

**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

---

**MEMORANDUM ORDER**

WHEREAS, on February 6, 2020, Magistrate Judge Burke issued a Report and Recommendation (“February Report”) (D.I. 386)<sup>1</sup>, recommending that the Court deny Defendant Foundation Medicine, Inc.’s (“FMI”) motion for summary judgment of no willful infringement (D.I. 297);

WHEREAS, on February 20, 2020, FMI filed objections to the February Report (“FMI February Objections”) (D.I. 396), specifically objecting that Judge Burke erred in applying Federal Circuit precedent that had not yet been issued at the time its summary judgment motion was being briefed, and advancing a new legal argument that Plaintiff Guardant Health, Inc. (“Guardant”) cannot prove willful infringement under the governing precedent;

WHEREAS, on March 5, 2020, Guardant filed a response to FMI’s February Objections (“Guardant’s February Response”) (D.I. 399);

---

<sup>1</sup> All citations are to the record in *Guardant Health, Inc. v. Foundation Medicine, Inc.*, C.A. No. 17-1616-LPS-CJB, unless otherwise noted.

WHEREAS, on April 22, 2020, Judge Burke issued a Report and Recommendation (“April Report”) (D.I. 419),<sup>2</sup> recommending that the Court deny Guardant’s motion for summary judgment of no improper inventorship and no inequitable conduct (D.I. 291), and granting FMI’s *Daubert* motion to exclude the testimony of Drs. Becker and Cooper (D.I. 300) and providing leave for Guardant to file supplemental expert reports (D.I. 419 at 36-37);<sup>3</sup>

WHEREAS, no objections to the April Report were filed by either party;

WHEREAS, on May 7, 2020, Judge Burke issued a Report and Recommendation (“May Report”) (D.I. 432),<sup>4</sup> recommending that the Court grant in part and deny in part FMI’s motion for summary judgment of noninfringement (D.I. 296), deny FMI’s motion for summary judgment of invalidity (D.I. 290), deny Guardant’s motion for summary judgment on FMI’s obviousness combinations (D.I. 291), and also denying FMI’s motion for leave to submit a declaration (D.I. 318);

WHEREAS, on May 21, 2020, FMI filed objections to the May Report (“FMI’s May Objections”) (D.I. 438), specifically objecting that Judge Burke erred in finding factual disputes existed as to infringement of the “grouping” limitations in claim 1 of U.S. Patent No. 8,834,822

---

<sup>2</sup> Judge Burke’s April Report also addressed motions brought by the parties in related case *Guardant Health, Inc. v. Personal Genome Diagnostics, Inc.*, C.A. No. 17-1623-LPS-CJB. That matter was dismissed on August 31, 2020, mooted the motions then pending in that action. (See C.A. No. 17-1623-LPS-CJB D.I. 622)

<sup>3</sup> Guardant served supplemental reports from Drs. Becker and Cooper, which FMI has moved to strike (D.I. 453), a motion which remains before the Court and will be addressed by separate order.

<sup>4</sup> The May Report also addressed motions brought by the parties in the now-closed (and mooted) *Personal Genome Diagnostics* matter.

(the “’822 patent”) and claim 1 of U.S. Patent No. 9,902,992 (the “’992 patent”) and as to the “processing” limitations of claim 10 of U.S. Patent No. 9,840,743 (the “’743 patent”);

WHEREAS, on June 4, 2020, Guardant filed a response to FMI’s May Objections (“Guardant’s May Response”) (D.I. 443);

WHEREAS, on May 21, 2020, Guardant also filed objections to the May Report (“Guardant’s May Objections”) (D.I. 439), specifically objecting that Judge Burke improperly applied the disclosure-dedication rule on the basis of an incorrect claim construction of the “grouping” limitations found in the ’822, ’922, and ’731 patents;

WHEREAS, on June 4, 2020, FMI filed a response to Guardant’s May Objections (“Guardant’s May Response”) (D.I. 442);

WHEREAS, no objections were filed by either party to certain portions of the May Report, specifically: the recommendations that the Court deny FMI’s motion for summary judgment of invalidity (D.I. 290), deny Guardant’s motion for summary judgment on FMI’s obviousness combinations (D.I. 291), grant in part and deny in part FMI’s motion for summary judgment of noninfringement (D.I. 296) as to the “plurality limitations” found in claim 1 of U.S. patent No. 9,598,731 and claims 1 and 10 of the ’743 patent,<sup>5</sup> and grant FMI’s motion for

---

<sup>5</sup> FMI’s footnote objection (without significant – or persuasive – substantive support) to this portion of the May Report is waived. *See John Wyeth & Bro. Ltd. v. CIGNA Int’l Corp.*, 119 F.3d 1070, 1076 (3d Cir. 1997) (“[A]rguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived.”). In any event, to the extent FMI is trying to object to Judge Burke’s claim construction, the Court (considering that objection *de novo*) overrules it, instead agreeing with Judge Burke that the word “each” in the ’743 patent modifies its predicate step. (D.I. 432 at 20 n.15) It is not the case, as FMI contends, that “each” modifies “extracellular polynucleotides from a bodily sample.” Instead, “each” modifies “sequencing extracellular polynucleotides.” (D.I. 432 at 20 n.15) (“[T]he plain language of the claims would require each of the extracellular polynucleotides **that are being sequenced** to generate two or more sequence reads.”)

summary judgment of noninfringement (D.I. 296) with respect to literal infringement of the “grouping limitation” of the ’731 patent, as well as Judge Burke’s denial of FMI’s motion for leave to submit a declaration (D.I. 318);<sup>6</sup>

WHEREAS, the Court has reviewed *de novo* the portions of Judge Burke’s Reports addressing dispositive issues,<sup>7</sup> *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, as more fully described below, (i) the February Report (D.I. 386) is **ADOPTED** and FMI’s motion for summary judgment of no willful infringement (D.I. 297) is **DENIED**; (ii) the April Report (D.I. 419) is **ADOPTED** and Guardant’s motion for summary judgment relating to improper inventorship and inequitable conduct (D.I. 291) is **DENIED**; and (iii) the May Report (D.I. 432) is **ADOPTED**, so FMI’s motion for summary judgment of invalidity (D.I. 290) and Guardant’s motion for summary judgment on FMI’s obviousness combinations (D.I. 291) are **DENIED** while FMI’s motion for summary judgment of noninfringement (D.I. 296) is **GRANTED IN PART** and **DENIED IN PART**, as more fully described in the May Report and in this Memorandum Order.

### **February Report**

FMI’s February Objections are **OVERRULED**.

The February Report recommends that the Court deny FMI’s motion for summary judgment of no willful infringement (D.I. 297) because the motion is premised upon an incorrect legal standard. (D.I. 386 at 2) FMI objects that Judge Burke predicated his analysis on

---

<sup>6</sup> FMI’s footnote objection to this portion of the Report is waived. *See John Wyeth & Bro.*, 119 F.3d at 1076.

<sup>7</sup> The Court adopts and incorporates by reference the legal standards applicable to summary judgment motions articulated in *Wasica Fin. GmbH v. Schrader Int’l, Inc.*, 2020 WL 1150135 at \*1 n.1 (D. Del. Jan. 14, 2020).

precedent not-then existing when FMI filed its summary judgment motion. (D.I. 396 at 3-4, 8) (citing *Eko Brands, LLC v. Adrian Rivera Maynez Enters.*, 946 F.3d 1367, 1378-79 (Fed. Cir. 2020))

Notwithstanding the Report's reliance on the recently-issued *Eko Brands* decision, the Court agrees with Judge Burke that the standard he applied for evaluating claims of willful infringement at summary judgment predates *Eko Brands* and FMI's briefing in the instant action. This fact is demonstrated by Judge Burke's citation to *Valinge Innovation AB v. Halstead New England Corp.*, 2018 WL 2411218, at \*9 (D. Del. May 29, 2018), in which this Court held that stating a claim for willful infringement (and, therefore, proving such a claim) does not "require that the patentee plead facts plausibly evidencing 'egregious' infringement conduct." *See also id.* at \*6 ("Although it was previously in the former camp [of requiring pleading and proof of "egregious" conduct], after having further considered *Halo [Elecs., Inc. v. Pulse Elecs., Inc.]*, 136 S. Ct. 1923 (2016)] and Federal Circuit precedent, the Court has now determined that it was wrong." ).<sup>8</sup>

It follows that FMI's attempt to rely on an earlier decision of this Court is unavailing. (See D.I. 299 at 13) (citing *Vehicle IP, LLC v. AT&T Mobility LLC*, 227 F. Supp. 3d 319, 331 (D. Del. 2017)) Moreover, *Eko Brands* was issued days before FMI's reply brief was due, so FMI had an opportunity to address it.

---

<sup>8</sup> *Sunoco Partners Mktg & Terminals L.P. v. Powder Springs Logistics, LLC*, 2019 WL 8641303, at \*2 (D. Del. Aug. 7, 2019) ("[I]n order to sufficiently plead willful infringement, a plaintiff must allege facts plausible showing that as of the time of the claim's filing, the accused infringer: (1) knew of the patent-in-suit; (2) after acquiring that knowledge, it infringed the patent; and (3) in doing so, it knew, or should have known, that its conduct amounted to infringement of the patent.") (internal quotation marks omitted)); *Align Tech., Inc. v. 3Shape A/S*, 339 F. Supp. 3d 435, 448-49 (D. Del. 2018) ("This Court sides with those decisions that do not require allegations of egregiousness at the pleading stage.").

Under the circumstances, the Court is not persuaded that FMI has demonstrated good cause for raising new arguments in its objections that it did not present to Judge Burke. *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 377 (D. Del. 2014) (“[N]ew arguments . . . are problematic.”).

### **April Report**

Pursuant to 28 U.S.C. § 636(b)(1), the Court need not review unobjected-to portions of magistrate judges’ reports and recommendations. *See also Goney v. Clark*, 749 F.2d 5, 6-7 (3d Cir. 1984). As there were no objections to the April Report, it is adopted in full.

### **May Report**

The parties filed no objections to the portions of the May Report recommending denial of FMI’s motion for summary judgment of invalidity (D.I. 290) and of Guardant’s motion for summary judgment on FMI’s obviousness combinations (D.I. 291). The parties also filed no objections to any portion of the May Report that relates to the “plurality limitation.”<sup>9</sup> Below, the Court addresses the parties’ objections to other portions of the May Report.

### **The “Grouping Limitation”**

#### **Literal Infringement**

The parties filed no objections to the recommendation that the Court grant the motion for summary judgment of no literal infringement of the “grouping limitation” of the ’731 patent, so the May Report is adopted to that extent and the motion is granted to that extent as well.

---

<sup>9</sup> The plurality limitation is found in the ’731, ’992, and ’743 patents, although FMI moved for summary judgment on this basis only as to the ’731 and ’743 patents. (D.I. 432 at 20-21 & n.15) As recommended by Judge Burke, summary judgment of non-infringement is granted with respect to literal infringement of the ’731 patent and denied with respect to infringement of the ’731 and ’743 patents under the doctrine of equivalents.

FMI's May Objections with respect to literal infringement of the "grouping limitation" in the '822 and '922 patents are **OVERRULED**.

The "grouping limitations" of the claims of the '822 and '922 patents require that generated "sequence reads" that are mapped to a reference genome be subsequently grouped. (D.I. 432 at 24) The Court agrees with Judge Burke that the record contains evidence from which a reasonable juror could find that the accused processes complete filtering, mapping, and grouping functionalities at different temporal periods. (*Id.* at 25-26) If and when the sequence of those components is filtering, then mapping, then grouping, FMI literally infringes. (*Id.*; *see also* D.I. 302-2 Ex. 18 at 5 § 7.2 (describing separation of samples into read files, filtering read files, mapping read files, and then grouping those mapped files))

Guardant's expert, Dr. Cooper, describes FMI's process and opines that it is capable of meeting the grouping limitations. (D.I. 443 at 6; D.I. 339-2 Ex. 80 ¶¶ 187-97) Contrary to FMI's contention (*see* D.I. 438 at 6-7), Dr. Cooper's report (which expressly addresses doctrine of equivalents infringement) could be credited by a reasonable juror (taking the evidence in the light most favorable to Guardant) as a basis for finding (in conjunction with the other evidence of record) literal infringement.

### **Doctrine of Equivalents**

Guardant's May Objections with respect to doctrine of equivalents infringement of the "grouping limitation" in the '731, '822, and '922 patents are **OVERRULED**.

As an initial matter, the Court is no more persuaded by Guardant's claim construction arguments than it was when it overruled Guardant's objections to Judge Burke's previous rejection of those contentions. (*See* D.I. 404 at 5, 9-10; *see also* D.I. 337 at 25-29)

Guardant argues that FMI's experts understand the claims to encompass intermediate filtration steps, so the Court should too. The Court is not persuaded. Guardant cites to evidence and arguments advanced in parallel IPR litigation but that proceeding was limited to dependent claims in the '731 and '822 patents – not the independent claims at issue here. (See D.I. 439 at 5-6; *see also* D.I. 404 at 10 (considering IPR evidence); *see also generally Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1360 (Fed. Cir. 2016) (“The dependent claim tail cannot wag the independent claim dog.”)) The Court's construction (which is not altered and, therefore, still governs) requires that generated “sequence reads” or “mapped” “sequence reads” all be placed into families; no intermediate filtration is permitted. (See D.I. 260 at 24 (“[The] claims do not actually speak to *when* the sequence reads must be filtered out, and thus do not seem to ‘preclude filtering sequence reads after grouping.’”) (internal citations omitted), *adopted*, D.I. 404 at 9-10) The independent claims, like the dependent claims that depend from them, do not encompass intermediate filtration.

The Court also rejects Guardant's objection to the May Report's application of the disclosure-dedication rule. When matter is described in the specification but not claimed, that matter is dedicated to the public. *See Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019). The specification of the '731 patent discloses certain embodiments in which a process generates “sequence reads” or “mapped” “sequence reads,” followed by a filtration step, and then followed by grouping. (D.I. 432 at 27) As already noted, Guardant's claims, however, do not include an intermediate filtration step.<sup>10</sup> Judge Burke correctly applied the disclosure-dedication rule to exclude from the scope of the claims such embodiments. Therefore, Guardant

---

<sup>10</sup> Guardant argues that dependent claims 5 and 10 are directed to post-mapping, pre-grouping filtration. (D.I. 439 at 5) For the reasons given above, the Court agrees with Judge Burke that these claims claim post-grouping filtration and not intermediate filtration. (D.I. 432 at 27)



cannot try to recapture such claims under a doctrine of equivalents infringement theory. *See Eagle Pharm. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020).<sup>11</sup>

### **The “Processing Limitation”**

FMI’s May Objections relating to the “processing limitation” are **OVERRULED** and FMI’s motion for summary judgment for non-infringement of claim 10 (and its dependent claims) of the ’743 patent due to failure to satisfy the “processing limitation” is **DENIED**. The Court agrees with Judge Burke that there is sufficient record evidence from which a jury could find that FMI’s accused process meets this limitation. (*See* D.I. 438 at 3-4)

FMI’s non-infringement position rests on its source code, which FMI asserts controls only the calculation of a ratio, leaving no basis for a finding that the ratio is processed “with a similarly derived number from a reference sample.” (D.I. 438 at 3-4) However, as Guardant points out, FMI “has never unambiguously denied that its product performs step 10(g) [i.e., the pertinent claim step] through the use of control samples in some form or another,” and further there is no “rule that infringement must always be proven through source code.” (D.I. 443 at 2) Moreover, as Judge Burke observed (D.I. 432 at 28), FMI failed to adequately account for (or even discuss in its opening brief) a document referenced by Guardant’s expert, Dr. Cooper, that was submitted to the New York State Department of Health’s Clinical Laboratory Evaluation Program (the “CLEP document”) (D.I. 302 Ex. 25 ¶ 456). The CLEP document states that the FMI process is performed using “two positive controls per plate” for accuracy that are analyzed for SNP presence and allele frequency. (*Id.*) Taking the CLEP document and Dr. Cooper’s

---

<sup>11</sup> In sum, FMI’s motion for summary judgment of non-infringement is granted with respect to literal infringement of the ’731 patent and with respect to doctrine of equivalents infringement of the ’731, ’822, and ’922 patents.

opinion about it in the light most favorable to Guardant, along with the other evidence of record, could lead a reasonable juror to find that FMI's process calculates a ratio derived from a reference sample. (*See* D.I. 432 at 28) (Judge Burke properly crediting CLEP document as "one source among multiple potential sources that all are valuable" in resolving fact dispute as to what happens in FMI's process)


FMI's citation to cases finding that marketing materials and other self-serving documents cannot overcome uncontroverted facts – *see, e.g., MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1377 (Fed. Cir. 2016) (non-technical marketing document did not create dispute); *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 939 (Fed. Cir. 2013) (same for sales literature) – does not change the outcome, for reasons including that the CLEP document is not the type of "soft" marketing or sales document involved in these cases. Instead, the CLEP document is a technical document created in a regulatory context (D.I. 302 Ex. 19) which FMI itself cited it in its own infringement contentions (although its reasons for doing so are disputed) (D.I. 432 at 28 n.24; *see also* D.I. 438 at 4 (FMI acknowledging CLEP document "generally describes parts of FMI's process to a regulator"); D.I. 443 at 5 n.3)

### **Moving Forward**

As the Court discussed with the parties during a teleconference on October 2, the jury trial currently scheduled to begin on November 6 will be rescheduled (potentially for as soon as November 30). The Court has reviewed the parties' October 6 joint status report and is still considering how and when to proceed with this case (as well as numerous others). That subject will be addressed in a further order and/or during a teleconference to be scheduled in the very near future.

Accordingly, **IT IS FURTHER ORDERED** that the pretrial conference scheduled for October 23 and the jury trial scheduled to begin on November 6 are **CONTINUED AND RESCHEDULED** to dates to be determined.

October 9, 2020  
Wilmington, Delaware

  
HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT JUDGE