



May 7, 2019

VIA E-FILING

The Honorable Christopher J. Burke  
United States District Court  
844 North King Street  
Unit 28, Room 2325  
Wilmington, DE 19801

**Re: *Guardant Health, Inc. v. Personal Genome Diagnostics Inc.*  
C.A. No. 17-1623-LPS-CJB**

Dear Judge Burke:

Plaintiff Guardant Health Inc. (“Guardant”) respectfully seeks leave to file Third Amended Complaint against Personal Genome Diagnostics Inc. (“PGDx”), which sets forth an allegation of willful infringement. A copy of the amended complaint is attached as Exhibit A along with a redline version attached as Exhibit B.

Guardant brings this motion two weeks after the depositions of Mr. Douglas Ward, CEO of PGDx, and Dr. Velculescu, a founder of PGDx, on April 17, 2019 and April 19, 2019, respectively. For over a year, PGDx has claimed that it only learned of the patents-in-suit on the day that the respective complaints were filed. Exhibit C (PGDx’s response to Guardant’s Interrogatory No. 1 dated April 23, 2018). However, as the testimony of Mr. Ward and Dr. Velculescu plainly shows, this was false. *See e.g.*, Exhibit D at 199:11-18 (Dr. Velculescu’s Deposition Transcript) (PGDx “was aware of the patents and patent applications that were publically available of Guardant at this point in time in July of 2017.”) PGDx had full knowledge of the ’731 patent, and the applications leading of the ’822, ’743, and ’992 patents during the summer of 2017, months before the original complaint was filed.<sup>1</sup> Despite this actual knowledge, PGDx continued to willfully develop and launch its infringing products even after the suit was filed. PGDx’s concealment of its knowledge and continual infringement constitutes egregious misconduct.

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). 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

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<sup>1</sup> The ’731 patent issued on March 21, 2017, over 6 months before the filing of the original complaint on November 9, 2017. D.I. 1. The ’822 and ’743 patents issued in December 2017 and were added to the case in the first amended complaint on February 5, 2018. D.I. 10. The ’992 patent issued on February 27, 2018 and was added to the case on March 23, 2018 in the second amended complaint. D.I. 20.

of the allowance of the amendment, futility of amendment, etc.” *Collectis S.A., v. Precision Biosciences, Inc.*, 881 F. Supp. 2d 609, 614 (D. Del. 2012). None of these factors are present here.

Federal Rule of Civil Procedure 16(b) also applies when a party moves to amend past the date set by the scheduling order. *E. Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000); *Meda Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 15-785-LPS, 2016 WL 6693113, at \*1 & n.2 (D. Del. Nov. 14, 2016). Rule 16(b)(4) provides, “A schedule may be modified only for good cause and with the judge's consent.” Fed. R. Civ. P. 16(b)(4). “Good cause is present when the schedule cannot be met despite the moving party's diligence.” *Meda Pharm.*, 2016 WL 6693113, at \* 1. “In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *S. Track & Pump, Inc. v. Terex Corp.*, 722 F. Supp. 2d 509, 521 (D. Del. 2010). As discussed below, Guardant has good cause for filing this motion, PGDx will suffer no undue prejudice, and its amendment is not futile. Accordingly, the Court should grant Guardant’s Motion.

### **I. Guardant has not unduly delayed in seeking leave to amend and brings this motion in good faith with no dilatory motive**

Guardant acted promptly in seeking leave to amend. After learning that PGDx’s interrogatory responses were false from Mr. Ward and Dr. Velculescu, Guardant approached PGDx within a week about amending Guardant’s complaint to include willful infringement. PGDx’s counsel stated that they were “not confident [they would] be able to give [Guardant] an answer before [April 29, 2019].” Ex. E. The parties then met and conferred on May 6, 2019. Because Guardant could not have known that PGDx’s interrogatory response was untrue until the depositions of Mr. Ward and Dr. Velculescu, Guardant acted reasonably in filing this motion at this stage of the case. *See Novartis et. al. v. Medimmune et. al.*, Case No. 11-84-SLR, D.I. 449 (D. Del. July 22, 2013) (“When the delay is not of the plaintiff's making, the courts have found good cause.”); *TC Tech. LLC v. Sprint Corp.*, No. 16-CV-153-RGA, 2019 WL 529678, at \*4 (D. Del. Feb. 11, 2019) (amendment permitted when movant filed motion two months after deposition); *Roquette Freres v. SPI Pharma, Inc.*, No. 06-540-GMS, 2009 WL 1444835, at \*5-6 (D. Del. May 21, 2009) (amendment permitted when depositions did not occur until six months after cut-off date for amendment, and movant filed motion a month and a half after deposition). There is no evidence to indicate that Guardant’s motion to amend is a delay tactic.

### **II. Granting Guardant’s Motion would not cause undue prejudice to PGDx**

Adding Guardant’s willful infringement assertion will not unduly prejudice PGDx. As the parties have already conducted significant discovery into the infringement by PGDx, this issue should require little additional discovery. Guardant describes much of the evidence in its amended pleading. Ex. A at ¶¶ 29-36. Further, PGDx has not shown that any additional discovery is needed. In any case, the discovery would all be within PGDx’s custody. *See TC Tech. LLC*, 2019 WL 529678, at \*3 (finding insufficient prejudice to deny leave to amend in part because information addressing the new issue would primarily be within the control of the non-moving party).

To the extent that PGDx suffers any prejudice from the addition of a willful infringement allegation, it is by their own doing by intentionally concealing its knowledge of the patents-in-suit since March 2018.

### III. Guardant's willful infringement allegations are not futile

Finally, Guardant's 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). As this Court has held, "[I]n order to sufficiently plead willful infringement, a plaintiff must allege facts plausibly 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." *Valinge Innovation AB v. Halstead New England Corp.*, No. CV 16-1082-LPS-CJB, 2018 WL 2411218, at \*13 (D. Del. May 29, 2018). "At the pleading stage, it is not necessary to show that the case is egregious." *Bio-Rad Labs. Inc. v. Thermo Fisher Sci. Inc.*, 267 F. Supp. 3d 499, 501 (D. Del. 2017).

Guardant's proposed amended complaint explains in detail how PGDx knew of the patents-in-suit and subsequently denied its knowledge. For example, [REDACTED]. Ex. A at ¶ 30. Further, Dr. Velculescu admitted that PGDx had knowledge of Guardant's publicly available patents and applications when the presentation was made in complete contrast to PGDx's previous representations. *Id.*

PGDx also has no reasonable belief that it does not infringe the patents-in-suit or that they are invalid. [REDACTED]. Ex. A at ¶ 35. Also, PGDx filed post grant reviews on only two of the patents-in-suit (the '743 and '822 patents), but withdrew them before a decision on institution could be reached. Ex. A at ¶¶ 33-34. PGDx has not filed any requests for *inter partes* review. These facts plainly show that PGDx knew of the patents-in-suit before Guardant filed its complaints, that PGDx is willfully and deliberately infringing, and that it knew that its conduct amounted to infringement. Guardant has provided more detail than what is necessary to plead willful infringement.

Accordingly, Guardant respectfully requests that the Court grant its motion for leave to file its Third Amended Complaint against PGDx.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (Via E-Mail)