

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

BAXALTA INCORPORATED,)	
BAXALTA US INC., and)	
NEKTAR THERAPEUTICS,)	
)	
Plaintiffs and)	
Counterclaim Defendants,)	
)	
v.)	Civil Action No. 17-1316-RGA-SRF
)	CONSOLIDATED
BAYER HEALTHCARE LLC,)	
)	
Defendant and)	
Counterclaim Plaintiff.)	

MEMORANDUM OPINION

I. INTRODUCTION

Presently before the court in this patent infringement action is the motion of defendant Bayer Healthcare LLC (“Bayer”) for leave to amend its answers and counterclaims.¹ (D.I. 515) For the following reasons, Bayer’s motion for leave to amend is GRANTED-IN-PART. Specifically, the motion is DENIED without prejudice to the extent that Bayer requests leave to amend the correction of inventorship allegations under 35 U.S.C. § 256. The motion to amend is GRANTED in all other respects.

II. BACKGROUND²

Plaintiffs Baxalta Incorporated, Baxalta US Inc., and Nektar Therapeutics (collectively, “Plaintiffs”) and Bayer have developed and launched a number of factor VIII replacement

¹ The briefing and other filings associated with the pending motion can be found at D.I. 516, D.I. 517, D.I. 518, D.I. 519, D.I. 547, and D.I. 559.

² The background set forth herein focuses on the recent procedural history of the case and the proposed amendments to the pleadings by Bayer. More detailed background on the technology at issue and the relevant factual allegations is found in the Court’s July 13, 2020 Report and Recommendation. (D.I. 494)

therapies in the United States to treat hemophilia A, which is a congenital bleeding disorder characterized by defective coagulation of the blood resulting from a deficiency in factor VIII protein. (D.I. 281 at ¶ 63) In this consolidated patent infringement action, Plaintiffs allege that Bayer's Jivi® product infringes two families of patents owned by Plaintiffs: the Bossard Patents³ and the Bentley Patents.⁴ (D.I. 281 at ¶ 66; C.A. No. 18-1355-RGA, D.I. 1 at ¶ 29) Plaintiffs initiated the infringement action regarding the Bossard Patents on September 15, 2017. (D.I. 1) On August 31, 2018, Plaintiffs filed another complaint against Bayer, alleging that Bayer's Jivi® product infringes the Bentley Patents. (C.A. No. 18-1355-RGA, D.I. 1) On September 4, 2019, Plaintiffs filed the operative second amended complaint against Bayer in Civil Action No. 17-1316-RGA-SRF, alleging that Bayer's Jivi® product infringes the Bossard Patents. (D.I. 281)

In response to Plaintiffs' allegations of infringement in the above-referenced pleadings, Bayer filed its amended answers, affirmative defenses, and counterclaims on October 11, 2019, asserting *Walker Process* fraud and antitrust allegations in addition to allegations of inequitable conduct and unclean hands. (D.I. 333; D.I. 381) Plaintiffs then filed a motion to dismiss Bayer's pleadings. (D.I. 383) The undersigned judicial officer issued a Report and Recommendation on July 13, 2020, recommending that the Court grant the motion to dismiss based on certain specified deficiencies in the pleadings. (D.I. 494)

The parties subsequently filed their motions for summary judgment and *Daubert* motions, which are fully briefed. (D.I. 447; D.I. 450) A hearing on the motions for summary judgment

³ The Bossard Patents include U.S. Patent Nos. 7,199,223 ("the '223 patent"); 7,863,421 ("the '421 patent"); 8,143,378 ("the '378 patent"); 8,247,536 ("the '536 patent"); 8,519,102 ("the '102 patent"); 8,618,259 ("the '259 patent"); 8,889,831 ("the '831 patent"); and 9,999,657 ("the '657 patent"). (D.I. 281 at ¶ 1)

⁴ The Bentley Patents include U.S. Patent Nos. 7,026,440 ("the '440 patent"); 7,872,072 ("the '072 patent"); 8,273,833 ("the '833 patent"); 8,809,453 ("the '453 patent"); and 9,187,569 ("the '569 patent"). (C.A. No. 18-1355-RGA-SRF, D.I. 1 at ¶ 1)

was held on November 12, 2020. (D.I. 597) On June 30, 2020, Bayer filed a motion to correct inventorship pursuant to 35 U.S.C. § 256. (D.I. 483) Plaintiffs responded with a motion to strike Bayer's motion to correct inventorship and a Rule 12(b)(1) motion to dismiss. (D.I. 490) Those motions also remain pending.

On August 4, 2020, Bayer filed the instant motion to amend its pleadings to address the deficiencies identified in the Report and Recommendation and to add allegations regarding its correction of inventorship claims under Section 256. (D.I. 515) The following month, the Court terminated Bayer's motion to dismiss, the Report and Recommendation, and the objections to the Report and Recommendation as moot due to the filing of the motion to amend. (D.I. 591)

The deadline for amended pleadings expired on October 11, 2019, and the deadline to complete fact discovery was November 1, 2019. (D.I. 293 at ¶¶ 2-3) The court has reserved the date of March 15, 2021 for a jury trial. (D.I. 549)

III. LEGAL STANDARD

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that a party may amend its pleading after a responsive pleading has been filed “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 court’s discretion. *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, 486-87 (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. *See WebXchange Inc. v. Dell Inc.*, C.A. No.08-132-JJF, 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, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 618 (D. Del. 2008). 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. *See Glaxosmithkline LLC v. Glenmark Pharms. Inc.*, C.A. No. 14-877-LPS-CJB, 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 Rule 15(a) standard. *See E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).

IV. ANALYSIS

A. Good Cause and Undue Delay⁵

1. Inequitable conduct, unclean hands, and *Walker Process* allegations

Bayer contends that it has satisfied the good cause standard under Rule 16(b)(4) because it acted diligently in seeking leave to amend after Plaintiffs withheld production of certain key witnesses for deposition until October 2019, following expiration of the deadline for amended pleadings. (D.I. 519 at 6-7) Bayer further alleges that the incorporation of details from the depositions in the proposed amended pleadings serves only to bolster the already-existing inequitable conduct, unclean hands, and *Walker Process* claims, and not to assert new claims. (D.I. 559 at 3-4) Consequently, Bayer argues that it was appropriate to delay seeking leave to amend until after resolution of Plaintiffs' motion to dismiss. (D.I. 519 at 8-9)

Plaintiffs respond that Bayer cannot satisfy the good cause standard under Rule 16(b)(4) because Bayer relies on the October 2019 depositions as the basis for its proposed amendments made nearly nine months later in August 2020. (D.I. 547 at 7) Plaintiffs argue that Bayer had an opportunity to amend its pleading as a matter of course within the twenty-one day period after Plaintiffs filed their motion to dismiss on November 8, 2019. (*Id.*) Because Bayer forfeited its

⁵ The parties' briefing reflects the overlap between the good cause analysis under Rule 16(b)(4) and consideration of undue delay under Rule 15(a). (D.I. 519 at 6; D.I. 547 at 11) This is consistent with case authorities recognizing the overlap between good cause and undue delay because "both examine the timeliness of the motion to amend." *Fraunhofer-Gesellschaft Zur Forderung der angewandten Forschung e.V. v. Sirius XM Radio Inc.*, C.A. No. 17-184-JFB-SRF, 2018 WL 3425012, at *3 (D. Del. July 16, 2018), *rev'd and remanded on other grounds*, 940 F.3d 1372 (Fed. Cir. 2019); *see Benati v. Matevousian*, 2020 WL 58041, at *3 (E.D. Cal. Jan. 6, 2020) (acknowledging similarities between Rule 15 undue delay and Rule 16(b) diligence analyses).

opportunity to amend as a matter of right after the October 2019 depositions had been taken, Plaintiffs contend that Bayer cannot establish good cause for leave to amend now. (*Id.* at 7-8)

Good cause exists under Rule 16(b)(4) for the proposed amendments to the inequitable conduct, unclean hands, and *Walker Process* claims and defenses because Bayer promptly filed the pending motion on August 4, 2020, less than one month after the issuance of the Report and Recommendation addressing Plaintiffs' motion to dismiss. (D.I. 494; D.I. 515) The relevant facts are undisputed, and they demonstrate that Bayer exercised diligence in seeking leave to amend after the court issued its Report and Recommendation. Bayer requested the depositions of key witnesses having information relevant to the inequitable conduct allegations between August 6 and September 5, 2019, but those depositions did not go forward until late October 2019, weeks after the October 11, 2019 deadline for amended pleadings and only days before the November 1, 2019 close of fact discovery. (D.I. 293 at ¶¶ 2-3) Thus, the information obtained during the course of those depositions could not be incorporated in Bayer's pleadings filed on October 11, 2019. (D.I. 333; D.I. 381) Despite Bayer's diligence in timely requesting the depositions, the information forming the basis for the proposed amendments was not revealed until those depositions occurred, after the expiration of the deadline for amended pleadings.

Plaintiffs filed their motion to dismiss and strike Bayer's amended answers and counterclaims on November 8, 2019, less than a month after the depositions were taken. (D.I. 383) There is no dispute that Plaintiffs were on notice of Bayer's inequitable conduct, unclean hands, and *Walker Process* allegations prior to the deadline for amended pleadings, and Plaintiffs challenged the sufficiency of those allegations by filing the motion to dismiss. Specifically, Plaintiffs allege that Bayer used information gleaned from the depositions "to expand on the

‘mishmash of facts’ in its pleadings” regarding the inequitable conduct counterclaims to bolster the particularity of those allegations. (D.I. 547 at 10)

Plaintiffs argue that, had Bayer been diligent, it would have amended its pleadings as a matter of course under Rule 15(a)(1)(B) in response to the motion to dismiss. (D.I. 547 at 9-10) But “the mere fact that a [movant] files a motion to dismiss is not necessarily sufficient to put [the nonmovant] on notice that the court will find his complaint to be deficient.” *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016); *see also Fraunhofer-Gesellschaft Zur Forderung der angewandten Forschung e.V. v. Sirius XM Radio Inc.*, C.A. No. 17-184-JFB-SRF, 2018 WL 3425012, at *4 (D. Del. July 16, 2018) (finding that the plaintiff “satisfied the diligence standard under Rule 16(b)(4) by timely pursuing leave to amend following the issuance of the . . . Report and Recommendation.”), *rev'd and remanded on other grounds*, 940 F.3d 1372 (Fed. Cir. 2019). In this case, the October 2019 depositions did not give rise to new allegations of inequitable conduct. (D.I. 547 at 10) Instead, they revealed details providing additional support for the existing inequitable conduct, unclean hands, and *Walker Process* claims. Bayer could not be certain that inclusion of these details in the pleadings was critical to the survival of the claims until the motion to dismiss was resolved. Accordingly, Bayer filed its answering brief substantively challenging the merits of Plaintiffs’ motion and alternatively requesting leave to amend if the motion to dismiss was granted.⁶ (D.I. 396 at 27-28) Delaying the proposed amendments until after resolution of the motion to dismiss was appropriate under these circumstances because Bayer could not be certain the pleadings were deficient until after a ruling was made on the motion to dismiss. *See Victaulic*, 839 F.3d at 250

⁶ Bayer reiterated its alternative request for leave to amend at oral argument on the motion to dismiss and in its objections to the Report and Recommendation. (D.I. 559, Ex. A at 61:1-13; D.I. 504 at 9)

(finding good cause where the plaintiff promptly moved to amend after the district court ruled on a pending motion to dismiss).

These facts are distinguishable from the cases cited by Plaintiffs, which did not involve pleadings subject to pending motions to dismiss, and which involved efforts to add new claims or theories based on discovery produced months prior to the proposed amendments. In *Bayer Healthcare LLC v. Baxalta Inc.*, the court denied leave to amend because the plaintiff sought to add new pre-suit infringement and § 271(f) claims months after first discovering the evidence supporting those claims, with no explanation for its delay in seeking leave to amend.⁷ C.A. No. 16-1122-RGA, 2019 WL 291143, at *2-3 (D. Del. Jan. 22, 2019). Similarly, in *Asahi Glass Co., Ltd. v. Guardian Industries Corp.*, the court rejected the movant's efforts to add new inequitable conduct claims and theories after the deadline to amend pleadings based on information that was available to the movant months before the deadline to amend pleadings expired. 276 F.R.D. 417, 420 (D. Del. 2011); *see also Carrier Corp. v. Goodman Global, Inc.*, 49 F. Supp. 3d 430, 433 (D. Del. 2014) (same). In contrast, Bayer did not obtain the discovery underlying its proposed amendments until after the deadline to amend had passed. Moreover, Plaintiffs were on notice of the existing inequitable conduct, unclean hands, and *Walker Process* claims in the pleadings that were filed before the deadline to amend had expired. Because the sufficiency of the existing claims was in dispute from the filing of the motion to dismiss shortly after the October 2019

⁷ In an August 10, 2017 Memorandum Order issued in *Bayer Healthcare*, the Court dismissed causes of action for pre-suit infringement upon finding that the plaintiff had not sufficiently alleged knowledge of the patent-in-suit prior to the filing of the complaint. (C.A. No. 16-1122-RGA, D.I. 27 at 1-2) Unlike in this case, the motion to dismiss was not pending during the period of time between the June 2018 disclosure of evidence relevant to pre-suit infringement and the January 2019 motion for leave to amend the complaint to add allegations of pre-suit infringement. (*Id.*, D.I. 346)

depositions until the issuance of the Report and Recommendation, it was appropriate for Bayer to wait for resolution of the motion to dismiss before seeking further amendment.

2. Correction of inventorship under 35 U.S.C. § 256

With respect to the correction of inventorship allegations, Bayer contends that its proposed amendments are not necessary because the previous pleadings adequately alleged “incorrect inventorship” and lack of standing. (D.I. 497⁸ at 8-9 (citing D.I. 333 at 25-26; D.I. 381 at 14-15)) Bayer made the proposed amendments in the event that “the Court deems it necessary in response to Plaintiffs’ motion to strike,” while maintaining that the amendments are not necessary. (D.I. 519 at 9) Bayer also points to the Federal Circuit’s decision in *Hydril Co. v. Baker Hughes Inc.*, which remanded the correction of inventorship issue to the district court for consideration despite the fact that it had not been raised in the pleadings. 121 F.3d 728, 1997 WL 469722, at *4-5 (Fed. Cir. Aug. 19, 1997) (observing that the plaintiff “never sought unqualified correction of inventorship before the district court despite numerous opportunities to do so.”). The Federal Circuit determined that the district court “was aware of § 256 and, presumably . . . had the power to correct inventorship.” *Id.* at *5.

Plaintiffs do not separately discuss the good cause requirement in the context of the correction of inventorship allegations in their answering brief. (D.I. 547 at 7-10)

Bayer’s motion to amend is denied without prejudice as it pertains to the correction of inventorship allegations. Bayer repeatedly asserts that its proposed amendments are not necessary. (D.I. 519 at 9; D.I. 497 at 8-9) Bayer’s position that its proposed amendments are not necessary finds support in the Federal Circuit’s decision in *Hydril*, which suggests that correction

⁸ The court has considered portions of the briefing on the motion to correct inventorship and motion to strike as cited by Bayer in the briefing on the instant motion to amend. (D.I. 519 at 1, 10; D.I. 559 at 1, 6 n.6)

of inventorship is to be considered by the district court when it is raised, even if it was not raised in the pleadings. *See HydriL*, 1997 WL 469722, at *5. The proposed amendments in this case were made in the event that “the Court deems it necessary in response to Plaintiffs’ motion to strike.” (D.I. 519 at 9) The motion to correct inventorship and the motion to strike are both currently pending before the assigned District Judge. Accordingly, Bayer may seek leave to amend to the extent that the District Judge deems it necessary upon consideration of the motion to correct inventorship and the motion to strike.

B. Prejudice

Bayer further contends that Plaintiffs are not prejudiced by the proposed amendments. According to Bayer, Plaintiffs have been on notice of the inequitable conduct, unclean hands, and *Walker Process* allegations for nearly a year, and Plaintiffs took discovery on the relevant facts underlying the allegations. (D.I. 519 at 10)

In response, Plaintiffs contend that they would be prejudiced by the proposed amendments because the case is trial-ready, further modifications at this stage pose a risk of further litigation, and additional discovery would be required. (D.I. 547 at 12-13) Specifically, Plaintiffs indicate that no fact discovery has been taken on the antitrust components of Bayer’s *Walker Process* claims to date. (*Id.* at 14) Plaintiffs’ arguments regarding prejudice otherwise focus on Bayer’s proposed correction of inventorship amendments. (*Id.* at 13-14)

Plaintiffs have not shown that they would suffer prejudice as a result of the amendments to the inequitable conduct, unclean hands, and *Walker Process* allegations proposed by Bayer. As a preliminary matter, the inequitable conduct counterclaims and defenses are not subject to a jury trial, and there is no indication that Bayer’s proposed amendments would result in further

postponement of the March 2021 jury trial. Plaintiffs do not refute Bayer’s position that extensive discovery on the inequitable conduct claims has occurred, including deposition testimony from nearly every witness. (D.I. 519 at 10) This evidence also advances the *Walker Process* allegations because the showing required to prove inequitable conduct is “nearly identical” to the showing required to establish the fraud component of *Walker Process* liability. *TransWeb, LLC v. 3M Innovative Proprs. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016).

Moreover, the record before the court does not support Plaintiffs’ position that no discovery was taken on the antitrust portion of the *Walker Process* counterclaims. (D.I. 547 at 14) The proposed amended pleadings cite documents reflecting that the parties engaged in fact discovery relating to the antitrust issues alleged by Bayer, including discovery regarding control of the relevant market. (D.I. 515, Ex. A at ¶¶ 159-60; Ex. B at ¶¶ 169-70) To the extent that supplemental discovery is necessary, the parties shall confer on supplemental discovery regarding the inequitable conduct, *Walker Process*, and unclean hands claims in accordance with the amended scheduling order. (D.I. 392 at 1 n.1)

C. Futility

Amendment is not futile in this case because Bayer has adequately amended its pleadings to address the four deficiencies identified in the Report and Recommendation. First, the pleadings now identify specific individuals accused of inequitable conduct and state that the individuals knew their misconduct was material. (D.I. 515, Ex. D at ¶¶ 77-94, 100-05, 108, 110-13, 116, 129, 131; Ex. C at ¶¶ 73-87, 92-94, 97-99, 102-04, 108, 112-14, 117-19, 156-158) Second, Bayer independently alleges inequitable conduct regarding the ’072 patent instead of relying on a theory of infectious unenforceability. (D.I. 515, Ex. D at ¶¶ 89-90, 94) Third,

Bayer sufficiently amended the *Walker Process* claims to allege that Baxalta had pre-suit knowledge of the fraud based on its attendance at the 2013 German Entitlement Hearing and collaborated with Nektar on the substance of the asserted patents during prosecution. (D.I. 515, Ex. D at ¶¶ 166-168; Ex. C at ¶¶ 156-158) Fourth, the amended pleadings adequately specify that Nektar jointly developed Adynovate® with Baxalta, that Nektar supplies the PEG in Adynovate®, that Nektar receives 4-13% of Adynovate® net sales, that Nektar has 50% voting power over R&D and clinical trials, and that Nektar jointly enforces the fraudulent patents and splits the proceeds of any infringement award with Baxalta. (D.I. 515, Ex. C at ¶¶ 70, 166, 169; Ex. D at ¶¶ 73, 156, 159) These allegations are sufficient to satisfy the requisite pleading standard and remedy the deficiencies cited in the Report and Recommendation.

V. CONCLUSION

For the foregoing reasons, Bayer's motion for leave to amend its answers and counterclaims is DENIED without prejudice regarding the correction of inventorship claim under 35 U.S.C. § 256, and the motion is GRANTED in all other respects. (D.I. 515) 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 shall jointly submit a proposed redacted version by no later than **December 18, 2020**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In*

re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within thirty (30) days of the date the Memorandum Opinion issued.

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: December 11, 2020



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE