IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVARTIS VACCINES AND DIAGNOSTICS, INC.; AND NOVARTIS PHARMA AG,	)	
Plaintiffs,	)	
v.	)	Civ. No. 11-84-SLR
MEDIMMUNE, LLC, BIOGEN IDEC, INC.; AND ALEXION PHARMACEUTICALS, INC.,	)	
Defendants.	)	

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MEMORANDUM OPINION

Dated: July 30, 2013
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On January 26, 2011, Novartis Vaccine and Diagnostics, Inc. ("NVD") filed a complaint against defendants MedImmune, LLC ("MedImmune"), Alexion Pharmaceuticals, Inc. ("Alexion"), and Biogen Idec, Inc. ("Biogen") (collectively, "defendants"), alleging that each defendant infringed U.S. Patent No. 5,688,688 ("the '688 patent"). (D.I. 1) In their respective answers, each defendant counterclaimed, seeking a declaratory judgment of non-infringement and invalidity of the '688 patent. (D.I. 14; D.I. 17; D.I. 19) NVD filed its first amended complaint ("FAC") against all defendants on July 22, 2011. (D.I. 27) Defendants answered and repeated their request for a declaratory judgment. (D.I. 37; D.I. 38; D.I. 39) On July 1, 2012, Novartis Pharma AG ("Pharma") became the exclusive licensee of the '688 patent (*see* D.I. 161 at 15), and on July 18, 2012, Pharma was added as a co-plaintiff on the first supplemental complaint ("FSC"). (D.I. 161) On August 1, 2012, defendants answered with a reiteration of their requests for declaratory judgment. (D.I. 165; D.I. 166; D.I. 169) On November 14, 2012, MedImmune was dismissed pursuant to a settlement agreement. (*See* D.I. 246, 247) Presently before the court is NVD's and Pharma's (collectively, "plaintiffs") motion for leave to file a second amended complaint ("SAC"). (D.I. 417) The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. BACKGROUND

A. Parties

NVD is a corporation organized and existing under the laws of Delaware, having

places of business in Emeryville, California and Cambridge, Massachusetts. (D.I. 1 at ¶ 2) Pharma is a corporation organized and existing under the laws of Switzerland, having a place of business in Basel, Switzerland. (D.I. 161 at ¶ 3) Biogen is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Cambridge, Massachusetts. (D.I. 1 at ¶ 4) Alexion is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located in Cheshire, Connecticut. (*Id.* at ¶ 5)

B. Facts

On November 18, 2010, NVD approached Biogen through a third party, Lonza Biologics, notifying them of the '688 patent and requesting NVD and Biogen to enter into a confidentiality, standstill, and tolling agreement ("the standstill agreement"). (D.I. 424 at 1, exs. 1, 2, 3) On November 19, 2010, the two parties executed the standstill agreement. (D.I. 424 at 1, ex. 4)

On January 26, 2011, the present suit was filed in the District of Delaware, per the standstill agreement. (D.I. 424, ex. 4) The proposed scheduling order (D.I. 36) was confirmed on August 4, 2011, and required any pleading amendments to be filed prior to July 15, 2012 (*id.* at ¶ 3).

On July 13, 2012, plaintiffs filed a motion for leave to file a supplemental complaint naming Pharma as a co-plaintiff. (D.I. 158) This motion was granted five days later. (D.I. 161) In defendants' answers and counterclaims filed on August 1, 2012, no issue was raised with respect to Pharma's standing. (D.I. 165; D.I. 166; D.I. 169)

On February 5, 2013, approximately six months after licensee Pharma was

added as a co-plaintiff, Alexion raised a concern regarding the FSC. (D.I. 418, ex. E) Specifically, when NVD globally replaced its name with "plaintiffs" in its amended complaint (D.I. 161), the replacement led to an erroneous assertion that both NVD and Pharma were alleging infringement by Alexion. (D.I. 418 at 6) NVD sent a proposed SAC to defendants on February 8, 2013. (*Id.*, ex. E) Changes included clarification regarding the infringement by Alexion, as well as removing claims against MedImmune. (*Id.*)

On February 22, 2013, Alexion stated it would not oppose the filing of the SAC. (*Id.*, ex. F) NVD requested a response from Biogen on February 22, 2013; having received none, it requested again on March 11, 2013. (*Id.* at 6, ex. G at 3-4) On March 13, 2013, Biogen replied that "[Biogen] will not oppose the Plaintiffs' motion to file an amended complaint that removes Pharma's claim against Alexion," and that it reserved the right to "assert that Pharma lacks standing to make a claim against [Biogen]." (*Id.*, ex. G at 2-3)

On March 25, 2013, Pharma proposed additional revisions to the SAC (*id.*, ex. G at 2) that Alexion did not object to amending aside from replacing one instance of "plaintiff" with "V&D" (*id.*, ex. H). On April 1, 2013, Biogen indicated it would not consent to the motion to amend, stating it "will not consent to any amendment alleging willfulness and requesting treble damages."[1] (*Id.*, ex. G at 2) Biogen also requested that plaintiffs identify the Fed. R. Civ. P. 11 basis for the pleading. (*Id.*) NVD attempted

[1] Allegations of willfulness and requesting treble damages have appeared in all three of the complaints filed in this action. (*See* D.I. 1 at ¶ 23; D.I. 27 at ¶ 24; D.I. 161 at ¶ 26)

to resolve the dispute on April 2, 2013. (D.I. 418 at 6) Biogen reiterated its opposition to amend on April 8, 2013 and April 11, 2013. (*Id.*, exs. G at 2, I) On April 22, 2013, Pharma met and discussed further revisions to the claims of willful infringement contained in the SAC, providing more detail surrounding the timeframe of the willfulness allegations, to which Biogen maintained its objection. (*Id.*, ex. J)

III. STANDARD OF REVIEW

The Federal Rules of Civil Procedure require courts to "freely give" leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). Nevertheless, courts "ha[ve] discretion to deny a motion to amend for reasons of 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.'" *Merck & Co., Inc. v. Apotex, Inc.*, 287 Fed. App'x 884, 888 (Fed. Cir. 2008) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). After a pleading deadline has passed, courts have required the movant to also satisfy the more rigorous "good cause" standard of Fed. R. Civ. P. 16(b)(4).[2] *See, e.g., E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000); *ICU Med. Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 578 (D. Del. 2009); *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371 (D. Del. 2009). "Under this provision, '[g]ood cause' exists when the [s]chedule cannot reasonably be met despite the diligence of the party seeking the extension," *ICU Med*, 674 F. Supp. 2d at 577 (citing Fed.R.Civ.P. 16(b)(4), Advisory Committee's Notes (1983 amendments)). "In contrast to Rule 15(a),

[2] Rule 16(b)(4) provides that a scheduling order "may be modified only for good cause and with the judge's consent."

the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." *Id.* at 577–78 (quoting *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at *4 (D. Del. May 21, 2009)).

IV. DISCUSSION

A. Good Cause

As plaintiffs' motion was filed nine months after the deadline to amend pleadings, they must show good cause under Rule 16(b) for the delay. After reviewing the relevant documents, the court concludes that plaintiffs have shown good cause. Despite having reviewed the FSC prior to filing on July 13, 2012, defendants did not raise the FSC interpretation issue until February 5, 2013, approximately six and a half months after the deadline. When the delay is not of the plaintiff's making, the courts have found good cause. *See Roquette Freres*, 2009 WL 1444835, at *5-6 (amendment permitted when inventors' depositions did not occur until six months after cut-off date for amendment, and movant filed motion a month and a half after deposition); *Intervet Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, 2012 WL 4808427, at *1 (D. Del. Oct. 9, 2012) (amendment permitted when movant informed non-movant of intention to amend one week following a deposition that occurred four months after the cut-off date for amendment). Here, NVD's first proposed revision was sent to defendants three days after NVD was notified of the interpretation issue. (D.I. 418, ex. E) Further, plaintiffs continued to be diligent throughout the revision process. In the two and a half months between February 5, 2013 and April 24, 2013, plaintiffs made three separate proposed

revisions (*id.*, exs. E, G at 2, J), engaged in at least two "meet and confer" sessions (*id.*, exs. E, J), and regularly corresponded with defendants (*id.*, exs. F, G, H).

B. Leave To Amend

The factors to consider in weighing a motion for leave to amend are well-settled: (1) whether the amendment has been unduly delayed; (2) whether the amendment would unfairly prejudice the non-moving party; (3) whether the amendment is brought for some improper purpose; and (4) whether the amendment is futile. *See Foman v. Davis*, 371 U.S. 178, 182 (1962). The only question before the court is Biogen's assertion that the amendment contains a futile claim for willful infringement and treble damages.[3] (D.I. 424 at 3).

An amendment is futile when it "fails to state a claim upon which relief can be granted, or 'advances a claim or defense that is legally insufficient on its face.'" *Bigband Networks, Inc. v. Imagine Commc'ns, Inc.*, 2010 WL 2898286, at *1 (D. Del. July 20, 2010) (quoting *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006)); *see also Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 2013 WL 571801 (D. Del. Feb. 13, 2013) (denying motion for leave to amend complaint because amendment would be futile). However, 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).

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[3] Biogen also states plaintiffs have no good-faith basis for pursuing a willful infringement claim under Fed. R. Civ. P. 11 "in light of paragraph 4(b) of the Tolling Agreement." (D.I. 424 at 7-8, ex. 4 at 7; D.I. 418, ex. G at 1) However, this factual dispute may be determined by summary judgment motions or at trial, but is not properly considered in determining a motion to amend.

Seagate sets forth the two-prong analysis the Federal Circuit has mandated for establishing willful infringement. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). First, plaintiff must provide "clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* Second, plaintiff must show that the risk "was either known or so obvious that it should have been known to the accused infringer." *Id.*

Here, plaintiffs allege that Biogen made and continues to make the product Tysabri (D.I. 418, ex. N at ¶ 17); Tysabri utilizes a third party product, the Lonza GS Expression System (*id.*); and the Lonza GS Expression System infringes NVD's patent (*id.*, ex. N at ¶ 15). Plaintiffs provided evidence that Biogen knew about the infringement as early as November of 2010 (*id.*, ex. L at 2), two months prior to the filing of the suit. Biogen has further stated it does not dispute it was informed of the patent as of November 18, 2010 (D.I. 424 at 1).[4] Assuming all factual allegations as true, plaintiffs' claims meet both the objective and subjective prongs of the *Seagate* analysis.

Biogen argues that because willful infringement claims examine pre-litigation conduct, and Pharma did not enter into the license agreement until July 1, 2012, eighteen months after the beginning of the lawsuit, Pharma is barred from making a willfulness claim.[5] (D.I. 424 at 7) This argument is not persuasive, as courts have upheld willfulness claims based on conduct occurring before a plaintiff had standing to

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[4] The parties dispute whether November 18, 2010 was the earliest date Biogen was aware of the '688 patent and potential infringement. (D.I. 424 at 1; D.I. 426 at 4) However, this factual dispute is not appropriately considered in a motion to amend.

[5] Biogen does not cite any case law other than *Seagate* to support its position. (D.I. 424 at 7)

sue. *See Copease Mfg. Co. v. Am. Photocopy Equip. Co.*, 298 F.2d 772, 783-84 (7th Cir. 1961) (affirming finding of willful infringement for assignee based in part on infringer's conduct occurring before patent assignment, even though assignee did not have right to sue for past infringement); *Pentech Int'l, Inc., v. Hayduchok*, 931 F. Supp. 1167, 1178-79 (S.D.N.Y. 1996) (finding willful infringement for exclusive licensee based in part on infringer's conduct occurring before patentee granted exclusive license). As Pharma is not barred from making the willfulness claim,[6] it has a good-faith basis for making the complaint. Therefore, the amendment is not futile.

V. CONCLUSION

For the foregoing reasons, the court grants NVD and Pharma's motion for leave to file an amended complaint. (D.I. 417) An appropriate order shall issue and plaintiff's amended complaint is deemed filed and served as of the date of the issued order.

[6] Even if, as Biogen claims, Pharma's willfulness claims were limited to the timeframe in which it had standing prior to the original complaint, Pharma's original complaint occurred on July 18, 2012, 17 days after it gained standing under the license agreement. Therefore, those 17 days would fall into Biogen's proposed timeframe, and Pharma would still be entitled to bring a willful infringement claim.