

**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)
LIFE SCIENCES 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-SLR-SRF

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the court in this patent infringement action is the motion for leave to amend an answer pursuant to Federal Rule of Civil Procedure 15(a)(2), filed by defendant and counterclaim plaintiff, Edwards Lifesciences Corporation, as well as counterclaim and third-party plaintiffs, Edwards Lifesciences PVT, Inc. and Edwards Lifesciences LLC (collectively, “Edwards”). (D.I. 65) Plaintiffs and counterclaim defendants, Boston Scientific Corporation

and Boston Scientific Scimed, Inc. (collectively, “Boston Scientific”), oppose the motion. (D.I. 75) For the following reasons, the court will grant Edwards’ motion for leave to amend its answer.

II. BACKGROUND

On April 19, 2016, Boston Scientific filed this suit against Edwards, 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. (D.I. 10) On November 30, 2016, Edwards filed a motion to amend its answer to add a prior use affirmative defense under 35 U.S.C. § 273. (D.I. 65 at ¶ 1) Pursuant to the scheduling order,¹ the deadline to amend pleadings was November 30, 2016. (D.I. 34 at ¶ 2) The motion presently pending before the court was filed on the final day for amending pleadings set forth in the scheduling order. Fact discovery is scheduled to be completed by May 26, 2017. (*Id.* at ¶ 1(a))

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*, 921 F.2d 484, 487 (3d Cir. 1990). In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment

¹ The parties have entered into three joint stipulations to amend the scheduling order. (D.I. 51; D.I. 59; D.I. 69) However, none of the modifications to the original scheduling order have altered the deadline for amended pleadings or the fact discovery deadline.

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.

IV. ANALYSIS

A. Sufficiency of the Pleading

Boston Scientific argues that Edwards' proposed amendment lacks sufficient information to allege an affirmative prior use defense, although it does not formally raise a futility challenge. (D.I. 73 at ¶ 7) Edwards counters that the proposed amendment provides sufficient information to put Boston Scientific on notice that Edwards is asserting a prior use defense pursuant to § 273, and more detailed facts supporting that defense will be revealed during the course of fact discovery. (D.I. 75 at ¶ 9)

The court concludes that Edwards' prior use affirmative defense is factually sufficient at this stage of the proceedings because affirmative defenses pleaded pursuant to Rule 8(c) are not held to the same pleading requirements as claims for relief brought in accordance with Rule 8(a). "Due to the differences between Rules 8(a) and 8(c) in text and purpose, [] *Twombly* and *Iqbal* do not apply to affirmative defenses, which need not be plausible to survive. [An affirmative defense] must merely provide fair notice of the issue involved." *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013) (internal quotation marks and citations omitted). "Rule 8(a) requires a 'statement of the claim showing that the pleader is entitled to relief' while Rule 8(c) only requires a pleader to 'state' an affirmative defense." *Tyco Fire Prod. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 899 (E.D. Pa. 2011) (emphasis in original) (citing *Charleswell v. Chase Manhattan Bank, N.A.*, C.A. No. 01-119, 2009 WL 4981730 (D.V.I. Dec. 8, 2009)). Boston Scientific has failed to point to any authority requiring a heightened pleading

standard for asserting an affirmative defense. Consequently, the court concludes that Edwards' prior use affirmative defense is factually sufficient.

B. Undue Delay

The court does not find that Edwards' proposed amended answer would cause undue delay. First, Edwards' motion for leave to amend was filed within the deadline set forth in the scheduling order for amending pleadings, which generally precludes a finding of undue delay. (D.I. 34 at ¶ 2); *see Invensas Corp. v. Renesas Elecs. Corp.*, C.A. No. 11-448-GMS-CJB, 2013 WL 1776112, at *3 (D. Del. Apr. 24, 2013) (granting plaintiff's motion to amend and finding no undue delay when plaintiff filed on the last day set by the scheduling order to amend pleadings); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2012 WL 2365905, at *2 (D. Del. June 21, 2012) (holding that a motion to amend filed on the deadline for amended pleadings was "filed timely and, therefore, there can be no unfair prejudice to defendant"); *LifePort Scis. LLC v. Endologix Inc.*, C.A. No. 12-1791-GMS, D.I. 105 at 2 (D. Del. July 29, 2015) ("Even assuming the plaintiff is correct that the defendant *could* have filed its motion sooner, the court cannot say the delay was undue . . . when this was explicitly contemplated as a possibility."). Second, the case is still in its early stages, and fact discovery is not scheduled to close until May 26, 2017. Edwards' purported failure to explain the delay between the filing of its initial answer and the filing of the proposed amended answer is insufficient to deny leave to amend under the facts of the present case. "The mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay." *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001).

C. Prejudice

Boston Scientific has also failed to show it will be unduly prejudiced by Edwards' amended answer. A non-moving party's opposition to an amended pleading 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. Although Boston Scientific claims that it did not anticipate the addition of Edwards' prior use defense when it negotiated the discovery limits in the scheduling order, Boston Scientific acknowledged the possibility of an amended answer by stipulating to the deadline for amended pleadings in the scheduling order at the time of discovery negotiations. (D.I. 73 at ¶ 10) To the extent Boston Scientific would be prejudiced by the need to obtain additional discovery directed to the prior use defense, a limited grant of additional discovery is warranted, as discussed at § IV.D, *infra*.

D. Additional Discovery

Boston Scientific requests additional discovery in the form of three (3) additional interrogatories, five (5) additional requests for production of documents, and fifteen (15) additional requests for admission, limited to the new prior use defense, as well as a forty-five (45) day extension to serve the document requests. (D.I. 73 at ¶ 11) In response, Edwards expresses willingness to expand the agreed-upon discovery limits, but notes that Boston Scientific still has seven (7) unused interrogatories, forty-three (43) unused requests for production, and one hundred (100) unused requests for admission. (D.I. 75 at ¶¶ 14, 17)

Edwards also indicates that a substantial number of documents already produced in discovery serve as a basis for its prior use defense. (*Id.* at ¶ 15)

The court concludes that additional limited discovery is appropriate in light of the newly asserted prior use defense. In view of the unused requests available to Boston Scientific under the scheduling order, however, the number of additional requests sought by Boston Scientific is unnecessary. Therefore, Boston Scientific's request for additional discovery is granted as follows: two (2) additional interrogatories, five (5) additional requests for production of documents, and ten (10) additional requests for admission. In the event a further extension is necessary to serve the additional discovery requests, the court will consider a reasonable extension absent a stipulation from the parties.

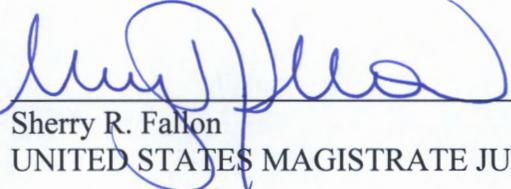
V. CONCLUSION

For the foregoing reasons, Edwards' motion for leave to amend is granted. (D.I. 65) An Order consistent with this Memorandum Opinion shall issue.

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: February 28, 2017


Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE