

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

DR. MARK A. BARRY,

Plaintiff,

v.

STRYKER CORPORATION, ET AL.,

Defendants.

C.A. No. 20-1787-RGA

**MEMORANDUM OPINION**

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is Defendants' motion for leave to amend. (D.I. 89). The motion has been fully briefed. (D.I. 90, 96, 97). For the reasons set forth below, Defendants' motion is DENIED.

## I. BACKGROUND

On June 2, 2021, Plaintiff Dr. Mark Barry filed his Complaint alleging infringement of U.S. Patent Nos. 7,670,358 (the "358 Patent"), 8,361,121 (the "121 Patent"), 9,339,301 (the "301 Patent"), 9,668,787 (the "787 Patent"), and 9,668,788 (the "788 Patent") (collectively, the "Asserted Patents") against the Seaspine Defendants. (C.A. No. 21-806, D.I. 1). On March 21, 2022, the present action was consolidated with *Barry v. Stryker Corp.*, C.A. No. 20-1787. (D.I. 43). The deadline to amend the pleadings was June 3, 2022. (*Id.* at 2).

On July 20, 2022, Defendants notified Plaintiff that they would seek leave to amend its answer to assert a counterclaim and affirmative defense that the Asserted Patents are unenforceable because of Plaintiff's inequitable conduct. (D.I. 96, Ex. E). Plaintiff did not consent to the amendment. (D.I. 89 at 3). Defendants filed the instant motion on August 19, 2022.

## II. LEGAL STANDARD

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). The Third Circuit has instructed that "absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless 'denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.'" *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994)) (emphasis omitted). An

amendment is futile if it “would fail to state a claim upon which relief could be granted.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The futility analysis follows the standard that applies to a motion under Rule 12(b)(6). *Id.*

A request to amend filed after the court’s deadline to amend must also meet the “good cause” standard of Rule 16(b)(4). *Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020). 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’ exists when the [s]chedule cannot reasonably be met despite the diligence of the party seeking the extension.” *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009). Unlike Rule 15(a), the Rule 16(b) standard focuses on the “diligence of the movant, and not on prejudice to the non-moving party.” *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at \*4 (D. Del. May 21, 2009). “A party must meet [Rule 16(b)’s] standard before a district court considers whether the party also meets Rule 15(a)’s more liberal standard.” *Premier Comp*, 970 F.3d at 319.

### III. DISCUSSION

The Asserted Patents claim a method and system for aligning vertebrae that can be used in spinal surgeries. In their proposed amendment, Defendants allege that Plaintiff and his counsel “made a series of knowing and intentional omissions and false statements over a course of several years that establish a pattern and practice of deceptive intent rendering the Asserted Patents unenforceable.” (D.I. 89, Ex. A at 26). For example, Defendants allege that Plaintiff failed to disclose to the PTO surgeries that practiced the invention prior to the critical date of the patent, failed to “disclose material details of the surgery shown in Figure 6 of the ’358 Patent,” and submitted multiple certificates of correction to the PTO that contained materially false statements.

(*Id.* at 55). Defendants now seek leave to amend their answer to add a counterclaim and affirmative defense that the Asserted Patents are unenforceable due to Plaintiff's inequitable conduct.

#### **A. RULE 16(b)(4) GOOD CAUSE**

Defendants argue there is good cause for leave to amend because they were diligent. Defendants state that they pieced together Plaintiff's alleged pattern of conduct through reviewing "document production, prior case histories, deposition transcripts, patent file histories, and Plaintiff's prior admissions." (D.I. 90 at 1). Defendants claim to have relied upon prior lawsuits, which also involved defendants alleging Plaintiff to have committed inequitable conduct. *See, e.g., Barry v. Medtronic, Inc.*, C.A. No. 14-104 (E.D. Tex. Feb. 4, 2014); *Barry v. DePuy Synthes Products, Inc.*, C.A. No. 17-3003-PD (E.D. Pa. July 5, 2017), *consolidated with Barry v. Globus Medical, Inc.*, C.A. No. 17-2998-PD (E.D. Pa. July 5, 2017). Defendants also claim they learned pertinent facts from reviewing the "150,000 pages of documents" Plaintiff produced in March 2022. (D.I. 97 at 5-6). Defendants argue they could not have met the deadline to amend due to the voluminous record to review and the timing of document production. Defendants contend that the time taken to investigate their "theories and marshal[] the facts was necessary given that Rule 9(b) requires that claims of inequitable conduct in patent cases be pled with particularity." (D.I. 90 at 16).

Plaintiff asserts Defendants cannot show good cause or diligence because Defendants possessed the information required to bring their inequitable conduct claim ahead of the deadline to amend. Plaintiff argues that the information Defendants relies on to support its claim of inequitable conduct is "mostly, if not entirely, based on public material and allegations" from prior cases, which Defendants could have obtained prior to the amendment deadline. (D.I. 96 at 9-10).

Plaintiff also argues that Defendants cannot show diligence because Defendants brought the motion five months after they possessed the information necessary to bring the claim.

I find that Defendants possessed the information that serves as the basis for their proposed amendment in March 2022 when Plaintiff produced “150,000 pages of documents.” (D.I. 96 at 12; D.I. 97 at 5-6). Defendants contend that they relied on the March 2022 document production to uncover “pertinent facts” that were not public. (D.I. 97 at 5-6). Plaintiff argues the *Medtronic* and *DePuy* cases and Plaintiff’s filings with the PTO were publicly available and accessible to Defendants much earlier. (D.I. 96 at 8). Even though these sources were accessible to Defendants prior to March 2022, I do not find Defendants lacked diligence for taking additional discovery to confirm facts. *See Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at \*5 (D. Del. May 21, 2009) (“[I]n light of the pleading with particularity requirement under Rule 9(b), it was appropriate for SPI to confirm the factual allegations through discovery.”); *see also Targus Int’l LLC v. Victorinox Swiss Army, Inc.*, 2021 WL 2291978, at \*3 (D. Del. June 4, 2021) (“Victorinox was reasonable in waiting to file this motion until after Targus had responded to discovery requests . . . especially given the heightened standard of proof required for inequitable conduct claims.”). Therefore, I find that Defendants possessed the requisite information to file their amendment in March 2022 and did not lack diligence in waiting for that production.

I find, however, that Defendants cannot show good cause because they have not shown that they could not meet the court’s scheduling order despite their diligence. Defendants came into possession of the requisite information over two months prior to the deadline to amend the pleadings. Defendants argue that they could not have met the deadline to amend pleadings because they “needed time to carefully review thousands of pages of documents to piece together its inequitable conduct claims.” (D.I. 90 at 15). Courts in this district, however, have rejected



“voluminous document production during discovery” as an excuse for delay. *Pfizer Inc., v. Sandoz Inc.*, 2013 WL 5934635, at \*3, \*5 (D. Del. Nov. 4, 2013).

Furthermore, the cases Defendants cite in support of their argument are either inapposite or distinguishable. The courts in *Diaz-Cruz v. Williams*, 2013 WL 2249293 (D. Del. May 22, 2013); *Eisai Co. v. Teva Pharms. USA, Inc.*, 247 F.R.D. 445, 448 n.1 (D.N.J. 2009); and *Biovail Lab'ys Int'l SRL v. Andrx Pharms., LLC*, 2007 WL 3231684 (D. Del. May 4, 2007), applied Rule 15's less demanding standard, not Rule 16's good cause standard. They are, therefore, not applicable to this analysis. Defendants also cite to *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003), and *Roquette Freres*, 2009 WL 1444835, at \*5, but the movants in both of those cases filed their motions within two months of learning of the required information for their proposed amendments. Defendants in this case, however, had the information over two months prior to the deadline to amend pleadings. Therefore, Defendants have failed to meet their burden of demonstrating that even with diligence they could not meet the court's scheduling order.

“[O]ther courts in the Third Circuit have found diligence when a party has sought to leave to amend within three months of learning new information . . . .” *Home Semiconductor Corp. v. Samsung Elecs. Co.*, 2019 WL 2135858, at \*5 (D. Del. May 16, 2019). Even if I were to find that Defendants could not meet the court's scheduling order due to the timing and volume of Plaintiff's document production, Defendants still cannot demonstrate good cause because they were not diligent in filing this motion. *See NRT Tech. Corp. v. Everi Holdings Inc.*, 2022 WL 354291, at \*3 (D. Del. Jan. 11, 2022) (rejecting the argument “that an inability to timely amend a pleading within the scheduling order deadline excuses a party from exercising diligence in seeking leave to amend outside of the deadline”).

First, five months elapsed from the time Defendants acquired the information to the time they filed the motion, and shorter delays have been found to negate arguments for good cause. *See Pfizer*, 2013 WL 5934635, at \*4 (finding a “substantial delay” of four months from the final deposition to filing the motion was undue delay under Rule 15(a) and evidence of lack of good cause under Rule 16(b)).

Second, Defendants appear to have been able to have brought the claim of inequitable conduct in late June, two months before they filed this motion, as they included an inequitable conduct theory in their invalidity contentions, which Defendants served on June 30, 2022. (D.I. 96 at 12-13; D.I. 64). Defendants provide no explanation for the delay between then and when they notified Plaintiff they intended to move to amend their answer on July 20, 2022 (D.I. 96, Ex. E at 1), or for the further delay to when they filed the motion on August 19, 2022, which undermines their argument of diligence. *See Genentech, Inc. v. Amgen Inc.*, 2020 WL 708113, at \*1 (D. Del. Feb. 12, 2020) (finding the movant failed to show good cause when it had the ability to plead an inequitable conduct claim two months before it filed its motion and did not provide an explanation for the delay).

Third, Defendants appear to have brought this motion at this time not because of their diligence, but, instead, in response to Plaintiff’s threat to file a motion to strike the inequitable conduct claim from Defendants’ invalidity contention. (D.I. 96, Ex. D at 1-2; D.I. 96, Ex. E at 1).

Therefore, even if the proximity of Plaintiff’s document production to the deadline to amend pleadings were to excuse Defendants from meeting the deadline, that does not excuse their lack of diligence thereafter. *See, e.g., NRT Tech.*, 2022 WL 354291, at \*3 (“Defendants’ delay in producing documents does not give Plaintiffs license to delay seeking leave to amend for an additional six months.”).

Because I find that Defendants have not satisfied Rule 16(b)(4)'s standard, it is not necessary to determine whether Defendants meet Rule 15(a)'s requirements. *See Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020).

**IV. CONCLUSION**

For the reasons stated above, Defendants' motion is DENIED.

An appropriate order will issue.