IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC NEUROMODULATIONN CORP. Plaintiff, v. NEVRO CORP. Defendant.	Civil Action No. 16-1163-CFC CONSOLIDATED

MEMORANDUM ORDER

Plaintiffs Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, Boston Scientific) sued Defendant Nevro Corporation for patent infringement. D.I. 1. Before me is Nevro's motion to amend its Answer to Boston Scientific's Complaint to add an affirmative defense and declaratory judgment counterclaim of patent unenforceability based on inequitable conduct by Boston Scientific. D.I. 193. Nevro seeks to assert inequitable conduct on the grounds that Boston Scientific "both secured issuance of and defended the patentability of one of its asserted patents in this case, U.S. Patent No. 6,895,280 [the #280 patent], by concealing material information from [and misrepresenting material information to] the Patent Office." D.I. 194 at 1.

I. LEGAL STANDARD

Federal Rule of Civil Procedure 15 governs amendments to pleadings generally, providing that "[t]he court should freely give leave [to amend] when justice so requires." *See* Fed. R. Civ. P. 15(a)(2). When a party moves to amend past the date set by the scheduling order, Federal Rule of Civil Procedure 16(b) also applies. *See* Fed. R. Civ. P. 16(b)(4); *see also E. Minerals & Chems. Co. v. Mohan*, 225 F.3d 330, 340 (3d Cir. 2000). In pertinent part, Rule 16(b) 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. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at *1 (D. Del. Nov. 14, 2016).

If a movant meets its burden under Rule 16(b)(4) to show that good cause exists, the court may then consider whether it should grant leave to amend under Rule 15(a)(2). *See Intellectual Ventures I LLC v. Toshiba Corp.*, 2016 WL 4690384, at *1 (D. Del. Sept. 7, 2016) ("Only after having found the requisite showing of good cause will the court consider whether the proposed amended pleading meets the standard under Fed. R. Civ. P. 15."). "The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities." *S. Track & Pump, Inc. v. Terex Corp.*, 722 F. Supp. 2d 509, 520 (D. Del. 2010) (citing *Dole v. Arco Chem.*

Co., 921 F.2d 484, 487 (3d Cir. 1990)). Absent a showing of undue delay, bad faith or dilatory motive, undue prejudice, repeated failure to cure deficiencies by amendment previously allowed, or futility of the amendment, leave to amend under Rule 15 should generally be permitted. *Id.* at 520–21 (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

II. DISCUSSION

Nevro filed the present motion to amend after the deadline for filing amendments to pleadings set by the scheduling order that was in place at the time Nevro filed this motion. D.I. 27; D.I. 193. Nevro, therefore, must show good cause under Rule 16(b) for seeking to amend after the deadline. I find that Nevro has met that burden to show good cause because the inequitable conduct claim Nevro seeks to add is based in part on evidence that Nevro discovered after the deadline. Specifically, Nevro bases its claim on evidence revealed in depositions taken after the deadline and on conduct that occurred at an *inter partes* review (IPR) proceeding that was resolved after the deadline. D.I. 194 at 1–2.

Boston Scientific argues that Nevro has not shown good cause because Nevro could have discovered from pubic information before the deadline the facts underlying its inequitable conduct claim. D.I. 215 at 13. Because inequitable conduct must be pled with particularity, however, even if Nevro could have obtained evidence to support its claims from public information, Nevro "was

entitled to confirm factual allegations before amending to include the inequitable conduct defense." *See Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 488 (D. Del. 2003). Nevro thus had good cause to wait until after it had taken the depositions of the relevant actors and after a decision had been issued in the relevant IPR proceeding before it sought to add the inequitable conduct claim so that it could confirm its allegations. *See id.* at 489 (allowing Digene to add a claim for inequitable conduct after the deadline for amendments because "Digene is pleading a new legal theory based on a new set of facts, which were recently confirmed by the depositions of Drs. Englehardt and Rabbani").

Because Nevro has met its burden to show good cause under Rule 16, I next consider whether I should grant Nevro leave to amend under Rule 15(a)(2). Boston Scientific argues that I should use my discretion under Rule 15 to deny leave to amend because (1) Nevro's proposed claim for inequitable conduct will be futile, (2) Nevro unduly delayed in seeking to amend, and (3) the proposed amendment will prejudice Boston Scientific. D.I. 215 at 15, 18, 19, 20. I disagree.

First, it does not appear at this time that Nevro's claim for inequitable conduct will be futile. A "proposed amendment is not futile [where it] would withstand a motion to dismiss." *Free Speech Coal., Inc. v. Attorney Gen. of U.S.*, 677 F.3d 519, 545 (3d Cir. 2012). And Nevro's claim would likely withstand a motion to dismiss—even with Federal Rule of Civil Procedure 9(b)'s heightened

pleading standard for inequitable conduct—to the extent that Nevro alleges that Boston Scientific's in-house prosecuting attorney Bryant R. Gold and inventors Joey Chen and Paul Meadows made material misrepresentations and omissions during prosecution of the #280 patent and the #280 patent's parent, U.S. Patent No. 6,516,227 (the #227 patent).

Inequitable conduct occurs when "(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the [Patent Office]." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). "[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [Patent Office]." *Id.* at 1328. The pleading must also "include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the [Patent Office]." *Id.* at 1328–29.

Here, Nevro has alleged the "who, what, when, where, and how" of Mr.

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