

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

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” or “the patents-in-suit”). Presently before the Court are two motions filed by Plaintiff pursuant to Federal Rule of Civil Procedure 12(b)(6) seeking an order dismissing Defendants’ counterclaims of unenforceability of the ‘992 patent due to inequitable conduct (the “Motions”). (Civil Action No. 17-1623-LPS-CJB, D.I. 285; Civil Action No. 17-1616-LPS-CJB, D.I. 169) For the reasons that follow, the Court recommends that the Motions be DENIED.

I. BACKGROUND

The Court hereby incorporates by reference the summary of the background of this matter set out in its September 6, 2019 Report and Recommendation. (Civil Action No. 17-1623-LPS-CJB, D.I. 354 at 2-3) Below, it will include additional factual background relevant to the instant Motions.

In June 2019, both Defendants filed Answers and Counterclaims with regard to the operative Third Amended Complaint; among the counterclaims included in both of these pleadings were four counterclaims seeking a declaratory judgment of unenforceability for inequitable conduct of each of the four patents-in-suit. (Civil Action No. 17-1623-LPS-CJB, D.I. 284 at 12-29, 46-48 (filed June 13, 2019); Civil Action No. 17-1616-LPS-CJB, D.I. 168 at 12-40 (filed June 20, 2019)).¹ PGDx's counterclaims regarding inequitable conduct are generally very

¹ FMI had previously an Answer and Counterclaims in response to Plaintiff's Second Amended Complaint on May 7, 2019. (Civil Action No. 17-1616-LPS-CJB, D.I. 148) On the same day, May 7, 2019, Plaintiff filed its now-operative Third Amended Complaint. (Civil Action No. 17-1616-LPS-CJB, D.I. 149) On June 20, 2019, Plaintiff filed its instant Motion to dismiss FMI's inequitable conduct counterclaim as to the '992 patent, which was directed to the counterclaim found in the then-operative Answer and Counterclaims to Plaintiff's Second Amended Complaint. (Civil Action No. 17-1616-LPS-CJB, D.I. 169) But on that same date, June 20, 2019, FMI filed its Answer and Counterclaims to the Third Amended Complaint; that pleading simply re-alleged the inequitable conduct counterclaims that had previously been set out in FMI's May 7, 2019 pleading. (Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 1 n.1 (FMI confirming that the subsequently-filed counterclaims simply "re-alleg[ed] the inequitable conduct allegations"); *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 148)) This is all to say that although Plaintiff's instant Motion here was technically directed to the FMI counterclaim found in FMI's May 7, 2019 pleading, the Court assumes that Plaintiff's arguments apply in the just the same way to that same counterclaim found in FMI's now-operative June 20, 2019 pleading.

A similar thing happened in the PGDx matter. (*See* Civil Action No. 17-1623-LPS-CJB, D.I. 308 at 2 n.1) As with the FMI matter, there appears to be no dispute in the PGDx matter that Plaintiff's arguments regarding PGDx's inequitable conduct counterclaim apply to the counterclaim found in PGDx's now-operative Answer and Counterclaims to Plaintiff's operative Third Amended Complaint. (*Id.* ("PGDx interpreted the Motion as challenging the updated

similar to FMI's inequitable conduct counterclaims, though (as the Court will set out further below) the respective allegations are not identical. (*Id.*) Both sets of counterclaims allege misconduct involving Guardant's co-founder Dr. Helmy Eltoukhy. More specifically, Defendants allege that: (1) while he was still employed by his former employer (Illumina, Inc., or "Illumina"), Dr. Eltoukhy helped conceive of the purported inventions claimed in the four patents-in-suit; and (2) despite this, Dr. Eltoukhy was wrongfully omitted from the list of inventors on the applications for three of those four patents (i.e., all but the application leading to the '992 patent). (*Id.*)²

In response, Plaintiff filed the instant Motions, seeking to dismiss Defendants' inequitable conduct counterclaims regarding the '992 patent (that is, FMI's Twelfth Counterclaim and Count XII of PGDx's counterclaims). (Civil Action No. 17-1623-LPS-CJB, D.I. 285 (filed June 13, 2019); Civil Action No. 17-1616-LPS-CJB, D.I. 169 (filed June 20, 2019)) Briefing on the Motions was completed by July 19, 2019. (Civil Action No. 17-1616-LPS-CJB, D.I. 185)³

pleading because the updated pleading made no substantive changes to PGDx's inequitable conduct counterclaims."))

² Additional factual background information regarding the Motions will be addressed in Section III.

³ In Civil Action No. 17-1623-LPS-CJB, on August 22, 2019, after briefing on the Motion in that case was completed, Plaintiff filed what it titled a "Notice of Subsequent Activity Concerning Guardant's Motion to Dismiss." (Civil Action No. 17-1623-LPS-CJB, D.I. 345) This was a two-page brief in which Plaintiff made additional argument about a subsequent development that had occurred after the close of briefing, which (according to Plaintiff) supported grant of its Motion. (*Id.*) However, Plaintiff did not obtain leave of Court to file this additional brief. And the brief did more than simply provide "citation of subsequent authorities[.]" D. Del. LR 7.1.2(b). Thus, the filing violated D. Del. LR 7.1.2(b), and the Court ORDERS that it be STRICKEN. The Court will not consider its contents, nor the contents of

Although FMI’s answering brief is different in form from PGDx’s answering brief, the substance of the Defendants’ arguments in their respective briefs are largely the same. For this reason, the Court will largely discuss the Motions together below, and it will refer to the “D.I.” numbers in Civil Action No. 17-1623-LPS-CJB unless otherwise indicated.

II. STANDARD OF REVIEW

When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting “all of the complaint’s well-pleaded facts as true, but [disregarding] any legal conclusions.” *Id.* at 210-11. Second, the court determines “whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678.

In assessing the plausibility of a claim, the court must “construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). As such, a well-pleaded complaint may not be dismissed simply because “it strikes a savvy judge that actual proof of [the alleged] facts is improbable, and that a recovery is very remote and unlikely.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (internal quotation marks and citation omitted). Determining whether a

PGDx’s letter filed thereafter (in which, *inter alia*, PGDx objected to Plaintiff’s filing). (Civil Action No. 17-1623-LPS-CJB, D.I. 346)

claim is plausible is ““a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”” *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679).

III. DISCUSSION

As noted above, Plaintiff’s Motions seek dismissal of Defendants’ respective counterclaims alleging unenforceability of the ‘992 patent.⁴ Below, the Court will first summarize Defendants’ factual allegations relevant to the counterclaims at issue. Thereafter, the Court will assess the parties’ arguments regarding the Motions.

A. Relevant Factual Allegations

In its pleadings, Defendants assert that while he was still working at Illumina in 2012, Dr. Eltoukhy obtained information from Illumina documents that reflected all of the elements of the inventive solution touted in the patents-in-suit—i.e., the use of “communication theory” to help reduce or eliminate errors in the process of detecting mutations in cell-free DNA (“cfDNA”). (D.I. 284 at ¶¶ 14-18, 22-26; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 31-40)⁵ Defendants allege that Dr. Eltoukhy shared this information with Guardant co-founder Dr. AmirAli Talasaz, and that the two men thereafter used this information to conceive of the claimed inventions in the patents-in-suit. (D.I. 284 at ¶ 26; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 31-40)

⁴ Plaintiff does not challenge, at this stage, Defendants’ inequitable conduct counterclaims regarding the other three patents-in-suit.

⁵ Any citations herein to specific paragraphs in the respective relevant Answers and Counterclaims are to the portions of those pleadings that contain the counterclaims.

From there, Defendants allege that Dr. Eltoukhy and Dr. Talasaz intentionally deceived the United States Patent and Trademark Office (“USPTO”), when they identified Dr. Talasaz as the sole inventor on Guardant’s first two provisional patent applications filed in September 2012 (application number 61/696,734, filed on September 4, 2012, and application number 61/704,400, filed on September 21, 2012).⁶ (D.I. 284 at ¶ 39; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 57-58) Defendants assert that the reason why Dr. Eltoukhy and Dr. Talasaz failed to disclose Dr. Eltoukhy’s inventorship was that Dr. Eltoukhy was still employed at the time by Illumina; by omitting Dr. Eltoukhy’s role, the men allegedly sought to ensure that Guardant (not Illumina) would have full ownership and exclusive rights to the patents-in-suit in the future. (D.I. 284 at ¶ 39; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 58) Defendants further allege that Dr. Eltoukhy and Dr. Talasaz went on to make affirmative misrepresentations to the USPTO when they: (1) identified Dr. Talasaz as the sole inventor on documents submitted to the USPTO with the applications that led to the issuance of the '731 patent, the '743 patent and the '822 patent; and (2) thereafter failed to identify Dr. Eltoukhy as an inventor to the USPTO and “suppressed facts and evidence regarding [Dr.] Eltoukhy’s inventorship that should have been brought to the USPTO’s attention.” (D.I. 284 at ¶¶ 41-43; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 59-61)

Defendants ultimately assert that Dr. Eltoukhy’s and Dr. Talasaz’s conduct, discussed above, renders unenforceable the claims of the '731 patent, the '743 patent and the '822 patent. (D.I. 284 at ¶¶ 44-49; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 69-73) And with regard to the '992 patent, which is at issue in these Motions, Defendants allege:

⁶ These applications are listed on the front of the '992 patent and the other three patents-in-suit in the “Related U.S. Application Data” section. (D.I. 280, exs. 1-4)

Eltoukhy and Talasaz's broad pattern of inequitable conduct was also directly related to the '992 [p]atent, rendering the claims of that patent unenforceable as well. There is a significant relationship between and among the '731, '822, '743 and '992 [p]atents. The '992 [p]atent shares an almost identical specification to the '731, '822 and '743 patents, and relies on the earlier disclosed subject matter for written description support for its claims. By not naming Eltoukhy as an inventor on the '731, '822 and '743 [p]atents, Eltoukhy and Talasaz concealed that Eltoukhy also invented the fundamental ideas underlying the '992 [p]atent.

(D.I. 284 at ¶ 50; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 74)

Lastly, Defendants do make somewhat different allegations in their pleadings regarding one issue relevant to the instant Motions: the priority date of the '992 patent. PGDx alleges that all four of the patents-in-suit claim priority to the two September 2012 provisional applications referenced above (the "September 2012 applications" or the "September 2012 provisional patent applications"). (D.I. 284 at ¶ 40) FMI, however, alleges that the '992 patent claims priority to a provisional patent application that Plaintiff filed on March 5, 2014 (application number 61/948,530) (the "March 2014 application" or the "March 2014 provisional patent application").⁷ (Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 42)⁸

B. Discussion

Defendants' theory as to the unenforceability of the '992 patent is not primarily based on inequitable conduct said to have occurred during the '992 patent's prosecution itself. Instead, it rests on the relationship between the '992 patent and the prosecution of other related patent

⁷ This application is also listed on the front of the '992 patent in the "Related U.S. Application Data" section. (D.I. 280, ex. 4)

⁸ As to the other three patents-in-suit, FMI alleges (similar to PGDx) that they claim priority to the September 2012 applications. (Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 39)

applications—i.e., on what is known as the doctrine of “infectious unenforceability.” (D.I. 284 at ¶¶ 39-40, 50; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 14-19, 45, 51, 74; D.I. 308) In light of this, before the Court addresses the parties’ specific arguments regarding the Motions, it is first worth stepping back to discuss the infectious unenforceability doctrine (and the related law regarding inequitable conduct) more generally.

The law of inequitable conduct finds its origins in the unclean hands doctrine. *See Robocast, Inc. v. Apple Inc.*, 39 F. Supp. 3d 552, 570 (D. Del. 2014) (citing *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F. 2d 804, 812 (Fed. Cir. 1990)). The unclean hands doctrine applies where “some unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation.” *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933); *see also Robocast, Inc.*, 39 F. Supp. 3d at 570. The United States Court of Appeals for the Federal Circuit has found that “inequitable conduct” is no more than the unclean hands doctrine applied to particular conduct before the PTO.” *Consol. Aluminum*, 910 F.2d at 812.

Inequitable conduct regarding any single claim in the prosecution of a patent renders the entire patent unenforceable, not just that claim. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288-89 (Fed. Cir. 2011) (en banc). Moreover, the taint of a finding of inequitable conduct can affect not just the improperly-prosecuted patent, but can also “render unenforceable other related patents and applications in the same technology family.” *Id.*; *Consol. Aluminum*, 910 F.2d at 808-12. This concept is what courts have referred to as the doctrine of “infectious unenforceability.” *See, e.g., Int'l Bus. Machs. Corp. v. Priceline Grp. Inc.*, Civil Action No. 15-137-LPS-CJB, 2017 WL 1349175, at *20 (D. Del. Apr. 10, 2017) (citation omitted)); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, Civ. No. 08-

309-JJF-LPS, 2009 WL 4928024, at *9 (D. Del. Dec. 18, 2009), *report and recommendation adopted*, 2010 WL 2990039 (D. Del. July 22, 2010); *see also Robocast, Inc.*, 39 F. Supp. 3d at 570 n.10 (noting that while the Federal Circuit has recognized this legal concept, it has not yet “adopted [the] moniker [of ‘infectious unenforceability’] as its own”)).

Pursuant to this infectious unenforceability doctrine, inequitable conduct associated with one patent may render a related patent unenforceable—so long as the inequitable conduct at issue bears “an immediate and necessary relation” to the enforcement of the related patent. *See, e.g., Consol. Aluminum*, 910 F.2d at 810-11; *Hoffman-La Roche, Inc. v. Promega Corp.*, 319 F. Supp. 2d 1011, 1017 (N.D. Cal. 2004). An “immediate and necessary relation” requires that “the inequitable conduct that occurred earlier in the chain [of issued patents] ‘must be related to the targeted claims of the ultimately-issued patent or patents sought to be enforced.’” *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 595 (D. Del. 2006), *aff’d*, 480 F.3d 1129 (Fed. Cir. 2007) (quoting *Semiconductor Energy Lab., Inc. v. Samsung Elecs. Co.*, 24 F. Supp. 2d 537, 543 (E.D. Va. 1998)); *Truth Hardware Corp. v. Ashland Prods., Inc.*, No. Civ.A. 02-1541 GMS, 2003 WL 22005839, at *1 (D. Del. Aug. 19, 2003).

With this legal background now set out, the Court turns to the merits. In that regard, Plaintiff makes three distinct arguments for dismissal. First, Plaintiff notes that as to the '992 patent (unlike with the other three patents-in-suit), Dr. Eltoukhy is actually listed as an inventor on the face of the patent. It therefore argues that there “can [] be no inequitable conduct with respect to the '992 [p]atent based on misnaming of inventors because it is undisputed that the right inventors are named.” (D.I. 285 at 3; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 169 at 3) Second, Plaintiff asserts that Defendants’ counterclaims must fail because there is not a sufficient relationship “between the alleged inequitable conduct at issue and the *prosecution* of

the ['992 patent].” (D.I. 285 at 4 (certain emphasis omitted, certain emphasis added)); *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 169 at 4) And third, Plaintiff argues that differences between the '992 patent and the other patents-in-suit also preclude a finding of infectious unenforceability here. (D.I. 285 at 4-6; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 169 at 4-6) The Court will address each argument in turn.

1. The Fact that Dr. Eltoukhy is Listed as an Inventor on the '992 Patent Does Not Preclude a Finding that the Patent is Unenforceable.

Plaintiff’s first argument—that Defendant’s counterclaim fails because Dr. Eltoukhy is listed as an inventor on the '992 patent—is not dispositive. This is because, as noted above, Defendants’ theory as to the unenforceability of the '992 patent is not based on inequitable conduct in the '992 patent prosecution itself. Instead, the theory relies on the premise that inequitable conduct with regard to other, previously-filed patent applications is sufficiently related to the enforcement of the '992 patent, such that the '992 patent is also unenforceable.

Furthermore, as PGDx persuasively argues, if Dr. Eltoukhy and Dr. Talasaz *are* guilty of inequitable conduct with regard to the prosecutions of the other patents-in-suit, then the mere act of listing Dr. Eltoukhy as an inventor on the '992 patent would not amount to a sufficient cure for that wrongdoing. (D.I. 308 at 14-15) Merely disclosing, in a subsequent patent application, material that was previously withheld with intent to deceive the USPTO does not “save[] the later issued patent from the consequences of the misconduct.” *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571-72 (Fed. Cir. 1983); *see also* *Truth Hardware Corp.*, 2003 WL 22005839, at *2. Instead, to adequately cure any inequitable conduct that occurred during prosecution, the applicant would have to: (1) expressly advise the PTO of the existence of the misrepresentation; (2) advise the PTO of what the actual facts are and make clear that further examination in light thereof may be required if any PTO action has been based on the

misrepresentation; and (3) establish patentability on the basis of the factually accurate record. *Id.*; see also *Truth Hardware Corp.*, 2003 WL 22005839, at *2; *eSpeed, Inc.*, 417 F. Supp. 2d at 596. Plaintiff makes no assertion that it has met these “curing” requirements. Instead, its argument is that there was no inequitable conduct in the first place—or that even if there was, for other reasons, the doctrine of infectious unenforceability does not apply here as to the '992 patent.

So for these reasons, Plaintiff’s first argument for dismissal must fail.

2. Infectious Unenforceability Does Not Require Relation of the Inequitable Conduct to the *Prosecution* of the Challenged Patents.

Plaintiff’s next argument for dismissal is that Defendants’ counterclaims fail to sufficiently plead infectious unenforceability because that doctrine “requires a relationship between the alleged inequitable conduct and *the prosecution of [the '992 patent]*”; Plaintiff argues that no such relationship exists here. (*See, e.g.*, D.I. 285 at 4 (certain emphasis omitted, certain emphasis added)) In fact, however, the law on infectious unenforceability requires no direct linkage between the inequitable conduct at issue and the prosecution of the patent-in-question. This is clear to the Court for at least three reasons.

First, Plaintiff’s position to the contrary is undercut by the Federal Circuit’s description of the doctrine of infectious unenforceability. For example, in *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 910 F. 2d 804 (Fed. Cir. 1990), the Federal Circuit stated that to invoke this doctrine, there must be more than “mere relatedness of subject matter” between the patent as to which the patentee committed inequitable conduct and the patent-at-issue. 910 F.2d at 810-11. The *Consolidated Aluminum* Court explained, however, that if there was an “immediate and necessary relation” between the inequitable conduct and the “*equity* [the patentee now] seeks, namely *enforcement* of the [patent(s)-at-issue,]” this would be sufficient to

meet the doctrine's requirements. (*Id.* (internal quotation marks and citation omitted) (emphasis added)); *see also* D.I. 308 at 13; Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 7-8)⁹ In light of this, in various Federal Circuit and district court opinions where infectious unenforceability is found to be at play, the courts have made no mention of any direct linkage between (1) the inequitable conduct that occurred during prosecution of the infectious patent and (2) what happened during the *prosecution* of the patent(s)-at-issue. *See, e.g., Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (finding that inequitable conduct occurring during the prosecution of a parent patent's application infected a later-issued patent, because the later-issued patent was a continuation patent whose subject matter was not sufficiently distinct from that of the parent; in doing so, the Court made no mention of any misconduct occurring during the prosecution of the continuation patent itself); *see also IOENGINE, LLC v. PayPal Holdings*,

⁹ In *Consolidated Aluminum*, one of the patents-in-suit (the “917 patent”) was directed to an improved method of filtering molten material. 910 F.2d at 811. The Federal Circuit found that the patent applicant’s inequitable conduct in withholding the best mode of a claimed aqueous ceramic slurry during the prosecution of the ‘917 patent also rendered unenforceable three separate patents-in-suit that covered related subject matter. To that end, the *Consolidated Aluminum* Court concluded that the “inequitable conduct in prosecuting the [infectious ‘917] patent had ‘immediate and necessary relation’ . . . to the equity [plaintiff] [sought], namely enforcement of the [three other, related patents-in-suit].” *Id.* at 810-11. This was so because the patentee’s concealment of the best mode (the “CS1-B slurry”) during prosecution of the infectious patent allowed the patent applicant to present the CS1-B slurry as part of the invention disclosure in the specification of one of the three later-issued patents (the “‘081 patent”). *Id.* at 811. And because, *inter alia*, the other two patents’ applications were continuations-in-part of the ‘081 patent application and both included reference to the CS1-B slurry in their claims, they too were rendered unenforceable due to the inequitable conduct occurring regarding the ‘917 patent. *Id.* at 812. In these ways, the *Consolidated Aluminum* Court found that the patent owner’s inequitable conduct in concealing the CS1-B slurry from the ‘917 patent “permeated the prosecution of the other patents-in-suit [rendering] them unenforceable.” *Id.*

Inc., Civil Action No. 18-452-WCB, 2019 WL 2121395, at *4-5 (D. Del. May 15, 2019)

(Bryson, J., sitting by designation); *Truth Hardware Corp.*, 2003 WL 22005839, at *2.¹⁰

Second, requiring an “immediate and necessary relation” between the inequitable conduct at issue and the prosecution of the allegedly infected patent(s)-in-suit (as opposed to the “enforcement” of such patents more generally) would seem to render the doctrine of infectious unenforceability superfluous. As Defendants argue, “requiring a finding that withheld information from an earlier application be ‘material to the *prosecution* of the child application’ would ‘eviscerate the infectious unenforceability doctrine’ in that it would be ‘no different than traditional inequitable conduct pleading.’” (D.I. 308 at 13 (emphasis in original) (quoting *Eon Corp. IP Holdings, LLC v. T-Mobile USA, Inc.*, CASE NO. 6:10-CV-379-LED-JDL, 2011 WL 13134896, at *7 (E.D. Tex. Dec. 13, 2011), *report and recommendation adopted*, 2012 WL 12893881 (E.D. Tex. Jan. 18, 2012)); *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 12-13)

Third, the single Federal Circuit case that Plaintiff relies on in support of its argument here—*Pharmacia Corp. v. Par Pharmaceutical, Inc.*, 417 F.3d 1369 (Fed. Cir. 2005)—is inapposite. (D.I. 285 at 4-5) In *Pharmacia*, the Federal Circuit made clear that the defendant had “*not asserted on appeal*” the type of infectious unenforceability claim that Defendants are now pressing here: “that the [allegedly-infected] patent is unenforceable under a general unclean hands theory; i.e., that a broad pattern of inequitable conduct transfers inequitable conduct from

¹⁰ Defendants also argue that even if a relationship with the prosecution of the allegedly-infected patent is required, they have made such a showing here. (D.I. 308 at 13-14; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 3-4, 11 n.9) Because the Court finds that no such showing is required in order to invoke the infectious unenforceability doctrine, it need not address Defendants’ arguments in this regard.

one patent to another.” 417 F.3d at 1374 (emphasis added) (citing *Consol. Aluminum*, 910 F.2d at 812). Instead, the defendant in *Pharmacia* was making a very different argument, asserting that: (1) because the patentee had filed terminal disclaimers on the applications of two patents-at-issue, these disclaimers “b[ound the] two related patents together”; and thus (2) inequitable conduct occurring during the prosecution of the allegedly-infectious patent (the “‘368 patent”)—but *after the issuance* of the allegedly-infected patent (the “‘504 patent”)—nevertheless had “automatically infect[ed]” the *earlier-issued* ‘504 patent. *Id.* at 1374-75.

The *Pharmacia* Court ultimately concluded (affirming a district court’s decision issued after a bench trial) that this type of “reverse infectious inequitable conduct” allegation, (Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 8), could not serve to render the ‘504 patent unenforceable. 417 F.3d at 1374-75. In articulating the basis for its decision, the Federal Circuit stated in part that “[b]ecause the record shows no inequitable conduct during *prosecution of the* [earlier-issued, challenged] ‘504 patent itself, the district court did not abuse its direction in finding [that] patent to be valid and enforceable.” *Id.* at 1375 (emphasis added). Plaintiff relies on this statement here, suggesting that it means that for infectious enforceability to apply, there must be inequitable conduct shown to relate to the “prosecution of the” ‘922 patent. But that is a misreading of *Pharmacia*, as the next sentence of that opinion states “[i]n fact, the ‘504 patent had already issued before the inequitable conduct occurred.” *Id.* When read in context, it is clear that the *Pharmacia* Court’s decision (and the language it used, set out above) was meant to refer to the unique circumstances before it—i.e., to convey that since there had been no inequitable conduct during the prosecution of the ‘504 patent, *and because the ‘504 patent had already issued*, then one could not utilize later-occurring inequitable conduct to render that patent retroactively unenforceable. In contrast, here the inequitable conduct argument at issue is

a very different one—Involving allegations that inequitable conduct occurred *during the prosecution of earlier-prosecuted patent applications*, which thus infects the patentee’s ability to enforce a *later-issued* patent. For this reason, Plaintiff’s citation to *Pharmacia* is not helpful to it here.

For all of these reasons, the Court rejects Plaintiff’s second argument for dismissal.

3. The Relationship Between the Inequitable Conduct Occurring as to the '731, '743 and '822 Patents and the Enforcement of the '992 Patent Indicates that the Motions Should be Denied.

Lastly, Plaintiff asserts that the doctrine of infectious unenforceability is inapplicable here because there are too many differences between the inequitable conduct said to have occurred with regard to the '731, '743 and '822 patents on the one hand, and the enforcement of the '992 patent on the other hand.

The Court disagrees. Instead, it concludes that Defendants have pleaded sufficient facts to demonstrate the required “immediate and necessary relation” between the inequitable conduct at issue and the targeted claims of the '992 patent, in light of: (1) the close relationship between the content of the respective patents and the inequitable conduct allegations at issue; and (2) what is plausibly alleged regarding the family history and the priority relationship of the respective patents. Below, the Court discusses each of these two bases in turn.

a. The Close Relationship Between the Content of the Respective Patents and the Inequitable Conduct Allegations at Issue

Defendants persuasively allege that the patents-in-suit are closely related in substance, which ultimately helps their argument against dismissal.

For example, Defendants allege that there are great similarities between the *specifications* of the four patents, in that they are “almost identical[.]” (D.I. 284 at ¶ 50; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 45) This is essentially the case, as the only apparent

substantive difference between the specifications appears to be the addition of some material to the '992 patent disclosure that was not included in the disclosures for the other three patents. That material relates to non-unique identifiers and how, in some embodiments, ligation conditions can be utilized that can result in certain thresholds of ligation efficiency; it is set out in two columns of the 60+ column '992 patent disclosure. (*See* '992 patent, cols. 41:24-43:12) Accordingly, the abstracts of the patents-in-suit are word-for-word identical, and each of the patents contains the exact same figures. (D.I. 280, exs. 1-4); *see also Cognex Corp. v. VCode Holdings, Inc.*, Civ. No. 06-1040 (JNE/JHG), 2008 WL 2113661, at *27 (D. Minn. May 19, 2008) (noting that the claims of the patent-at-issue had an immediate and necessary relation to the inequitable conduct that had occurred in the prosecution of an earlier related patent application, where the patents' disclosures were “essentially identical” and the patents shared “almost identical written descriptions with identical diagrams”); *eSpeed, Inc.*, 417 F. Supp. 2d at 595 (noting the “strikingly similar” natures of the disclosures of the two patents-at-issue, in concluding that the doctrine of infectious unenforceability was applicable). It is also significant that the title of each patent is the same: “SYSTEMS AND METHODS TO DETECT RARE MUTATIONS AND COPY NUMBER VARIATION.” (D.I. 280, exs. 1-4)

Additionally, Defendants allege that the *claims* of the patents-in-suit are intimately related. In particular, Defendants pleaded that the claims of the patents-in-suit all relate to a “communication theory[,]” which allows for reduced errors in the amplification and sequencing of cfDNA when conducting a “liquid biopsy.” (D.I. 284 at ¶¶ 14-18; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶¶ 14-19 (referring to the allegedly-“innovative method” as “Digital Sequencing”), 31-33, 45, 51, 74) They also allege that the claims of all four patents—including at least independent claim 1 of the '992 patent—implement this “communication

theory” solution by invoking particular steps (including the tagging of sequence reads, the grouping of sequence reads with the same tags into families and the collapsing the sequence reads to create “consensus sequences”). (D.I. 284 at ¶ 18 (citing claims in each of the four patents-in-suit, including claim 1(b)-(f) of the '992 patent); *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 33 (noting the same three steps and asserting that they “closely resemble the elements of Guardant’s patented method”); *id.* at ¶¶ 45, 51 (similarly describing the “inventions claimed in each of the asserted patents” and noting that the inventions are captured in, *inter alia*, claim 1 of the '992 patent)); *see also eSpeed, Inc.*, 417 F. Supp. 2d at 596 (noting the “close relation” of the asserted claims of the two patents-at-issue). In light of this, if Defendants’ assertion is that the patentee committed inequitable conduct by failing to disclose Dr. Eltoukhy’s inventorship role with regard to certain aspects of the “communication theory” solution—and if those same purportedly inventive aspects make up a key part of the claims of the '992 patent—then this appears to persuasively demonstrate a close relationship between the inequitable conduct at issue and “the targeted claims of the ultimately-issued patent or patents sought to be enforced.” *eSpeed, Inc.*, 417 F. Supp. 2d at 595 (internal quotation marks and citation omitted); *see also* (Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 12-13 n.10).

Lastly, the prosecution history of the '992 patent shows that its claims are directed to very similar subject matter to that covered by at least one of the other three patents-in-suit. (D.I. 308 at 6, 9) During the prosecution of the '992 patent, the Examiner issued a double-patenting rejection of the '992 patent over the '731 patent. (D.I. 308, ex. 1 at 5-6, 12-14) To overcome this rejection, Plaintiff filed a terminal disclaimer. (*Id.*, ex. 2 at 1-2) Thus, the Examiner believed that the claims of the '992 patent were not “patentably distinct” from the claims of the '731 patent, *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985), and the applicant chose not to then-

challenge the Examiner's view. *See Cognex Corp.*, 2008 WL 2113661, at *27 (D. Minn. May 19, 2008) (finding that the claims of the purportedly infectious patent and the claims of the later-issued patent were "sufficiently related" for purposes of infectious unenforceability, in part because the patentees filed a terminal disclaimer as to the later-issued patent, avoiding the rejection of that patent's claims over the infectious patent's claims).¹¹ This is another indicator that the alleged inequitable conduct, which is said to have directly related to Guardant's ability to capture the inventions set out in the '731 patent, bears an immediate and necessary relation to the content of the claims of the '992 patent.

For all of these reasons, the significant overlap in the content of the respective patents (and, relatedly, the relationship between the inequitable conduct allegations at issue and the enforcement of the '992 patent), supports Defendants' position here.

b. The Allegations Regarding the Family History and Priority Relationship of the Respective Patents

¹¹ Plaintiff argues that the terminal disclaimer "means nothing in this context," citing *Pharmacia* in support. (D.I. 315 at 7) However *Pharmacia* does not stand for the broad proposition that terminal disclaimers are never relevant to an assertion of infectious unenforceability. As was noted above, the *Pharmacia* Court made clear that the defendant in that case (unlike here) had not asserted that the challenged patent was "unenforceable under a general unclean hands theory[.]" 417 F.3d at 1374. Instead, there the defendant was attempting to use the terminal disclaimer to argue that inequitable conduct in procuring a *later-prosecuted* patent automatically infected an *earlier-issued* patent. The *Pharmacia* Court rejected this proposition, finding that in those circumstances, "something more than a naked terminal disclaimer is required." *Id.* Here, in contrast, Defendants are asserting that inequitable conduct as to *earlier-issued* patents infects a *later-issued* patent, as the '992 patent issued on February 27, 2018, after the other three patents-in-suit issued. (D.I. 280, exs. 1-4) And, of course, as cited above, Defendants rely on much more to make this case than the "naked" fact of the terminal disclaimer described above.

The Court next assesses the facts of record regarding the family history and priority relationship between the '992 patent and the other three patents. Before doing so, it is useful to assess how the law treats such information in assessing infectious unenforceability claims.

Our Court, relying on prior Federal Circuit precedent, has noted that if a patentee commits inequitable conduct during prosecution of one patent, then a later continuation patent will almost surely be found to bear an “immediate and necessary relation” to the patent obtained by way of the inequitable conduct. *Robocast, Inc.*, 39 F. Supp. 3d at 571; *see also IOENGINE, LLC*, 2019 WL 2121395, at *4-5. This is in significant part because continuation applications are understood to “relate to the same invention.” *Robocast, Inc.*, 39 F. Supp. 3d at 571 (noting that “[i]f the same patentee split the claims into two applications, why should the result be any different?” and that “[t]o hold otherwise would fly in the face of the rule that inequitable conduct renders all claims unenforceable, ‘not just the particular claims to which the inequitable conduct is directly connected.’”) (quoting *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984)).¹² And more generally, with regard to the invocation of the infectious unenforceability doctrine, courts have found that if the patent-at-issue is linked to an infectious patent (or application) through a common claim of priority, this fact also helps to establish the requisite “immediate and necessary relation.” *See Eon Corp.*, 2011 WL 13134896, at *7 (denying a motion to dismiss an inequitable conduct counterclaim based on the doctrine of infectious unenforceability, in part because the allegations were that plaintiff claimed priority for

¹² On the other hand, our Court has noted that a divisional application may be “drawn to a different invention, and different inventions do not share an ‘immediate and necessary’ relation to each other.” *Robocast, Inc.*, 39 F. Supp. 3d at 571 (citing *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998)); *see also IOENGINE, LLC*, 2019 WL 2121395, at *4 (citing *Baxter Int’l, Inc.*, 149 F.3d at 1332).

the patent-at-issue based on the infectious patent); *eSpeed, Inc.*, 417 F. Supp. 2d at 596 (finding, after a bench trial, that the patent-at-issue was unenforceable because, *inter alia*, it “claim[ed] priority from the [infectious] application”).

The Court now turns to the record here on this topic. It is a bit of a mess.

On the one hand, in its counterclaims, PGDx alleges that all four patents-in-suit, including the '992 patent, claim priority to the two Guardant September 2012 provisional patent applications. (D.I. 284 at ¶¶ 39-40) These two provisional applications are listed on the front page of the '992 patent as “Related U.S. Application Data” (just as they are so listed on the front page of the other three patents-in-suit). (D.I. 280, exs. 1-4) And at various points in the prosecution history of the '992 patent (including as recently as via a June 2019 filing in an *inter partes* review proceeding regarding that patent—a filing made just days before the instant Motions were filed), *Guardant* affirmatively represented to the USPTO that the '992 patent in fact claims priority to the September 2012 provisional applications. (Civil Action No. 17-1616-LPS-CJB, D.I. 179, exs. 1-2)¹³ In light of this, PGDx argues in its briefing that the “'992 [p]atent [] arises from a continuation-in-part application that claims priority to many of the same earlier applications as the other three patents-in-suit.” (D.I. 308 at 9)

FMI, however, appeared to take a different tack in its counterclaims. There, it alleged that '992 patent claims priority to Guardant's *March 2014 provisional patent application* and did not mention the September 2012 applications in its discussion of the '992 patent's priority date.

¹³ These cited exhibits were attached to Defendants' respective answering briefs. (D.I. 308, exs. 3-4; Civil Action No. 17-1616-LPS-CJB, D.I. 179, exs. 1-2) The Court can consider such exhibits (and others referenced herein that are part of the patents-in-suit's prosecution history), as a patent's prosecution history is a public record that may be taken into account in resolving a motion to dismiss. *See Int'l Bus. Machs. Corp.*, 2016 WL 626495, at *20 n.18 (citing cases).

(Civil Action No. 17-1616-LPS-CJB, D.I. 168 at ¶ 42) Yet in its briefing, FMI seemed to now align itself with PGDx's position that: (1) the '992 patent claims priority to the September 2012 provisional patent applications; and (2) the '992 patent is a continuation-in-part of an application that led to the grant of the other three patents-in-suit. (Civil Action No. 17-1616-LPS-CJB, D.I. 179 at 10 (FMI arguing that "Guardant's '992 patent resulted from continuations and continuations-in-part of the original applications which were the subject of the inequitable conduct alleged by FMI in this litigation."))

As for Plaintiff, in its briefing, it now takes the position that "the '992 Patent derives priority from [the March 2014 provisional application] as opposed to the other three asserted patents which derive priority from [the Guardant provisional application] filed a year and a half earlier on September 4, 2012." (D.I. 285 at 4; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 169 at 4) Plaintiff argues that it has made this same contention in responding to certain interrogatories during the instant litigations. (D.I. 285 at 4 & ex. 2; Civil Action No. 17-1616-LPS-CJB, D.I. 169 at 4 & ex. 1) And although it acknowledges that this contention is directly contradictory to the priority-date-related statements it made to the USPTO in the past, Plaintiff asserts that as of July 2019, it has sought to correct those statements (which it now calls "inadvertent error") with the USPTO. (D.I. 315 at 7 & ex. 1; Civil Action No. 17-1616-LPS-CJB, D.I. 185 at 8 & ex. 2)¹⁴

¹⁴ It its reply briefs, Plaintiff for the first time explains *why* it is that it believes the '992 patent "can only derive support from the later 2014 Application." (D.I. 315 at 5; *see also* Civil Action No. 17-1616-LPS-CJB, D.I. 185 at 6) There, it asserts that this is because: (1) each of the claims of the '992 patent require ligation "compris[ing] using more than 10x molar excess of the adaptors as compared to the cfDNA molecules, thereby generating tagged parent polynucleotides"; (2) this concept was invented by Dr. Stephanie Mortimer, a listed inventor on the '992 patent (who is not listed as an inventor on the other three patents-in-suit) and thus is referenced only in the '992 patent specification; and (3) since this limitation "was only disclosed

Taking the entirety of this (confused) record into account, the Court concludes that it is at least plausible that the '992 patent shares a September 2012 priority date with the other three patents. This is because the record demonstrates that: (1) the relevant September 2012 provisional applications are listed on the front of the '992 patent; (2) the '992 patent shares deep similarities with the other three patents-in-suit that claim priority to this same 2012 date; and (3) as late as days prior to the filing of the Motions, even Plaintiff was asserting (in another forum) that the four patents all share that same priority date. Of course, it may well be that this is not the case, and that the '992 patent is entitled only to a March 2014 priority date instead. But the correct priority date for a patent is an issue that may turn on the resolution of disputed facts. See *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306-07 (Fed. Cir. 2008); *Johns Hopkins Univ. v. 454 Life Scis. Corp.*, 183 F. Supp. 3d 563, 574-78 (D. Del. May 2, 2016); *SimpleAir, Inc. v. AWS Convergence Techs., Inc.*, Case No. 2:09-cv-289, 2012 WL 12978274, at *2 (E.D. Tex. Apr. 3, 2012).¹⁵

and described in the 2014 Application, it would not have been possible for Guardant to file a patent application on this subject matter prior to 2014.” (*Id.*)

The substance of this more detailed argument should have been included in Plaintiff’s opening briefs, but was not. Thus, in their answering briefs, Defendants did not address this argument. As a result, the Court will not consider the details of this argument in resolving the instant Motions. D. Del. LR 7.1.3(c)(2) (“The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.”); *see also Lab. Skin Care, Inc. v. Ltd. Brands, Inc.*, 757 F. Supp. 2d 431, 439 (D. Del. 2010); *Rockwell Techs., LLC. v. Spectra-Physics Lasers, Inc.*, No. CIV.A.00-589 GMS, 2002 WL 531555, at *3 (D. Del. Mar. 26, 2002).

¹⁵ Even if the '992 patent, in fact, is not entitled to the same priority date as the other three patents-in-suit, precedent does not appear to strictly require identity of priority for infectious unenforceability to apply. Instead, priority claims linking the infectious/infected patents appear to be merely a factor for courts to consider in this analysis.

Moreover, it is at least clear from the “Related U.S. Application Data” listed on the front page of each of the patents that they are all part of the same genealogical chain. (D.I. 280, exs. 1-4) That familial relationship is also evidence of the close relationship of the subject matter of the ’992 patent and that of the other three patents-in-suit.

4. Conclusion

Defendants have pleaded facts demonstrating an extremely close connection between the content of the '992 patent and the other patents-in-suit (and, relatedly, between the nature of the inequitable conduct allegations and the content of the '992 patent's claims). Additionally, there are at least sufficient facts pleaded to plausibly allege that the four patents are part of the same family and that they all share the same priority date. Taking all of this together, Defendants have sufficiently alleged that the '992 patent is unenforceable pursuant to the doctrine of infectious unenforceability.

IV. CONCLUSION

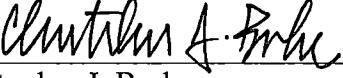
For the foregoing reasons, the Court recommends that Plaintiff's Motion be DENIED.

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 Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

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 **January 10, 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: January 7, 2020



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE