IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S, LEO LABORATORIES LIMITED, AND LEO PHARMA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 16-430-JFB-SRF
PERRIGO UK FINCO LIMITED PARTNERSHIP and PERRIGO COMPANY,	)	REDACTED VERSION
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the court in this patent infringement action is a motion for leave to file a first amended complaint pursuant to Federal Rule of Civil Procedure 15(a)(2), filed by plaintiffs LEO Pharma A/S, LEO Laboratories Limited, and LEO Pharma, Inc. (collectively, "LEO"). (D.I. 45) Defendants Perrigo UK Finco Limited Partnership and Perrigo Company (collectively, "Perrigo"), oppose the motion. (D.I. 50) For the following reasons, the court will grant LEO's motion to amend.

II. BACKGROUND

On June 10, 2016, LEO filed the present Hatch-Waxman suit claiming that Perrigo's Abbreviated New Drug Application ("ANDA") Nos. 209018 and 209019 infringe eleven of LEO's patents[1] (the "patents-in-suit") listed in the Orange Book in connection with the drug Picato®. (D.I. 1 at ¶¶ 1, 13) Perrigo produced the relevant ANDAs to LEO on October 26,

[1] The original complaint identifies U.S. Patent Nos. 6,432,452 ("the '452 patent), 6,787,161 ("the '161 patent"), 6,844,013 ("the '013 patent"), 7,410,656 ("the '656 patent"), 8,278,292 ("the '292 patent"), 8,372,827 ("the '827 patent"), 8,372,828 ("the '828 patent"), 8,377,919 ("the '919 patent"), 8,536,163 ("the '163 patent"), 8,716,271 ("the '271 patent"), and 8,735,375 ("the '375 patent").

2016, which indicated that they were submitted in reliance on a Drug Master File ("DMF") for the active pharmaceutical ingredient ("API") ingenol mebutate, Redacted

On May 24, 2017, LEO filed a motion to amend its complaint that added two counts for declaratory judgment of infringement of U.S. Patent Nos. 8,901,356 ("the '356 patent") and 9,416,084 ("the '084 patent")[2] which cover methods of synthesizing ingenol mebutate. (D.I. 45, Ex. 1 at ¶¶ 260-87) On June 14, 2017, in conjunction with the filing of its reply brief, LEO sought to substitute its proposed amended complaint with a revised version of the amended complaint, replacing the count directed to the '356 patent with a count directed to U.S. Patent No. 9,676,698 ("the '698 patent").[3] (D.I. 54, Ex. 1 at ¶¶ 260-87) Thus, LEO currently seeks to amend its complaint by adding two counts for declaratory judgment of infringement of the '698 patent and the '084 patent (together, "the Process Patents"), while also withdrawing two counts from its original complaint related to infringement of the '452 patent. (D.I. 54 at 1-2)

According to the proposed amended revised complaint, the Process Patents cover methods of producing ingenol mebutate, the API in Picato® and Perrigo's ANDA products. (D.I. 54, Ex. 1 at ¶¶ 57-58) The Process Patents are not in the same patent family as the patents-in-suit, and are not listed in the Orange Book. (*Id.* at ¶¶ 29-31) The Process Patents list five inventors, four based in Denmark and one in Sweden, who are not listed as inventors of the patents-in-suit. (D.I. 53 at 4)

[2] LEO's motion also withdrew two counts from its original complaint related to infringement of the '452 patent. (D.I. 45, Ex. 2 at 12-16)
[3] The '698 patent issued to LEO on June 13, 2017. (D.I. 55, Ex. 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 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. Undue Delay and Prejudice

The court does not find that LEO's proposed first amended complaint will cause undue delay. First, the pending motion for leave to amend was filed within the deadline to amend pleadings under the scheduling order, which generally precludes a finding of undue delay. *See Intellectual Ventures I LLC v. Toshiba Corp.*, C.A. No. 12-453-SLR-SRF, 2015 WL 4916789, at *2 (D. Del. Aug. 17, 2015) (citing *Invensas Corp. v. Renesas Elecs. Corp.*, C.A. No. 11-448-GMS-CJB, 2013 WL 1776112, at * 3 (D. Del. Apr. 24, 2013); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, C.A. No. 11-54-SLR, 2012 WL 2365905, at *2 (D. Del. June 21, 2012)). Second, the case is still in its early stages, and fact discovery remains open until December 22, 2017. (D.I. 19) LEO's purported failure to explain why it took almost seven months to file its motion to amend after receiving the ANDAs on October 26, 2016 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); *see also 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.").

The court recognizes that LEO's proposed amendment could potentially lead to additional fact discovery from Redacted, and could also result in further briefing on claim construction, both of which could jeopardize the completion of this case before the expiration of Perrigo's 30-month FDA approval stay with respect to its ANDAs.[4] However, 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). In the present case, the proposed amended complaint was filed within the time frame for amended pleadings, and fact discovery does not close until December 22, 2017. (D.I. 54, Ex. 1; D.I. 19) Trial in this case is not scheduled to commence until October 2018, which gives Perrigo additional time to conduct discovery if needed. *See Synopsys, Inc. v. Magma Design Automation*, No. 05-701-GMS, 2006 WL 1452803, at *5 (D. Del. May 25, 2006) (granting motion to amend to include the addition of four patent infringement claims less than six months before fact discovery closed when trial was more than fourteen months away).

[4] The 30-month stay in the present action expires on July 23, 2019, as calculated pursuant to New Chemical Entity status. (D.I. 3)

Moreover, nearly identical claims[5] regarding the Process Patents were added by stipulation of the parties on June 23, 2017 in a related case pending before this court, *Leo Pharma A/S v. Actavis Laboratories UT, Inc.*, Civil Action No. 16-333-JFB-SRF. (C.A. No. 16-333-JFB-SRF, D.I. 71; D.I. 73) Although Perrigo is not bound by or limited to the discovery obtained by Actavis and the claim construction arguments presented by Actavis regarding the Process Patents in the related action, the court encourages the Perrigo and Actavis defendants to coordinate their efforts as they did on the claim construction briefing[6] regarding the patents-in-suit. To the extent that collaborative efforts are insufficient to avoid delays in the case schedule resulting from the addition of the Process Patent claims, the court is open to consideration of the parties' proposals to incorporate the Process Patent claims within the framework of the existing schedule.

The deadline to amend pleadings under the scheduling order expired on August 3, 2017. (D.I. 19 at 5) To the extent that Perrigo is concerned that LEO will continue to broaden the scope of the case as new patents continue to issue (D.I. 59 at 4), the court emphasizes that the analysis of a motion to amend the pleadings changes after the expiration of the deadline to amend pleadings.

B. Futility

The court does not find LEO's proposed amended complaint to be futile. "An amendment is futile if it is frivolous, fails to state a claim upon which relief can be granted, or

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[5] [redacted] Redacted

[6] Supplemental claim construction briefing on the Process Patents was completed in the related case, prior to an agreement between Actavis and LEO regarding the proper construction of the disputed terms and the reservation of indefiniteness arguments for summary judgment. (C.A. No. 16-333-JFB-SRF, D.I. 93; D.I. 96; D.I. 116; D.I. 124; D.I. 142)

'advances a claim or defense that is legally insufficient on its face.'" *Intellectual Ventures*, 2015 WL 4916789, at *2 (quoting *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006)). The standard for analyzing futility of an 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, LEO seeks to add two claims for declaratory judgment of infringement of the Process Patents under Redacted. Perrigo argues that LEO's motion to amend is futile, because LEO's declaratory judgment claims under Redacte "are not yet ripe or justiciable." (D.I. 50 at 16)

The Declaratory Judgment Act requires the existence of an actual controversy between parties before a federal court can exercise its jurisdiction. 28 U.S.C. § 2201(a). When a patentee seeks a declaratory judgment against an alleged future infringer, the patentee must demonstrate that:

> (1) the defendant must be engaged in activity directed toward . . . an infringement charge . . . or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

Lang v. Pac. Marine & Supply Co., 895 F.2d 761, 763 (Fed. Cir. 1990). These criteria are met by the allegations in the proposed amended complaint, which establishes that Perrigo submitted letters to LEO expressing its intent to enter the market as soon as its ANDAs are approved prior

to the expiration of the patents beginning in August 2018. (D.I. 54, Ex. 1 at ¶¶ 33, 47-48) Re [redacted] Consequently, the proposed amended complaint withstands scrutiny under the Rule 12(b)(6) standard.

V. CONCLUSION

For the foregoing reasons, LEO's motion for leave to amend is granted. (D.I. 45) An Order consistent with this Memorandum Opinion shall issue.

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 **September 29, 2017**. 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: September 20, 2017

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE