

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 public 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.

Gold and the inventors' alleged material misrepresentation and omissions before the Patent Office. Nevro alleges facts to establish that (1) Mr. Gold knowingly made a false statement to the Patent Office during prosecution of the #227 patent that the patent's use of implantable pulse generators (IPGs) with rechargeable batteries was novel and (2) Mr. Gold and the inventors knowingly failed to list references that disclosed IPGs with rechargeable batteries in the #227 and #280 patent applications. D.I. 194 at 17–18. Nevro alleges that just two days after filing the #227 patent's application, Mr. Gold and the inventors filed an application for U.S. Patent No. 6,553,263 (#263 patent) that expressly stated that the use of rechargeable IPGs was already known in the prior art and that listed four references that disclose IPGs with rechargeable batteries. D.I. 194 at 7–8, 10–11. Nevro alleges further that Mr. Gold described one of the four references in detail in communications with the #263 patent examiner, D.I. 194 at 8, and that Mr. Gold and the inventors confirmed during their depositions the above allegations and expressly admitted during their depositions that they knew of at least one prior art reference that disclosed rechargeable IPGs, D.I. 194 at 9, 10–11. Nevro also alleges that Mr. Gold and the inventors' omissions and misrepresentation were material because the Patent Office allowed the #227 patent based on Mr. Gold's arguments that use of IPGs with rechargeable batteries was novel. D.I. 194 at 18. Finally, Nevro asserts that “[w]hen confronted at his deposition with his

misleading statements and failure to disclos[e] . . . Mr. Gold became nervous, evasive, and threatened to walk out of the deposition.” D.I. 194 at 9. “[A] district court may infer intent from indirect and circumstantial evidence,” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011), and thus these allegations are sufficient to allege inequitable conduct at the pleading stage.

Second, Boston Scientific argues that Nevro unduly delayed in filing the present motion to amend. D.I. 215 at 19. Nevro, however, promptly filed the present motion after obtaining evidence that confirmed the factual basis for its inequitable conduct claim. Nevro confirmed its allegations through the depositions of Mr. Gold, Mr. Chen, and Mr. Meadows taken by Nevro about a month before it filed the present motion and through the IPR proceeding that was resolved 15 days before Nevro filed the present motion. D.I. 194 at 16. Also, Nevro sought to take those depositions in October and December of 2017—well before fact discovery was scheduled to close on March 2, 2018 (in the scheduling order in place when Nevro filed the present motion). D.I. 186. Nevro thus did not unduly delay in filing the present motion.

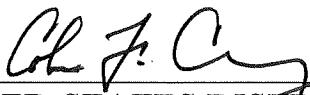
Finally, Boston Scientific argues that allowing Nevro to amend will unfairly prejudice Boston Scientific because “Nevro’s belated amendment would . . . forc[e] a reopening of the discovery period and require[e] [Boston Scientific] to defend against inequitable conduct allegations made against several witnesses,

including Mr. Gold and the patent agent who assisted him, who are no longer employed by [Boston Scientific], on a compressed timeframe after Nevro had more than a year to develop its theory.” D.I. 215 at 20. Boston Scientific will not, however, have to reopen discovery or respond to Nevro’s claim on a “compressed timeframe.” This case was consolidated with another case between Boston Scientific and Nevro on June 22, 2020. *See* Docket, June 2, 2020 Oral Order. And the schedule for the consolidated case sets the end of fact discovery for February 18, 2021, the end of expert discovery for May 28, 2021, and a trial for October 18, 2021. *Boston Scientific Corp. v. Nevro Corp.*, C.A. No. 18-644, ECF No. 51, Ex. A. Boston Scientific will therefore have sufficient time to respond to Nevro’s new claim.

Because Boston Scientific has not made a showing of undue delay, bad faith, dilatory motive, futility, or undue prejudice, I will grant Nevro’s motion to amend.

NOW THEREFORE, at Wilmington this Fifteenth day of September in 2020, **IT IS HEREBY ORDERED** that Defendant Nevro Corp.’s Motion for Leave to Amend Its Answer to Assert an Affirmative Defense and Counterclaim of

Unenforceability Due to Inequitable Conduct (D.I. 193) is **GRANTED**.



UNITED STATES DISTRICT JUDGE