

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

BOSTON SCIENTIFIC CORPORATION)
and BOSTON SCIENTIFIC SCIMED, INC.,)
)
Plaintiffs,)

v.)

EDWARDS LIFESCIENCES)
CORPORATION,)
)
Defendant.)

EDWARDS LIFESCIENCES)
CORPORATION, EDWARDS)
LIFESCIENCES PVT, INC., and EDWARDS)
LIFESCIENCES LLC,)
)
Counterclaim and Third-Party)
Plaintiffs,)

v.)

BOSTON SCIENTIFIC CORPORATION,)
BOSTON SCIENTIFIC SCIMED, INC., and)
SADRA MEDICAL, INC.,)
)
Counterclaim and Third-Party)
Defendants.)

C.A. No. 16-275-JFB-SRF

UNDER SEAL

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the court in this patent infringement action is Edwards Lifesciences Corporation, Edwards Lifesciences PVT, Inc., and Edwards Lifesciences LLC (collectively, “Edwards”) motion for leave to amend its answer and counterclaims pursuant to Federal Rules of Civil Procedure 15(a)(2) and 16(b)(4). (D.I. 166) Plaintiffs and counterclaim defendants Boston Scientific Corporation and Boston Scientific Scimed, Inc., and third-party defendant Sadra

Medical Inc. (“Sadra”) (collectively, “Boston Scientific”), oppose the motion. (D.I. 176) For the following reasons, the court will grant Edwards’ motion for leave to amend its answer and counterclaims.

II. BACKGROUND

A. Procedural History

On April 19, 2016, Boston Scientific filed this suit against Edwards Lifesciences Corporation, alleging infringement of U.S. Patent No. 8,992,608 (“the ‘608 patent”). (D.I. 1) On June 9, 2016, Edwards filed its answer and counterclaims for noninfringement, invalidity, and infringement of U.S. Patent Nos. 9,168,133, 9,339,383, and 7,510,575. (D.I. 10) Pursuant to the court’s scheduling order, the deadline to file a motion to amend pleadings was November 30, 2016. (D.I. 34 at ¶ 2) On November 30, 2016, Edwards filed its first motion for leave to amend its answer, which was subsequently granted by the court. (D.I. 65; D.I. 103)

On February 17, 2017, Edwards served subpoenas on Dr. Jennifer K. White (“Dr. White”),¹ seeking her deposition and the production of documents pertaining to her work on heart valves. (D.I. 94) The court’s scheduling order prohibited deposing individuals before February 24, 2017. (D.I. 34, ¶ 1 (f)(1)) Dr. White produced responsive documents on April 3, 2017 and April 12, 2017. (D.I. 167 at 8) Edwards deposed Dr. White on April 18, 2017. (D.I. 167, Ex. 1) On May 3, 2017, Edwards filed the present motion for leave to amend its answer to include new defenses and counterclaims involving improper inventorship of the ‘608 patent

¹ Dr. White is a medical doctor who was a research fellow and instructor of surgery at Massachusetts General Hospital (“MGH”) from December of 1998 to February of 2007. (D.I. 167, Ex. 1 at 16:23-18:7) In February 2007, Dr. White formed Jenesis Surgical (“Jenesis”), an entity that makes heart valves. (*Id.*) At the time of her deposition, Dr. White was still employed at Jenesis. (*Id.*)

based on information obtained during the deposition of Dr. White. (*Id.*) According to the most recent revised scheduling order, fact discovery closed on June 30, 2017. (D.I. 153)

B. Facts Underlying Inventorship Claim

During her deposition, Dr. White testified that she met with Amr Salahieh (“Mr. Salahieh”), one of the named inventors of the ‘608 patent and co-founder of Sadra, in August 2003 and September 2003 to discuss designing new transcatheter heart valves (“THVs”) for Sadra. (D.I. 167, Ex. 1 at 142:23-154:3) In October 2003, Dr. White met with Mr. Salahieh and others specifically to brainstorm ideas for a THV replacement device for Sadra that would address the problem of sealing paravalvular leaks. (*Id.* at 154:5-161:10) Dr. White described to Sadra how to use “pockets” in an external seal to improve THVs’ effectiveness. (*Id.* at 160:16-180:22) Shortly after these meetings, Dr. White created prototype THVs on her own, as well as with Robert Geshliger, a named inventor of the ‘608 patent. (*Id.* at 182:16-183:8; 189:19-191:7; 196:3-196:23; 201:7-201:16) The collaboration between Dr. White and Sadra concluded in December 2003. (*Id.* at 204:20-205:10)

On June 26, 2009, Sadra filed the application leading to the ‘608 patent, bearing number 12/492,512 (“the ‘512 Application”), with the United States Patent and Trademark Office. (D.I. 1, Ex. A) The ‘512 Application claimed a THV system that avoided paravalvular leaks. (*Id.*) The ‘512 Application listed Ulrich R. Huag, Hans F. Valencia, Robert A. Geshliger, Tom Saul, Amr Salahieh, Dwight P. Morejohn, and Kenneth J. Michlitsch as inventors. (D.I. 167, Exs. 2, 3) When the ‘512 Application issued as the ‘608 patent, the same individuals were listed as inventors. (D.I. 1, Ex. A) Dr. White was not included as one of the inventors in either the ‘512 Application or the ‘608 patent. (*Id.*)

On April 21, 2016, Edwards entered into an Asset Purchase Agreement with Dr. White and Jenesis.² (D.I. 167, Ex. 1 at 20:7-22) Thereafter, Dr. White informed Edwards' CEO that she had collaborated with members employed by Sadra before the '608 patent was filed. (*Id.* at 21:3-23:3) Dr. White met with Edwards an additional three times prior to her deposition on April 18, 2017. (*Id.* at 258:21-24) At these meetings with Edwards, Dr. White discussed her work on seal technology for heart valves. (*Id.* at 263:4-264:8)

On November 9, 2016, Edwards submitted its invalidity contentions to Boston Scientific alleging invalidity of the '608 patent pursuant under 35 U.S.C. §§ 102(f) or 116.³ (D.I. 167, Ex. 4 at 15) In the invalidity contentions, Edwards stated that it had reason to believe that Dr. White contributed to the conception of the '608 patent by explaining how to create THV seals by using pockets during an October 2003 meeting with Sadra employees. (*Id.*) On February 14, 2017, the General Hospital Corporation ("GHC"), an entity of MGH, purportedly assigned the rights and interests of Dr. White's inventions to Edwards.⁴ (D.I. 167, Exs. 6, 7) On May 3, 2017, Edwards filed the present motion for leave to amend its answer to include new defenses, including Edwards' alleged ownership interest in the '608 patent, and a correction of inventorship counter claim pursuant to 35 U.S.C § 256. (D.I. 166) On June 6, 2017, Dr. White filed a lawsuit against Boston Scientific in the United States District Court for the District of Massachusetts, seeking to be added as an inventor to the '608 patent and U.S. Patent Application No. 14/873,462. (D.I.

² The purchase involved a stent structure for use as a valve replacement or docking station. (D.I. 167, Ex. 1 at 20:7-22) The present litigation does not involve this sale.

³ Edwards asserted that Dr. White was either the inventor or co-inventor of the invention described in the '608 patent. (D.I. 167, Ex. 4 at 16)

⁴ Edwards contends that at the time of Dr. White's collaboration with Mr. Salahieh and the other co-inventors of the '608 Patent, Dr. White was employed by GHC and was obligated to assign rights to all of her inventions to GHC. (D.I. 167 at 9) However, it is disputed as to whether GHC owned Dr. White's inventions during her employment with MGH and while she collaborated with Sadra. (*Compare* D.I. 167 at 9; *with* D.I. 176 at 10)

223) However, Edwards is not a party to the Massachusetts action, no party has moved to transfer the case to this court, and the case does not concern the validity of the '608 patent. (*Id.*)

III. LEGAL STANDARD

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that after a responsive pleading has been filed, a party may amend its pleading “only with the opposing party’s written consent or the court’s leave,” and “[t]he court should freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2). The decision to grant or deny leave to amend lies within the discretion of the court. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The Third Circuit has adopted a liberal approach to the amendment of pleadings. *See Dole v. Arco*, 921F.2d484, 487 (3d Cir. 1990). In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434.

If a party seeks leave to amend after a deadline imposed by the scheduling order, the court must apply Rule 16 of the Federal Rules of Civil Procedure. *WebXchange Inc. v. Dell Inc.*, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010). A court-ordered schedule “may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P 16(b)(4). “The good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.” *Venetec Int’l v. Nexus Med.*, 541 F. Supp. 2d 612, 618 (D. Del. 2010). The focus of the “good cause” inquiry is, therefore, on diligence of the moving party, rather than on prejudice, futility, bad faith, or any of the other Rule 15 factors. *Glaxosmithkline LLC v. Glenmark Pharm. Inc.*, 2016 WL 7319670, at *1 (D. Del. Dec. 15, 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. *See E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).

IV. ANALYSIS

A. Good Cause

Boston Scientific argues that Edwards failed to establish good cause to amend its answer following the expiration of the amended pleading deadline set forth in the scheduling order under Fed. R. Civ. P. 16(b)(4) because the facts underlying Edwards' inventorship claim were known to Edwards well before the deadline. (D.I. 176 at 7) Namely, Boston Scientific points to Edwards' invalidity contentions to show that Edwards possessed enough information to bring forth its present motion before November 30, 2016. (D.I. 176 at 11) Edwards counters that it did not acquire sufficient information regarding its inventorship claim until after the deposition of Dr. White on April 18, 2017. (D.I. 167 at 11)

The court concludes that Edwards has demonstrated good cause to amend its answer as required by Rule 16(b)(4). Good cause exists "when the schedule cannot reasonably be met despite the diligence of the party seeking the extension." *Dickerson v. KeyPoint Gov't Sols., Inc.*, 2017 WL 2457457, at *4 (D. Del. June 7, 2017). Edwards' amended counterclaim regarding inventorship is based on a new set of facts obtained from the April 18, 2017 deposition of Dr. White, in conjunction with a set of documents corroborating Dr. White's contributions to the '608 patent, which were received only two weeks prior to her deposition. *See ICU Med., Inc. v. Rymed Techs., Inc.*, 674 F. Supp. 2d 574, 578 (D. Del. 2009) (finding good cause when defendant's motion to amend after pleading deadline was based on a new set of facts obtained during discovery). Specifically, Edwards obtained information involving meetings held in August and September 2003 between Dr. White and Sadra's founder, as well as the details of Dr.

White's "brainstorming" meeting with Sadra in October 2003. (D.I. 167, Ex. 1 at 149:8-25, 153:7-22, 154:14-22)

Although Edwards was aware as early as November of 2016 that Dr. White may have contributed as a co-inventor of the '608 patent, the court finds that Edwards did not acquire sufficient information to amend its defenses and add a counterclaim regarding improper inventorship until Dr. White was deposed on April 18, 2017. *See ICU Med.*, 674 F. Supp. 2d at 578. Under Federal Rule of Civil Procedure 11(b)(3), Edwards had an obligation to gather sufficient factual information to support its claim for relief before filing its proposed amendment. *See Fed. R. Civ. P. 11(b)(3)* (requiring that "factual contentions [in pleadings] have evidentiary support or...will likely have evidentiary support after a reasonable opportunity for further investigation or discovery"). Moreover, under the *Iqbal/Twombly* pleading standards, a pleading must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Refusing to allow such amendments could encourage "knee jerk, thoughtless, and poorly grounded assertions." *Biovail Labs. Int'l SRL v. Andrx Pharm., LLC.*, 2007 WL 3231684, at *2 (D. Del. May 4, 2007).

The court also finds that Edwards acted diligently in pursuing the information needed to state a plausible claim. Diligence is absent when a motion to amend an answer after the amended pleading deadline is based on information that it could have obtained prior to the deadline. *See Sonos, Inc. v. D&M Holdings, Inc.*, 2017 WL 476279, at *1 (D. Del. Feb. 3, 2017). Here, Edwards could not have deposed Dr. White before the amended pleadings deadline, because the scheduling order restricted the scheduling of depositions until February 24, 2017. (D.I. 34 at ¶ 1(f)(1)) Further, Edwards acted diligently in serving Dr. White with a

subpoena seven days before Edwards was permitted to depose Dr. White and filing its motion to amend two weeks after Dr. White's deposition testimony.

B. Undue Delay and Prejudice

The court finds that Edwards' proposed amended answer does not cause undue delay or prejudice. A party seeking an amended answer causes undue delay when "it places an unwarranted burden on the court or when it comes after previous opportunities to amend." *Intellectual Ventures I LLC v. Toshiba Corp.*, 2016 WL 4690384, at *1 (D. Del. Sept. 7, 2016). Justification in denying a motion to amend due to delay appears "when the amendment is grounded on 'bad faith or dilatory motive, truly undue or unexplained delay . . .'" *Inline Connection Corp. v. AOL Time Warner Inc.*, 237 F.R.D. 361, 369 (D. Del. 2006) (quoting *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing of the Virgin Islands, Inc.*, 663 F.2d 419, 425 (3d Cir. 1981)). Such a consideration "requires that [the court] focus on the movant's reasons for not amending sooner." *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001). Although Boston Scientific argues that Edwards' failure to amend its answer until six months after the deadline constitutes undue delay, the court concludes that Edwards had good reason to seek additional information to rebut the presumption of correct inventorship. (D.I. 176 at 15); *see* § IV(A), *supra*; *Intellectual Ventures*, 2016 WL 4690384, at *2. Furthermore, the scheduling order did not allow Edwards to depose Dr. White until after the deadline to amend pleadings, and Edwards filed the present motion two weeks after Dr. White's deposition. (D.I. 34; 166) To meet its obligations of pleading with particularity, Edwards needed the deposition testimony in order to support its claim. As such, the court finds the Edwards did not unduly delay in bringing the motion.

Boston Scientific has failed to show it will be unduly prejudiced by Edwards' amended answer. In the Third Circuit, the non-moving party "must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the amendments been timely." *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989) (internal quotation marks omitted). The court must consider "whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or new theories." *Cureton*, 252 F.3d at 273. Boston Scientific claims that it is prejudiced because it will need to seek additional "discovery from Edwards, and third-parties Dr. White and GHC regarding the purported assigned of rights to the '608 patent; documentation relating to the alleged ownership of the '608 patent; all documents reflecting the date of transfer of ownership, interest or title; and depositions of any individuals involved in the assignments at issue." (D.I. 176 at 17) However, the court does not find that this rises to the level of "undue prejudice." Dispositive motions are not due until January 12, 2018, and the parties have eight months to obtain limited discovery before trial begins on July 30, 2018. (D.I. 34 at ¶¶ 8(c); 13)

C. Futility

The court does not find that Edwards' proposed amended answer is futile. A proposed amendment is futile if it is frivolous, fails to state a claim upon which relief can be granted, or advances a claim or defense that is legally insufficient on its face. *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006). The standard for assessing futility of amendment under Rule 15(a) is the same standard of legal sufficiency applicable under Rule 12(b)(6). *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). Specifically, the amended pleading must fail to state a claim upon which relief could be granted even after the district court "take[s] all pleaded

allegations as true and view[s] them in a light most favorable to the plaintiff.” *Winer Family Trust v. Queen*, 503 F.3d 319, 331 (3d Cir. 2007); see also *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 175 (3d Cir. 2010).

In the present matter, Edwards seeks leave to amend its answer to add a cause of action for correction of inventorship for the ‘608 patent pursuant to 35 U.S.C. § 256.⁵ (D.I. 166, Ex. A at 20) In support of this claim, Edwards cites to Dr. Whites deposition testimony, as well as documentary evidence. (*Id.*) Boston Scientific argues that that Edwards does not meet “the heavy burden of proving its case by clear and convincing evidence.” (D.I. 176 at 18-19) However, at the pleading stage, Edwards must merely state a claim to relief that is plausible on its face. *Twombly*, 550 U.S. at 547. Because Edwards’ proposed amendment includes factual contentions which, when taken as true, creates a plausible claim for correction of inventorship, Edwards’ amended answer states a claim upon which relief can be granted and is not futile.

V. CONCLUSION

For the foregoing reasons, Edwards’ motion for leave to amend is granted. (D.I. 166) An Order consistent with this Memorandum Opinion shall issue.

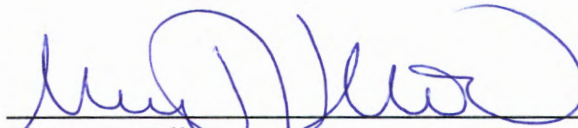
⁵ Section 256 creates a cause of action in the district courts for correction of non-joinder of an inventor on a patent provided the non-joinder error occurred without deceptive intent. See 35 U.S.C. § 256 (permitting correction of inventorship “[w]henver ... through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part”); *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1568, 1571 (Fed. Cir. 1988) (holding that deceptive intent in failing to join an inventor would not permit correction of inventorship under section 256 and could invalidate the patent). In a Section 256 proceeding, “[t]he inventors as named in an issued patent are presumed to be correct.” *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997). The general rule is that a party alleging misjoinder or non-joinder of inventors must meet the heavy burden of proving its case by clear and convincing evidence, see *id.* (citing *Garrett Corp. v. United States*, 422 F.2d 874, 880 (1970)), and must provide evidence to corroborate the alleged joint inventor’s conception, see *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1461 (Fed. Cir. 1998) (holding that “an alleged co-inventor must supply evidence to corroborate his testimony” of conception).

Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Opinion under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Opinion should be redacted, the parties should jointly submit a proposed redacted version by no later than **January 24, 2018**. The court will subsequently issue a publicly available version of its Memorandum Opinion.

This Memorandum Opinion is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Opinion. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Dated: January 10, 2018



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE