IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GUARDANT HEALTH, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 17-1623-LPS-CJB
	)	
v.	)	REDACTED PUBLIC VERSION
	)	
PERSONAL GENOME DIAGNOSTICS, INC.,	)	
	)	
Defendant.	)	

LETTER TO THE HONORABLE CHRISTOPHER J. BURKE
IN SUPPORT OF DEFENDANT PERSONAL GENOME DIAGNOSTICS, INC.'S
MOTION FOR LEAVE TO FILE AN AMENDED PLEADING

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Counsel for Defendant Personal Genome Diagnostics, Inc.

Dated: April 19, 2019

Dear Judge Burke:

Defendant PGDx respectfully seeks leave to file its Amended Answer to Second Amended Complaint, Affirmative Defenses and Counterclaims, which sets forth an additional defense and counterclaims based on inequitable conduct and improper inventorship. A "redline" copy of the proposed amended answer is attached as Exhibit A and a "clean" version is attached as Exhibit B.

PGDx brings this motion just days after the April 8, 2019, deposition of Helmy Eltoukhy, the co-founder and CEO of Guardant. Eltoukhy's deposition revealed that he fraudulently concealed from the United States Patent and Trademark Office ("USPTO") that he was a co-inventor of the Patents-in-Suit. *See, e.g.*, Ex. B, Counterclaims ¶¶ 8-50. At the time of conception, Eltoukhy [redacted] Eltoukhy's deposition revealed that he [redacted] Eltoukhy and AmirAli Talasaz (Guardant's other co-founder) then filed patent applications that fraudulently identified Talasaz as the sole inventor to obtain exclusive rights to the Patents-in-Suit [redacted]. *Id.* Guardant is now attempting to use its fraudulently obtained patents to exclude competitors and monopolize the liquid-biopsy market. *Id.* Accordingly, PGDx seeks to add an inequitable conduct defense and *Walker Process* monopolization and attempted monopolization counterclaims.

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that the Court "should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2).[1] Courts in this Circuit adopt "a liberal approach to the amendment of pleadings to ensure that a particular claim will be decided on the merits rather than on technicalities." *Abbott Labs v. Johnson & Johnson, Inc.*, 524 F. Supp. 2d 553, 557 (D. Del. 2007). Leave to amend should be freely given absent a showing of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, futility of amendment, etc." *Cellectis S.A., v. Precision Biosciences, Inc.*, 881 F. Supp. 2d 609, 614 (D. Del. 2011). As discussed below, none of these factors is present here. Accordingly, the Court should grant PGDx's motion.

PGDx Did Not Unduly Delay in Seeking Leave to Amend

PGDx acted promptly in seeking leave to amend. The core of PGDx's defense and counterclaims is fraud on the USPTO and deceptive intent by Guardant's co-founders, Eltoukhy and Talasaz. PGDx filed its motion just days after deposing Eltoukhy and before deposing Talasaz. Given the importance of deceptive intent to PGDx's defense and counterclaims, PGDx acted reasonably in exploring Eltoukhy's state of mind before seeking leave to amend. Indeed, the Federal Circuit has held that a close "temporal proximity of the amendment to [the inventor]'s deposition" is sufficient even to satisfy the higher "good cause" standard of Rule 16. *Aventis*

1 To the extent the Court treats the proposed amended pleading as a "supplemental pleading" under Rule 15(d), the standard is "essentially the same as that under 15(a) . . . ." *Micron Tech., Inc. v. Rambus Inc.*, 409 F. Supp. 2d 552, 558 (D. Del. 2006).

Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1333 (Fed. Cir. 2012) (affirming amendment to inequitable conduct defense).

PGDx's motion is also timely because the parties specifically agreed to extend PGDx's deadline to amend to May 3, 2019. *See* D.I. 140. As part of the dispute between the parties concerning whether PGDx's elio Plasma Resolve is an accused product, the parties agreed to extend the deadlines for both Guardant and PGDx to move to amend as of right. PGDx informed Guardant that it needed more time to explore potential defenses and counterclaims, including inequitable conduct and counterclaims relating to the fraudulent acquisition and enforcement of the Patents-in-Suit. The parties thus filed a stipulation stating: "the Parties seek to extend the date for pleading amendments/supplements as of right to (i) April 26, 2019 for infringement claims based on PGDx's elio Plasma Resolve; and to (ii) May 3, 2019 for any defenses and compulsory counterclaims related to the Complaint, (regardless of whether Guardant Health, Inc. ('Guardant') amends the Complaint)." D.I. 140 at 1. The Court approved that stipulation on February 25, 2019. *See* February 25, 2019, Order.

PGDx's motion is therefore timely because it comes before the May 3 deadline in the parties' stipulation and is limited to defenses and compulsory counterclaims. *See Rohm & Haas Co. v. Brotech Corp.*, 770 F.Supp. 928, 931-32 (D. Del. 1991) (*Walker Process* claims are compulsory); *Ragner Technology Corp. v. Berardi*, 2018 WL 6804486 at *5 (D.N.J. Dec. 27, 2018) (same); *Am. Packaging Corp. v. Golden Valley Microwave Foods*, 1995 WL 262522 at *4 (E.D. Pa. Apr. 28, 1995) (same). "The fact that the Motion was filed within this deadline, one agreed to by both parties, strongly supports a conclusion that the amendment was not untimely filed . . . ." *Invensas Corp. v. Renesas Elec. Corp.*, 2013 WL 1776112, at *3 (D. Del. 2013).

PGDx's Motion Is Made in Good Faith with No Dilatory Motive

PGDx brings this motion in good faith promptly after the deposition of Eltoukhy and within the deadline to amend. *See Trueposition, Inc. v. Allen Telecom, Inc.*, 2002 WL 1558531, at *2 (D. Del. July 16, 2002) (no bad faith or a dilatory motive because motion was filed within deadline to amend pleadings). PGDx brings its motion before even deposing Eltoukhy's co-founder and co-inventor, Talasaz. As soon as it became clear that Eltoukhy had no good-faith explanation for his improper conduct, PGDx notified Guardant that it would seek to add inequitable conduct and related antitrust counterclaims. PGDx did so before Eltoukhy's two-day deposition concluded. "[T]here is no evidence to indicate that [PGDx's] motion to amend is simply a delaying tactic . . . ." *Centerforce Tech. v. Austin Logistics Inc.*, 2000 WL 652943, *7 (D. Del. March 10, 2000).

Granting PGDx's Motion Would Not Cause Undue Prejudice to Guardant

Adding PGDx's inequitable-conduct defense and related antitrust counterclaims would not unduly prejudice Guardant. PGDx recently served discovery requests seeking the discovery it needs, and Guardant's return date is within the current deadline for fact discovery. Any discovery sought by Guardant should be limited because the facts and evidence concerning Guardant's inequitable conduct are largely within Guardant's own custody. Moreover, PGDx's related antitrust counterclaims are based on the same allegations as its inequitable-conduct defense and primarily add the issue of monopoly power. That issue should require little additional discovery

because Guardant admits it has an 80% share of the relevant market and that its position is protected by high barriers to entry. *See, e.g.,* Ex. B, Counterclaims ¶¶ 51-66. Moreover, the parties have already engaged in considerable discovery regarding the market in connection with Guardant's damages claims. *See Micron,* 409 F. Supp. 2d at 559 ("Rambus rightly asserts . . . the overlap will reduce any prejudice to Micron."). PGDx summarizes much of that evidence in its proposed amended pleading. *See, e.g.,* Ex. B ¶¶ 51-66.

To the extent Guardant believes it requires additional discovery, PGDx would agree to a reasonable extension. Guardant cannot claim a short extension would cause undue prejudice. In fact, the parties' stipulation expressly contemplated that an amendment might require additional discovery. D.I. 140 at 2 ("in the event any of the Parties amend their pleadings or contentions, the Parties reserve rights to seek discovery directed to any such amendments"). Thus, the amendment will not unduly prejudice Guardant. *See Invensas Corp.*, 2013 WL 1776112 at *3 ("The fact that the Motion was filed within this deadline, one agreed to by both parties, strongly supports a conclusion that the amendment...will not work to unfairly prejudice" the opposing party).

PGDx's Inequitable Conduct Defense and Related Antitrust Claims Are Not Futile

Finally, PGDx's proposed amendments are not futile. An amendment is futile only if it fails to satisfy the standards of legal sufficiency under Rule 12(b)(6). *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Here, PGDx's allegations clearly pass muster under Rule 12(b)(6). PGDx's proposed amended pleading explains the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009); *see* Ex. B, Counterclaims ¶¶ 8-50. PGDx also alleges in detail the "other elements necessary to establish a Sherman Act monopolization claim." *TransWeb LLC v. 3M Innovative Properties, Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016); *see, e.g.,* Ex. B, Counterclaims ¶¶ 51-66, 67-75. PGDx explains its allegations in great detail and even includes citations to specific witness testimony and documents. *See, e.g., id.* ¶¶ 51-86. PGDx has gone far and above what is required to plead its defense and counterclaims.

Accordingly, PGDx respectfully requests that the Court grant PGDx's motion for leave to file its Amended Answer to Second Amended Complaint, Affirmative Defenses and Counterclaims.

Respectfully,

/s/ John C. Phillips, Jr.

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cc: All counsel of record