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 PUBLIC VERSION
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the court in this patent infringement action is a motion for leave to file amended answer, affirmative defenses, and counterclaims pursuant to Federal Rule of Civil Procedure 15(a)(2), and to amend the scheduling order, which was filed by defendants Perrigo UK Finco Limited Partnership and Perrigo Company (collectively, "Perrigo"). (D.I. 178) Plaintiffs LEO Pharma A/S, LEO Laboratories Limited, and LEO Pharma, Inc. (collectively, "LEO") oppose the motion. (D.I. 199) For the following reasons, the court will grant Perrigo'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

[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").

Picato®. (D.I. 1 at ¶¶ 1, 13) Perrigo produced the relevant ANDAs to LEO on October 26, 2016, which indicated that they were submitted in reliance on a Drug Master File ("DMF") for the active pharmaceutical ingredient ("API") ingenol mebutate, [redacted]. (D.I. 21; D.I. 45, Ex. 1 at ¶ 55)

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) The court issued a Memorandum Opinion and Order granting the motion to amend the complaint on September 20, 2017. (D.I. 97; D.I. 98) Perrigo answered the amended complaint on October 4, 2017. (D.I. 108)

Following the addition of the LEO process patents, Perrigo began third-party discovery of its [redacted]. (D.I. 178, Ex. 1 at Exs. A & B) This discovery suggested that [redacted]. (*Id.* at Exs. E-F) Perrigo contends that this information was not disclosed to the United States Patent and Trademark Office ("USPTO") during prosecution of the LEO process patents, raising issues

[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) The '698 patent, together with the '084 patent, are identified as the "LEO process patents" throughout this decision.

of improper inventorship, unenforceability, and inequitable conduct. By way of its proposed amended answer, affirmative defenses, and counterclaims, Perrigo seeks to include allegations regarding the newly-discovered inequitable conduct and fraud by LEO. (D.I. 178, Ex. 2)

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

The court does not find that Perrigo's delay in seeking leave to amend its proposed amended answer, affirmative defenses, and counterclaims is unreasonable. Although the deadline to amend pleadings under the scheduling order passed on August 3, 2017, the evidence prompting Perrigo's proposed amendment was not known to Perrigo until November 2017, following LEO's amendment of the complaint on September 20, 2017. (D.I. 19; D.I. 99) Perrigo did not have the necessary information on which to base its inequitable conduct counterclaim until after discovery was produced in response to the filing of the amended

complaint. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009) (pleading the circumstances of inequitable conduct must be done with the requisite particularity under Rule 9(b)). Perrigo prepared draft counterclaims and notified LEO of its intent to pursue inequitable conduct allegations shortly after receiving the relevant discovery, and sought leave to amend from the court less than three months after the production of discovery revealing the purported role of [redacted]. (D.I. 178, Exs. 1 & 3) Perrigo should not be precluded from asserting a cause of action based on new facts not known to it prior to the August 3, 2017 deadline for amended pleadings. *See Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001) ("The mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay.").

B. Prejudice

The court further concludes that LEO will not be substantially prejudiced by Perrigo's amended pleading. 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). Perrigo's proposed amendment is unlikely to lead to substantial additional fact discovery because the parties' discovery efforts regarding the LEO process patents are well underway. (1/10/18 Tr. at 88:8-22) Additional time is available for limited further discovery, as trial in this case is not scheduled to commence until October 2018 and expert discovery is scheduled to be completed by July 27, 2018. (D.I. 159) Moreover, LEO's assertion of prejudice is not persuasive in light of the record before the court, which demonstrates that Perrigo's proposed amendment stems from LEO's decision to amend its complaint to add the LEO process patents.

C. Futility

Perrigo's proposed amended answer, affirmative defenses, and counterclaims are not futile. "An 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.'" *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, Perrigo seeks to add claims based in fraud, such as its amended counterclaim for inequitable conduct. To adequately plead claims sounding in fraud, Perrigo must establish the existence of a misrepresentation or omission, knowledge, and specific intent:

> [A]lthough "knowledge" and "intent" may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Exergen, 575 F.3d at 1328-29.

Perrigo's proposed amended pleading satisfies these criteria by establishing that the named inventors of the LEO process patents, working with LEO executives, submitted Oaths of Inventorship to the USPTO declaring that they were the original and first inventors of the claimed invention. (D.I. 178, Ex. 1 at ¶¶ 34-56; 70-73) The proposed amended pleading further

alleges that the representations made in the Oaths of Inventorship purposefully failed to identify or credit [redacted]. (*Id.* at ¶¶ 74-83) Perrigo's proposed amended answer, affirmative defenses, and counterclaims highlight LEO's failure to disclose to the USPTO any information it received from [redacted], suggesting that LEO intended to deceive the USPTO. (*Id.* at ¶ 80) Moreover, the proposed amended pleading sets forth in detail the similarities between the processes disclosed in the [redacted] documents and the claims of LEO's process patents. (*Id.* at ¶¶ 47-56) These allegations are sufficient at the pleadings stage to state a viable claim for inequitable conduct. Consequently, the proposed amended complaint withstands scrutiny under the Rule 12(b)(6) standard.

LEO contends that, even if the court upholds the addition of Perrigo's inequitable conduct claim, Perrigo's proposed amendment is futile with respect to Perrigo's added allegation of invalidity due to derivation pursuant to § 102(f). (D.I. 199 at 4-5) In accordance with pre-AIA § 102(f), an applicant is not entitled to a patent if "he did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f) (2006). "To show derivation, the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee." *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997). The Federal Circuit applies the same approach in both derivation and inventorship disputes. *See Cumberland Pharms. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1218 (Fed. Cir. 2017).

In the present case, the amended counterclaim explicitly bases its § 102(f) invalidity allegations[4] on the fact that "the subject matter of the claimed invention was the work of another

[4] LEO also alleges that Perrigo cannot properly raise new invalidity contentions at this stage of the proceedings because the deadline to do so passed two weeks after the issuance of the court's claim construction ruling on December 28, 2017. (D.I. 199 at 4 n.5; D.I. 159) However, Perrigo

and not conceived of by any of the named inventors" of the LEO process patents. (D.I. 178, Ex. 1 at ¶¶ 250, 265) These allegations are rooted in the same facts supporting Perrigo's inequitable conduct claim. In light of the similarities between the elements of a cause of action for derivation under § 102(f) and a claim for fraudulent and inequitable conduct based on the filing of purportedly false Oaths of Inventorship, the court concludes that Perrigo's amended pleading contains sufficient facts to support its § 102(f) derivation claim at this stage of the proceedings.

D. Good Cause

Federal Rule of Civil Procedure 16(b) states that when a pleading deadline imposed by a scheduling order has passed, a party seeking leave to amend must demonstrate "good cause" in support thereof. Fed. R. Civ. P. 16(b)(4); *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371 (D. Del. 2009). The good cause standard requires a showing that the existing case schedule cannot reasonably be met, despite the movant's diligence. *See Novartis Vaccines & Diagnostics, Inc. v. MedImmune, LLC*, C.A. No. 11-84-SLR, 2013 WL 3812074, at *2 (D. Del. July 22, 2013). "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." *Sonos, Inc. v. D&M Holdings Inc.*, C.A. No. 14-1330-RGA, 2017 WL 476279, at *1 (D. Del. Feb. 3, 2017) (citing *Glaxosmithkline LLC v. Glenmark Pharm. Inc.*, C.A. No. 14-877-LPS-CJB, 2016 WL 7319670, at *1 (D. Del. Dec. 15, 2016)).

Good cause exists to permit Perrigo's amended pleading in the present case. The record reflects that Perrigo moved for leave to amend its pleading shortly after Perrigo obtained the

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explicitly reserved its right to supplement its invalidity contentions "based on any future claim construction rulings by the Court." (D.I. 159 at 3 n.1) Objections to the December 28, 2017 Report and Recommendation on claim construction remain pending, and the court is scheduled to hold another *Markman* hearing on April 16, 2018, with a subsequent claim construction ruling due on June 5, 2018. (D.I. 159; D.I. 161; D.I. 170; D.I. 172)

discovery prompting the proposed amendment. There is no evidence that Perrigo failed to be diligent in pursuing its inequitable conduct claims following the filing of LEO's amended complaint on September 20, 2017. Therefore, good cause exists to permit the filing of Perrigo's amended answer, affirmative defenses, and counterclaims after the August 3, 2017 deadline to amend pleadings.

V. CONCLUSION

For the foregoing reasons, Perrigo's motion for leave to amend is granted. (D.I. 178) 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 **April 16, 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: April 2, 2018

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE