted) (concluding that the disclosure-dedication rule does not bar plaintiff from alleging equivalence as to a claim limitation reciting a species of the compound genus recited in another claim). With a related patent expressly claiming processes that do not generate a plurality of sequence reads from each parent polynucleotide, the disclosure-dedication rule does not preclude Guardant from asserting DOE with respect to the '731 patent. (*See* D.I. 466 at 23; Tr. at 164)

6. "Grouping Sequence Reads" Limitations (Both Defendants)

The '731, '822 and '992 patents recite "grouping" terms that require grouping "every one of the sequence reads" from the prior steps. (D.I. 402 at 25-26; D.I. 541 at 9-10) For the '731 patent, this requires grouping every sequence read that is generated into a family, and for the '822 and '992 patents, this requires that every sequence read that is mapped to the reference genome be grouped. (D.I. 402 at 25-26; D.I. 466 at 25)

Here again, Guardant first argues that the Court's constructions are erroneous. (D.I. 466 at 25-29) But the District Court has since overruled Guardant's objections and adopted the constructions. (D.I. 541 at 5, 9-10)

Next, Guardant contends that even under the Court's construction of the "grouping" terms, summary judgment of non-infringement is not warranted "for at least the '822 and '992 patents" with respect to literal infringement. (D.I. 466 at 29)[20] The infringement issue with respect to these limitations is where exactly the filtering, mapping and grouping functionalities happen in Defendants' accused processes—if they filter some sequence reads *after* mapping (but before grouping), they would not literally infringe the grouping steps, because that would mean that not every mapped sequence read could be grouped. (*See id.* at 30; Tr. at 129, 144) Guardant's expert Dr. Gregory Cooper provided opinions as to why the Accused Products literally infringe the "grouping" terms. (D.I. 468, ex. 79 at ¶¶ 190-94, 526; *id.*, ex. 80 at ¶¶ 187-97, 591)[21] Further, Guardant cites to evidence from Defendants' experts' reports that could

[20] Guardant does not dispute that the Court should grant summary judgment of non-infringement of the '731 patent with respect to literal infringement of the "grouping" limitation. (D.I. 466 at 29; *see also* Civil Action No. 17-1616, D.I. 366 at 3; D.I. 495 at 9; Tr. at 128, 144, 166) Thus, the Court recommends that Defendants' motions be granted with respect to literal infringement of the '731 patent.

[21] PGDx moves to strike Guardant's literal infringement theory with respect to the "grouping" terms, arguing that prior to serving its answering brief in opposition to PGDx's motion, Guardant had only asserted infringement under DOE with respect to these terms. (D.I. 497; D.I. 498 at 1; D.I. 517 at 1) It is true that in one portion of Dr. Cooper's expert report, there was a chart indicating that with respect to these terms, there would be "at a minimum infringement under the doctrine of equivalents[.]" (D.I. 498, ex. 4 at 26-27) But the arguments and evidence that Guardant cites to in its answering brief here all were found in later portions of Dr. Cooper's report that address the "grouping" terms. (D.I. 466 at 29 (citing D.I. 468, ex. 79 at ¶¶ 190-94, 527)) PGDx's expert Dr. Harismendy responded to these opinions. (*See, e.g.*, D.I. 432, ex. 1 at ¶¶ 70-71, 80, 123-24) Under these circumstances, the Court is not sure that this theory was untimely disclosed, but even if it was, the *Pennypack* factors would not warrant exclusion of this evidence.

suggest that the Accused Products [redacted] (D.I. 466 at 30 (citing D.I. 432, ex. 1 at ¶ 75; D.I. 467, ex. 78 at ¶ 187))[22] Thus, the motion should be denied as to literal infringement regarding these two patents.

With respect to the DOE, here again Dr. Cooper's report contains detailed opinions as to why Defendants' products infringe these limitations under the DOE. (D.I. 468, ex. 79 at ¶¶ 199-210; *id.*, ex. 80 at ¶¶ 199-12) And Defendants do not substantively challenge those opinions, but instead assert that Guardant's DOE theories are foreclosed by claim vitiation, specific exclusion and the disclosure-dedication rule. (D.I. 431 at 19-20; Civil Action No. 17-1616, D.I. 299 at 7, 9)

The Court agrees with Defendants that the disclosure-dedication rule bars Guardant's DOE argument. (D.I. 431 at 19-20; Civil Action No. 17-1616, D.I. 299 at 7) As previously

[22] FMI filed its Motion for Leave, in which it asks for leave to submit the Declaration of Dr. Gary Benson in Support of FMI's MSJ of Non-Infringement. (Civil Action No. 17-1616, D.I. 318) Dr. Benson is FMI's source code expert, and at issue is his declaration that FMI submitted in support of FMI's MSJ of Non-Infringement with respect to the "grouping" terms in the '822 and '992 patents. (Civil Action No. 17-1616, D.I. 319 at 1-2) In the declaration, Dr. Benson analyzed the same source code files that had been available to and cited by Dr. Cooper in light of the Court's construction of the "grouping" terms. (*Id.* at 2)

With this motion, FMI suggests that Dr. Benson's declaration was not untimely served because the Court had altered Defendants' proposed constructions for these terms, and so it was that alteration that necessitated the declaration. (*Id.* at 1-2) But the Court actually *adopted* Defendants' proposed construction for the "grouping" term in the '992 patent (which, obviously, Defendants were pressing long before Dr. Benson submitted his rebuttal expert report), and it modified Defendants' proposed construction for the '822 patent to align with the construction for the '992 patent. (D.I. 402 at 20, 25-26; Civil Action No. 17-1616, D.I. 341 at 1) The Court therefore agrees with Guardant that FMI's explanation "makes no sense." (Civil Action No. 17-1616, D.I. 341 at 1) The Scheduling Order in the case did not provide for leave to serve sur-reply expert reports. And FMI has not shown good cause for why that schedule should be altered here to allow it to provide what is, in essence, a sur-reply expert report. (*Id.* at 2) The Court therefore denies FMI's Motion for Leave.

explained, the specification discloses embodiments that filter out sequence reads before grouping, (*see* D.I. 431 at 19-20), and after mapping, (*see* D.I. 495 at 10; Civil Action No. 17-1616, D.I. 366 at 5). While Guardant relies on dependent claims 5 of the '731 patent and dependent claim 10 of the '822 patent as encompassing filtering before grouping, (D.I. 466 at 31), in line with the Court's prior discussion of this issue during claim construction, it concludes that (in light of the entire intrinsic record) this is not how those claims should be understood, (D.I. 402 at 24). Instead, such claims appear to speak to filtering sequence reads after grouping. (*Id*.)

Therefore, the Court recommends that summary judgment of no DOE infringement be granted with respect to the '731, '822 and '992 Patents.

7. "Processing the Ratio With a Similarly Derived Number From a Reference Sample" Limitation (FMI Only)

Claim 10 of the '743 patent requires, *inter alia*: (1) for each mappable base position, calculating a ratio of (a) a "number of mapped unique sequence reads that include a variant as compared to the reference sequence" to (b) a "number of total unique sequence reads for each mappable base position" and (2) "processing the ratio with a similarly derived number from a reference sample" (the "processing the ratio step"). ('743 patent, col. 63:43-49) FMI asserts that in light of the undisputed evidence, Guardant has failed to meet its burden to prove that its Accused Products "process[] the ratio with a similarly derived number from a reference sample." (D.I. 299 at 10-11; D.I. 366 at 7-9)[23] In support, FMI's opening brief relied exclusively on its source code, arguing that: (1) it controls whether the Accused Products process a ratio from a

[23] In this sub-section, references are to the docket in Civil Action No. 17-1616-LPS-CJB, the case in which FMI is the Defendant.

reference sample; (2) FMI's expert's non-infringement analysis of the source code is unrebutted; and (3) summary judgment of non-infringement should be granted because Guardant has failed to produce sufficient evidence to prove that FMI's Accused Products infringe the processing the ratio step. (D.I. 299 at 10-11)

However, FMI's opening brief fails to address a document that Dr. Cooper pointed to as disclosing the processing the ratio step. (*See* D.I. 337 at 15) In his report, Dr. Cooper opined that responses that FMI had provided to "New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP Communications) ['the CLEP document'] []explain[] that the [redacted] (D.I. 302, ex. 25 at ¶ 456; *see also id.*, ex. 29 at 265) When Guardant showed the CLEP document to FMI's expert Dr. Benson at deposition, he stated that he had never seen the document and that he did not have an opinion on how FMI uses [redacted] in its liquid biopsy products. (D.I. 338, ex. 65 at 80-82)

In response, FMI argues that this "secondary, less technical" document cannot create a genuine dispute of fact with respect to this limitation in light of FMI's source code, (D.I. 366 at 8; Tr. at 155-56), but the Court is not convinced. It is true that Dr. Cooper testified that "source code is ultimately the instructions that are given to the computer[,]" (D.I. 302, ex. 30 at 799), but he also explained that source code is "one source among multiple potential sources that all are valuable" in determining what is happening in a process, (*id.* at 798).[24]

[24] While FMI did not address the CLEP document with respect to this limitation in its opening brief, it did affirmatively cite to the document in that brief in support of its argument that the Accused Products do not meet different limitations in different patents. (D.I. 299 at 8 (citing D.I. 302, ex. 19); *see also* Tr. at 168-69) This seems to contradict FMI's suggestion that this document should be given no weight in the analysis with respect to the processing a ratio step.

The issue is a close one. But drawing all reasonable inferences in Guardant's favor, as it must at this stage, the Court concludes that in light of the CLEP document, there remains a genuine dispute of material fact as to whether FMI's Accused Products meet the processing the ratio step in claim 10 of the '743 patent.

B. Invalidity

1. Defendants' MSJ of Invalidity

In their MSJ of Invalidity, Defendants move for invalidity of the asserted patents on four grounds. The Court will take up each ground in turn.

a. Claims 1-3, 5-14 and 16-17 of the '731 Patent and Claims 19 and 20 of the '992 Patent are Invalid for Indefiniteness

Claim 1 of the '731 patent (and dependent claims 2-3, 5-14 and 16-17 of the '731 patent) and claims 19 and 20 of the '992 patent recite "sequence information at a beginning of the sequence derived from cell-free DNA/the cfDNA [or 'cell-free DNA'] molecule" and "sequence information at an end of the sequence derived from cell-free DNA/the cfDNA molecule" (the "sequencing terms"). (*See* D.I. 389 at 12) During claim construction, the Court issued a Report and Recommendation finding that Defendants proved by clear and convincing evidence that the sequencing terms are indefinite (and accordingly recommending that the District Court adopt such a finding). (*Id.* at 12-20) Defendants argue that summary judgment should be entered invalidating these claims as indefinite in light of that recommendation. (D.I. 438 at 2; D.I. 492 at 1-2)

However, the District Court recently issued a Memorandum Order in which it sustained Guardant's objections with respect to the sequencing terms, concluding that Defendants did not produce evidence that would "necessarily persuade all reasonable factfinders that a [person of

ordinary skill in the art, or 'POSITA'] would be unable to determine, with reasonable certainty, the scope of the disputed claims." (D.I. 541 at 5, 7) The Court therefore recommends that Defendants' motion be denied on these grounds.

b. Claim 2 of the '822 Patent and Claims 1-7, 9, 13-15, 18-20, 22 and 29-31 and 33 of the '992 Patent are Invalid for Lack of Written Description

Defendants argue that claim 2 of the '822 patent and claims 1-7, 9, 13-15, 18-20, 22 and 29-31 and 33 of the '992 patent are invalid for lack of written description. (D.I. 438 at 3-5) The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification[.]" *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (internal quotation marks and citation omitted). To satisfy this requirement, a patent specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (internal alterations, quotation marks and citations omitted). To meet this standard, the specification must convey that the patentee "had possession of the claimed subject matter as of the filing date." *Id*. This test requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id*. Whether a specification satisfies the written description requirement is a question of fact. *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014). Nevertheless, "[c]ompliance with the written description requirement . . . is amenable to summary judgement in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008).

Invalidity for lack of written description must be proven by clear and convincing evidence. *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015).

Claim 2 of the '822 patent recites "detecting, at one or more loci, at least one single nucleotide variant, at least one gene fusion and at least one copy number variant" and claim 1 of the '992 patent (and dependent claims 2-7, 9, 13-15, 18-20, 22, 29-31 and 33) recites "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), an insertion or deletion (indel), and a gene fusion" (the "detecting terms"). (*See* D.I. 389 at 3-6)[25] The Court has construed the detecting terms to mean, respectively, "[a]cross one or more genetic loci, detecting at least one single nucleotide variant, at least one gene fusion, and at least one copy number variant" and "[a]cross one or more genetic loci, detecting 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), an insertion or deletion (indel), and a gene fusion[.]" (*Id.* at 20-21; D.I. 541 at 6-7)[26]

It is undisputed that the specification does not disclose a specific embodiment in which multiple mutations at a single locus are detected. (*See* D.I. 389 at 6; D.I. 492 at 2) Defendants

[25] The detecting terms "pertain to 'detecting' various kinds of cancer-causing mutations (e.g., single nucleotide variants, gene fusions, and copy number variations) in DNA that may be found in the bloodstream of a cancer patient[.]" (*See* D.I. 405 at 2)

[26] Defendants had asserted during claim construction that the detecting terms were indefinite because "the methods disclosed in the specification identify only one mutation per locus, but the claims require identifying more than one mutation per locus." (D.I. 389 at 7 (internal quotation marks and citations omitted)) The Court rejected this argument. (*Id.* at 7-11; D.I. 541 at 6-7)

assert that: (1) with the challenged claims encompassing the detection of either one type of mutation at a single locus or multiple types of mutations at a single locus, and (2) the specification describing only the detection of one type of mutation at a single locus, (3) these claims lack adequate written description support and thus summary judgment must be granted. (D.I. 438 at 5; D.I. 492 at 2)

Viewing the evidence in favor of Guardant, as it must at this stage, the Court finds that there is at least a material question of fact as to whether the patents' disclosure is sufficient to demonstrate possession of the full scope of the challenged claims to a skilled artisan. A patent specification is not required to contain "examples explicitly covering the full scope of the claim language [as] only enough must be included to convince a person of skill in the art that the inventor possessed the invention[.]" *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). The evidence could demonstrate that the same approach disclosed in the specification to detect a single mutation at a particular locus (molecular barcoding) would allow for detection of multiple mutations at that locus. (*See, e.g.*, D.I. 468, ex. 81 at ¶ 338; *see also* D.I. 541 at 6-7 (citing D.I. 405 at 4-5)) And various portions of the specification seem to suggest that certain disorders could cause two types of mutations at a single loci, as Guardant asserts. (D.I. 465 at 5-7 (citing '992 patent, col. 54:35-39 ("For example, in certain cases, genetic disorders or infectious diseases may cause a certain genetic mosaicism within a subject. This genetic mosaicism may cause copy number variation and rare mutations that could be observed."))) The specification further explains that "[t]he methods of this disclosure may be used to generate or [sic] profile, [or] fingerprint [a] set of data that is a summation of genetic information derived from different cells in a heterogeneous disease. *This set of data may comprise copy number variation and rare mutation analyses alone or in combination*." ('992

patent, col. 55:16-21 (emphasis added); *see also id.*, col. 55:1-6) Guardant explains that such disclosures in the specification "contemplate[] analysis that would lead to observation of multiple types of genetic aberrations, which supports the claim limitations at issue in combination with disclosures elsewhere in the specification that describe the process for detecting such aberrations." (D.I. 465 at 8)

In sum, even though the challenged claims may be broader than the specific examples disclosed in the specification, the evidence demonstrates a dispute of fact as to whether the skilled artisan reading the specification would understand that the inventors possessed the full scope of the challenged claims. Thus, the Court recommends that this portion of Defendants' motion be denied. *See Gen-Probe Inc. v. Becton Dickinson & Co.*, 899 F. Supp. 2d 971, 981-82 (S.D. Cal. 2012) (noting that the patentee was not required to specifically describe or provide an example in the specification of the analyzer performing particular functions to satisfy the written description requirement and that the inquiry raised disputed issues of fact, where the parties' respective experts provided conflicting testimony on whether one of skill in the art reading the specification would understand the inventors possessed the full scope of the asserted claims); *see also NovelPoint Learning LLC v. Leapfrog Enters., Inc.*, No. 6:10-cv-229 JDL., 2012 WL 629530, at *5 (E.D. Tex. Feb. 27, 2012).[27]

[27] Guardant's first response to Defendants' motion on this ground was difficult to understand, as it contended that the Court's claim construction "does not require that multiple types of genetic aberrations be detected at *each loci* of a plurality of loci, but rather that multiple types of aberrations are detected *across* multiple loci." (D.I. 465 at 4 (certain emphasis in original)) The Court agrees with Defendants that this position is clearly not in line with the Court's construction (or Guardant's own previously-expressed understanding thereof). (*See, e.g.*, D.I. 492 at 3 n.7; D.I. 405 at 1-2, 4 (Guardant noting that as "underscored" in the Court's Report and Recommendation in which the Court recommended constructions for the "detecting" terms, "the claims 'recite detecting more than one mutation at the same locus at a time'"))

c. Claim 2 of the '822 Patent and Claims 1-7, 9, 13-15, 18-20, 22, 29-31 and 33 of the '992 Patent Are Not Entitled to an Earlier Priority Date and Are Invalid Under 35 U.S.C. § 102(a)

Defendants argue that summary judgment should be granted that claim 2 of the '822 patent and claims 1-7, 9, 13-15, 18-20, 22, 29-31 and 33 of the '992 patent are not entitled to an earlier priority date and thus are invalid under 35 U.S.C. § 102(a). (D.I. 438 at 5) In support, they make the same argument as above—that the priority applications that Guardant relies on (which would allow for priority dates of September 4, 2012 for the '822 patent and March 5, 2014 for the '992 patent) do not describe detecting multiple aberrations at a single locus; in light of this, Defendants assert that Guardant has not established entitlement to an earlier priority date for these claims. (*Id.* at 5-6; *see also* D.I. 465 at 8-9 (Guardant noting that "if Defendants' written description arguments fail, its priority arguments must fail as well")) Defendants then argue that upon summary judgment of no priority, there is no dispute that Guardant's prior sales of its own product more than a year before the actual filing dates of the '822 and '992 patents invalidate the challenged claims of these patents. (D.I. 438 at 6)

However, the earliest priority application at issue (that dating to September 4, 2012) contains some of the same disclosures relied upon above by the Court in recommending that Defendants' motion for summary judgment of lack of written description be denied. (D.I. 465 at 8 (citing D.I. 467, ex. 84 at ¶ [0099])) And the next earliest provisional application filed on September 21, 2012 contains some of those disclosures as well. (*Id.* at 8-9 (citing D.I. 467, ex. 85 at ¶ [00121], ¶ [00124], ¶ [00125])) Thus, the Court recommends that this portion of Defendants' motion be denied as well.

d. Claims 1-7, 9, 13-15, 18-20, 22, 29-31 and 33 of the '992 Patent are Invalid for Lack of Enablement

Defendants assert that claims 1-7, 9, 13-15, 18-20, 22, 29-31 and 33 of the '992 patent are invalid for lack of enablement. (D.I. 438 at 6-8) "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2012). Pursuant to the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the *full scope* of the claimed invention without undue experimentation." *Id.* at 1380 (internal quotation marks omitted; emphasis added). Because the enablement inquiry takes into account what is known to one skilled in the art, the specification need not include that which is already known to and available to one of ordinary skill in the art. *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). Enablement is a "legal question based on underlying factual determinations." *Vasudevan Software, Inc.*, 782 F.3d at 684. Invalidity for lack of enablement must be proven by clear and convincing evidence. *Id.*

Independent claim 1 of the '992 patent recites "attaching tags comprising barcodes" to "at least 20% of the cfDNA molecules[.]" ('992 patent, col. 64:6-8) Claim 12 depends from claim 1 and requires "wherein at least 80% of the cfDNA molecules are tagged by the attaching." (*Id.*, col. 65:3-4) Therefore, to enable the full scope of claim 1, the patent specification must teach those skilled in the art how to tag at least 80% of the cfDNA molecules without undue experimentation. *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368 (Fed. Cir. 2012) ("Because [dependent] claim 2 sets forth a concentration range, that range at a minimum must be included in [independent] claim 1, whatever its limitations."). Defendants assert that the '992 patent does not satisfy this requirement, as it does not include an explanation of how to achieve at least 80% tagging, nor provide any examples of such efficiency. (D.I. 438 at 7) At most,

according to Defendants, the patent is an "invitation for further research" regarding how to achieve at least 80% tagging. (*Id.* at 8)

The Court agrees with Guardant that there is a genuine dispute of material fact with respect to whether the optimization process to achieve at least 80% tagging was routine, and that summary judgment of lack of enablement is therefore inappropriate. (*See* D.I. 465 at 9-11) Guardant's expert Dr. Cooper opines that the patent discloses a protocol for tagging that includes "the use of a molar excess of adaptors relative to cell-free DNA, in addition to identifying appropriate enzymes and kits for carrying out the barcoding reaction." (D.I. 468, ex. 81 at ¶ 334 (citing '992 patent, cols. 42:50-43:6)) Furthermore, Dr. Cooper asserts that the patent provides additional details with respect to "conditions, enzymes and avenues of optimization for carrying out the barcoding reaction" and that such instructions (particularly the guidance to use a molar excess of adaptors) "provide extensive guidance" for achieving 80% tagging. (*Id.* at ¶ 335 (citing '992 patent, cols. 36:48-37:6))

As further evidence that a skilled artisan would not have problems achieving the full range of barcoding efficiency from the disclosure in the patent, Guardant points out that one of the inventors of the '992 patent, Dr. Stefanie Mortimer, achieved 50% tagging upon experimenting with a greater than 10x molar excess of adaptors. (D.I. 465 at 10 (citing D.I. 467, ex. 91 at GUARDPG00149384; D.I. 468, ex. 90 at ¶ 168)) And Guardant also contends that certain testimony from Defendants' experts supports the notion that the optimization process was routine (and that the relevant claims of the '992 patent are thus enabled). (*Id.* at 10-11) For example, PGDx's expert Dr. Olivier Harismendy, in opining that the asserted patents are invalid for obviousness, asserted that: (1) it was routine to attach barcodes using ligation; (2) it was a "routine process of optimization to increase the efficiency of the ligation process[;]" and the

steps for doing so were "well known in the art[;]" and (3) the prior art explained that it "attache[d] barcodes to nucleotides with quantitative (approaching 100% yield) labeling[.]" (D.I. 467, ex. 77 at ¶¶ 497, 500-01; *see also id.*, ex. 89 at ¶ 661 (FMI's expert Dr. Stacey Gabriel opining that attaching tags to at least 20% of the cfDNA molecules was "well understood and conventional activity"))

For all of these reasons, the Court recommends that this portion of Defendants' motion be denied, as the record demonstrates that there is a genuine issue of material fact with respect to enablement. *See, e.g.*, *Ventura Ltd. v. GlaxoSmithKline LLC*, Civil Action No. 16-638-RGA, 2019 WL 1244942, at *4-5 (D. Del. Mar. 18, 2019) (denying defendant's motion for summary judgment with respect to enablement, where both parties presented evidence as to the quantity of experimentation that would be required to make the full scope of the claims); *Amgen Inc. v. Sanofi*, Civil Action No. 14-1317-RGA, 2019 WL 259099, at *3 (D. Del. Jan. 18, 2019) (denying defendant's motion for summary judgment with respect to enablement where the parties disputed whether the "specification's disclosed process is an 'unpredictable, trial and error process' requiring years or decades to make additional embodiments within the claimed genus").

2. PGDx's MSJ of Invalidity

PGDx (but not FMI) moved for summary judgment of invalidity on dependent claims 5-7, 9, 15-17 and 19 of the '743 patent, asserting that they improperly expand the scope of the claims from which they depend. (D.I. 431 at 20-21; D.I. 495 at 10-11) Independent claims 1 and 10 of the '743 patent each require "sequencing extracellular polynucleotides from a bodily sample from [a/the] subject[.]" ('743 patent, cols. 62:45-46, 63:28-29) Dependent claims 5-7 and 9 (which depend from claim 1) and 15-17 and 19 (which depend from claim 10) each recite a

step of attaching "one or more barcodes to the extracellular polynucleotides *or fragments thereof* prior to sequencing[.]" (*Id.*, cols. 63:7-17, 21-24, 64:12-21, 25-28 (emphasis added))

A dependent claim must specify a "further limitation of the subject matter claimed" in the independent claim from which it depends. 35 U.S.C. § 112(d). If a dependent claim has a scope that is broader than the claim from which it depends, then the dependent claim is invalid under this provision. *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006) (holding that a claim that did not "narrow the scope" of the claim from which it depended and instead recited "non-overlapping subject matter" was invalid under Section 112(d)); *see also Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1362 (Fed. Cir. 2016) ("A dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid.") (citing cases). A defendant bears the burden of establishing that a dependent claim fails to satisfy Section 112(d). *See Team Worldwide Corp. v. Wal-Mart Stores, Inc.*, CIVIL ACTION NO. 2:17-CV-00235-JRG, 2018 WL 1353116, at *14 (E.D. Tex. Mar. 15, 2018).

The dependent claims at issue, as noted above, are directed to extracellular polynucleotides *or fragments* thereof, and PGDx asserts that such fragments are "different from extracellular polynucleotides" because a fragment is a "different piece of DNA created by breaking apart the isolated extracellular polynucleotide." (D.I. 431 at 20-21; D.I. 495 at 10-11; *see also* D.I. 432, ex. 3 at ¶¶ 487-88; D.I. 433, ex. 16 at ¶ 98) And so according to PGDx, the dependent claims "cover sequencing of a completely different pool of polynucleotides" and thus "improperly broaden the scope of the independent claim[s] from which they depend." (D.I. 431 at 21)

Guardant, for its part, argues that PGDx's position is misplaced because fragments of extracellular polynucleotides are a *subset* of extracellular polynucleotides. (D.I. 465 at 11) Therefore, Guardant contends, the reference to "extracellular polynucleotides" in claims 1 and 10 is "broad" in that it "covers a chain of nucleotides found outside of a cell, including those that are fragments." (*Id.* at 12)[28] According to Guardant, then, the dependent claims do not improperly broaden the scope of the independent claims; rather, they "merely clarify that the extracellular polynucleotides may be fragmented (or not) before they are barcoded." (*Id.*)

The claim language of the dependent claims (reciting extracellular polynucleotides "or fragments *thereof*") supports Guardant's view. So too does the specification of the '743 patent, which states that "this invention also provides compositions of tagged polynucleotides. The *polynucleotides can comprise fragmented DNA*." ('743 patent, col. 41:57-59 (emphasis added)) The language at issue in the dependent claims thus seems to have the same scope as the reference to "extracellular polynucleotides" in the independent claims, while adding further limitation(s) with respect to attaching barcodes thereto. Section 112(d) is not violated by these dependent claims, as this is not a situation where the dependent claims contradict or claim non-overlapping subject matter as the claims from which they depend. *Cf. Multilayer Stretch Cling Film Holdings*, 831 F.3d at 1362 (concluding that Section 112(d) was violated and dependent claim 10 was invalid where the claim from which it depended "excludes LDPE from the inner layers, while dependent claim 10 includes it [and] [a]s such, claim 10 is inconsistent with claim 1 and, indeed, contradicts claim 1"); *Amgen Inc. v. Hospira, Inc.*, Civil Action No. 15-839-RGA, 2016

[28] The parties agreed to construe "extracellular polynucleotides" to mean "[p]olynucleotides that exist(s) within a bodily fluid within the body outside of a cell and in solution, including in blood, plasma, serum, urine, saliva, mucosal excretions, sputum, stool or tears." (D.I. 53, ex. A)

WL 7013483, at *3-4 (D. Del. Nov. 30, 2016) (finding that dependent claim 8 was invalid in violation of Section 112(d) where independent claim 1 required only one isoform and claim 8 "contradicts claim 1's limitation that the isoform is 'isolated' by requiring a mixture 'consisting essentially of two or three' isoforms" and "[c]laim 8 thus improperly narrows claim 1").[29] For these reasons, the Court recommends that PGDx's MSJ of Invalidity be denied.

3. Guardant's MSJ Regarding FMI's Obviousness Combinations

Guardant requests that the Court grant summary judgment on FMI's 14 obviousness combinations, arguing that FMI's expert, Dr. Gabriel, failed to establish how or why a skilled artisan would have combined them. (D.I. 437 at 2, 21-22)[30] Instead, according to Guardant, Dr. Gabriel provides charts that piece together multiple references without explaining how these

[29] In an expert report, Guardant's expert Dr. Cooper appears to state that fragments of extracellular polynucleotides are *not* a subset of extracellular polynucleotides. (D.I. 468, ex. 90 at ¶ 386 (stating that he "disagree[s] that the reference to 'fragments' of the 'extracellular polynucleotides' merely specifies a subset of the broader category 'extracellular polynucleotides'")) In light of Guardant's argument here, (D.I. 465 at 12), and the content of the patent at issue, the Court presumes that this portion of Dr. Cooper's report is just a typographical error.

[30] A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). A party seeking to invalidate a patent on the basis of obviousness must establish (by clear and convincing evidence) that a POSITA would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the POSITA would have had a reasonable expectation of success in doing so. *Id.* In determining what would have been obvious to a POSITA, the use of hindsight is not permitted. *See KSR*, 550 U.S. at 421 (cautioning the trier of fact against "the distortion caused by hindsight bias" and "arguments reliant upon *ex post* reasoning" in assessing obviousness); *see also Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 664 (D. Del. 2012).

pieces fit together on a claim-by-claim basis. (*Id.* at 22 (citing D.I. 441, ex. 43 at exs. A1-D4)) In addition to these charts, Dr. Gabriel also submitted an accompanying report. (D.I. 441, ex. 45) Guardant's opening brief addresses the report in a single sentence, contending that the report "provides sweeping generalizations on the motivations of a person of ordinary skill in the art generically." (D.I. 437 at 22-23 (citing D.I. 441, ex. 45 at Section XII.C.2.c-f, XII.D.2.c-e, XII.E.c-d, XII.F.2.c-d))

Guardant's Motion is not well-taken. Guardant's focus on Dr. Gabriel's charts ignores their purposes, and it also ignores the content of her actual expert report. (D.I. 456 at 22, 25) She testified that her charts were intended to "enumerate the elements of the prior art that disclose the various claim limitations" and not constitute an "analysis of motivation to combine[,]" and that those arguments "are laid out more fully in the report." (D.I. 461, ex. 38 at 99-100; *see also id.* at 101) And in her report, Dr. Gabriel provides sufficient analysis to create a dispute of fact with respect to motivation to combine.

To take one example, Guardant contends that FMI failed to meet its burden to show a motivation to combine with respect to the combination of Fan, Forshew, Schmitt and Schmitt 2012. (D.I. 437 at 23; D.I. 499 at 12) Yet in Dr. Gabriel's expert report, numerous paragraphs set out her opinion as to why a person of ordinary skill in the art would have been motivated to combine the methods disclosed in these references (and why the skilled artisan would have a reasonable expectation of success in combining such methods to arrive at the claimed invention in the '822 patent). (D.I. 461, ex. 26 at ¶¶ 270-86) Further, Dr. Gabriel's corresponding claim chart notes which prior art reference(s) assertedly maps to each claim limitation. (*See, e.g.*, D.I.

441, ex. 43 at Exhibit B-1)[31] In light of this evidence, summary judgment on FMI's obviousness combinations is not warranted. *See, e.g.*, *TQ Delta, LLC v. ADTRAN, Inc.*, Civil Action No. 14-954-RGA, Civil Action No. 15-121-RGA, 2019 WL 4394931, at *3-4 (D. Del. Sept. 13, 2019); *Chapco, Inc. v. Woodway USA, Inc.*, 282 F. Supp. 3d 472, 495 (D. Conn. 2017).

IV. CONCLUSION

For the foregoing reasons, the Court recommends that PGDx's MSJ of Non-Infringement be GRANTED-IN-PART and DENIED-IN-PART; FMI's MSJ of Non-Infringement be GRANTED-IN-PART and DENIED-IN-PART; Defendants' MSJ of Invalidity be DENIED; PGDx's MSJ of Invalidity be DENIED and Guardant's MSJ Regarding FMI's Obviousness Combinations be DENIED. Further, the Court DENIES Guardant's Motion to Strike, PGDx's Motion to Strike, and FMI's Motion for Leave.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

[31] In response, Guardant's expert Dr. Cooper submitted a rebuttal report in which he spends several paragraphs refuting these opinions of Dr. Gabriel. (*See, e.g.*, D.I. 461, ex. 31 at ¶¶ 179-84) He did not appear to have trouble determining which prior art references Dr. Gabriel was relying on for the various claim limitations. (*See, e.g., id.* at ¶ 182 ("Dr. Gabriel relies on Fan and Forshew to teach the limitation of providing cell-free DNA.")) In the Court's view, Dr. Cooper's rebuttal analysis underscores that Dr. Gabriel's analysis with respect to motivation to combine is sufficient to survive summary judgment. (D.I. 456 at 23)

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **May 12, 2020** for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: May 7, 2020

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE