

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

EXELTIS USA, INC., LABORATORIOS
LEON FARMA, S.A., CHEMO IBERICA,
S.A., and CHEMO RESEARCH, S.L.,

Plaintiffs,

v.

LUPIN LTD. and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 22-434-RGA

MEMORANDUM ORDER

Before me is Defendants’ motion for leave to file an amended answer, affirmative defenses, and counterclaims. (D.I. 189). Defendants seek to add an affirmative defense and counterclaim alleging that Plaintiffs engaged in inequitable conduct during the prosecution of two of the fifteen asserted patents—U.S. Patent Nos. 10,849,857 (“the ’857 patent”) and 10,603,281 (“the ’281 patent”). (*See generally* D.I. 190-1 ¶¶ 240–98). Defendants contend that omissions made during these prosecutions taint each of the thirteen other patents asserted in this suit. (*Id.* ¶¶ 299–350).

I have considered the parties’ briefing. (D.I. 190, 200, 205). I do not separately recite any of the facts except as I see necessary to explain my decision. For the reasons set forth below, I **DENY** Defendants’ motion.

I. LEGAL STANDARDS

A. Amendment of Pleadings

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, “a party may amend its pleading only with the opposing party’s written consent or the court’s leave. The court should freely give leave when justice so requires.” Fed. R. Civ. P.

15(a)(2). The Third Circuit has instructed that “absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless ‘denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.’” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (emphasis omitted) (citation omitted). An amendment is futile if it “would fail to state a claim upon which relief could be granted.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The futility analysis follows the standard that applies to a motion under Rule 12(b)(6). *Id.*

A request to amend filed after the court’s deadline to amend must also meet the “good cause” standard of Rule 16(b)(4). *Premier Comp Sols. v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020). Rule 16(b)(4) provides, “A schedule may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “‘Good cause’ exists when the [s]chedule cannot reasonably be met despite the diligence of the party seeking the extension.” *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009). Unlike Rule 15(a), the Rule 16(b) standard focuses on the “diligence of the movant, and not on prejudice to the non-moving party.” *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at *4 (D. Del. May 21, 2009). “A party must meet [Rule 16(b)’s] standard before a district court considers whether the party also meets Rule 15(a)’s more liberal standard.” *Premier Comp*, 970 F.3d at 319.

B. Inequitable Conduct

To show inequitable conduct, an accused infringer must generally show (1) “that the patentee acted with the specific intent to deceive the PTO” and (2) materiality. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). Allegations of inequitable conduct must be pled with particularity. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009); *see also Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, at *5 (D. Del. Feb. 3, 2012) (“Although inequitable conduct is conceptually broader than fraud, any such allegations must be pled in accordance with Rule 9(b), which requires that ‘the circumstances constituting fraud or mistake shall be stated with particularity.’” (citation omitted)). “[T]o plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp.*, 575 F.3d at 1328.

Courts must assess materiality of withheld references by “determin[ing] whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.” *Therasense*, 649 F.3d at 1291. While “but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, [the Federal Circuit has] recognize[d] an exception in cases of affirmative egregious misconduct.” *Id.* at 1292. In those cases, “such as the filing of an unmistakably false affidavit, the misconduct is material.” *Id.*

II. DISCUSSION

Defendants’ proposed amended counterclaim contends that the inequitable conduct for the ’857 patent relates to withheld testing results. For the ’281 patent, the inequitable conduct claim relates to a lack of discussion about an example in the “Davila” prior art.

A. Testing Results

Defendants argue that Dr. Sandra Blatnik, an employee at Plaintiff Laboratorios Leon Farma, intentionally misled the PTO by filing a declaration that omitted material experimental evidence that contradicted her declaration. (D.I. 190 at 15).

During prosecution, the examiner rejected the claims for lack of written description. In response to the rejection, Dr. Blatnik tested various formulations and signed a declaration. (*Id.* at 16). In the declaration, she stated, “[I]t is readily apparent that one of ordinary skill in the art could not only select various species of excipients but also the relevant proportions of the various excipients to combine with the drospirenone having the recited particle size profile to prepare pharmaceutical compositions that would maintain the desired slow dissolution profile.” (*Id.*). Defendants contend, however, that Dr. Blatnik “cherry-picked several favorable test results to support her declaration while intentionally omitting other test results that contradicted her opinion.” (*Id.* at 15). Defendants argue she should have disclosed “***all*** of the material test results.” (*Id.* at 17).

Defendants’ proposed inequitable conduct counterclaim makes two materiality allegations. (D.I. 190-1 ¶¶ 288–89). Plaintiffs argue that the allegations are insufficient. (D.I. 200 at 17–19). Plaintiffs argue that the first, based on 37 C.F.R. § 1.56,¹ is inapposite in light of Federal Circuit precedent. (*Id.* at 17). They argue that the second allegation, but-for materiality, lacks factual support. (*Id.* at 17–18). Plaintiffs contend that the proposed counterclaim “fails to identify a specific formulation or dissolution endpoint not met.” (*Id.* at 18).

¹ The section states, “[I]nformation is material to patentability when it . . . refutes, or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the [o]ffice, or (ii) [a]sserting an argument of patentability.” 37 C.F.R. § 1.56(b)(2).

I agree with Plaintiffs that Defendants have failed to plead materiality with regard to Dr. Blatnik's testing results. First, Defendants cannot rely on § 1.56(b) for the purpose of pleading inequitable misconduct. *See Therasense*, 649 F.3d at 1294 ("This court declines to adopt the current version of Rule 56 in defining inequitable conduct . . ."). Second, the proposed counterclaim alleges that Dr. Blatnik withheld testing results showing formulations that "did not satisfy the 'desired dissolution profile.'" (D.I. 190-1 ¶¶ 280, 282). The "desired dissolution profile" includes two limitations: (1) "no more than 50% of the active drug initially present in the daily active dosage unit is dissolved within 30 minutes," and (2) "at least 50% of the active drug is dissolved in a time range from 3 hours to 4 hours." (*Id.* ¶ 257 (citation omitted)). Defendants make no allegations about the thirty-minute limitation. They do allege that the omitted testing batches failed to release more than 50% of drospirenone after four hours. (*Id.* ¶¶ 285–86). The patent claims, however, do not recite the three-to-four-hour limitation of the desired dissolution profile. (*See* '857 patent at 49:44–48; '857 patent at 50:27–31; '281 patent at 49:64–50:2). Although the claims originally included both limitations, the patentee amended the claims to remove the limitations. (*See* D.I. 190-3 at 65 of 83).² The patentee submitted this amendment at the same time as Dr. Blatnik's declaration. (*See id.* at 79–80 of 83). The claims thus did not recite either the thirty-minute or the three-to-four-hour limitation at the time the examiner reviewed Dr. Blatnik's declaration.

Defendants' allegations regarding testing results are thus immaterial. The three-to-four-hour limitation was not in the claims when the declaration was submitted and has not been re-

² An examiner's amendment later added back the thirty-minute limitation. (D.I. 190 at 4–5; *see also* '857 patent at 49:44–48; '857 patent at 50:27–31; '281 patent at 49:64–50:2).

added since. The proposed counterclaim fails to plead any facts to suggest that the claims would not have issued but for the disclosure of the omitted testing batches.

Given that Defendants' proposed counterclaim does not plead materiality with regard to Dr. Blatnik's testing results, the testing allegations are insufficient to satisfy the pleading requirement for inequitable conduct.

B. Davila Reference

Defendants argue that Dr. Blatnik, in a separate declaration, intentionally misled the examiner regarding prior art. (D.I. 190 at 17). Defendants contend that after the examiner's obviousness rejection in view of the Davila reference, Dr. Blatnik "intentionally diverted the examiner away from the exemplary formulation in Davila that she knew disclosed the claimed dissolution profile (Example 3)." (*Id.*). Defendants argue that Example 3 in Davila "clearly discloses a slow-dissolution profile." (*Id.* at 18). They contend, "If Dr. Blatnik had provided the examiner with the correct information with respect to Davila, one or more of the claims of the '281 patent may not have issued." (D.I. 205 at 8).

Defendants' proposed inequitable conduct counterclaim makes two materiality allegations. (D.I. 190-1 ¶¶ 296–97). Plaintiffs argue that the allegations are insufficient. Plaintiffs note that the proposed counterclaim pleads § 1.56(b) materiality even though the Federal Circuit has rejected § 1.56(b) as the standard for inequitable conduct. (D.I. 200 at 13–14).³ Plaintiffs also contend that the crux of Defendants' argument—"that Dr. Blatnik, should have, but did not, direct the examiner's attention to Davila 3"—is insufficient as a matter of law to plead but-for materiality. (*Id.* at 14). Plaintiffs note that "the examiner had Davila, was able

³ Although Defendants' briefing mentions "egregious misconduct," Plaintiffs contend that the proposed counterclaim does not allege it. (D.I. 200 at 13–14). I agree.

to read and understand Example 3, and used it to argue that the claimed invention was obvious.” (*Id.* at 15). Plaintiffs argue that the proposed counterclaim “does not identify a single issued claim of the ’281 patent to explain how that claim would not have issued ‘but for’ Dr. Blatnik’s omission.” (*Id.*).

I agree with Plaintiffs that Defendants have failed to plead materiality with regard to Davila. First, Defendants do not explicitly plead egregious misconduct in their proposed counterclaim. Second, as explained above, Defendants cannot rely on § 1.56(b) to plead inequitable misconduct. Third, Defendants have failed to plead but-for materiality. Defendants’ proposed counterclaim concedes that “the examiner specifically relied on Example 3’s disclosure of a slow-dissolution profile in rejecting the pending claims as obvious over Davila in view of Sansom.” (D.I. 190-1 ¶ 292). In other words, the examiner knew about the Davila reference before Dr. Blatnik submitted her declaration. Defendants’ proposed counterclaim therefore does not plead any facts to suggest that Dr. Blatnik withheld Davila. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1185 (Fed. Cir. 1995) (“When a reference was before the examiner, whether through the examiner’s search or the applicant’s disclosure, it cannot be deemed to have been withheld from the examiner.” (citation omitted)).

Defendants’ allegations regarding Davila are insufficient to satisfy the pleading requirement for inequitable conduct.

C. Good Cause and Remaining Arguments

The parties also dispute whether Defendants have good cause to amend their answer. (*See* D.I. 190 at 11–13; D.I. 200 at 17, 20). The parties further dispute whether Defendants adequately pleaded intent (*see* D.I. 190 at 19–20; D.I. 200 at 15–16), and Plaintiffs contend that

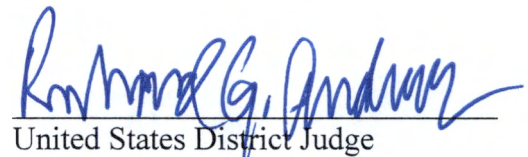
Defendants failed to properly allege infectious unenforceability (*see* D.I. 200 at 20). Since the materiality allegations are insufficient, I do not need to resolve these issues.

III. CONCLUSION

For the reasons discussed above, I **DENY** Defendants' motion for leave to file an amended answer, affirmative defenses, and counterclaims. (D.I. 189).

IT IS SO ORDERED.

Entered this 16th day of November, 2023


United States District Judge