IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI & CO., LTD., HOFFMANN-LA ROCHE INC., and GENENTECH, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 23-161-MN
NORWICH PHARMACEUTICALS, INC. And ALVOGEN PB RESEARCH & DEVELOPMENT LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION[1]

At Wilmington this **23rd** day of **September, 2024**, the court having considered the motion of Norwich Pharmaceuticals, Inc. and Alvogen PB Research & Development LLC ("Norwich") for leave to amend the answer and counterclaims (D.I. 85), and the associated filings (D.I. 87; D.I. 88), I recommend that the court DENY Norwich's motion without prejudice for the following reasons:

1. Background. Plaintiffs Shionogi & Co., Ltd., Hoffmann-La Roche Inc., and Genentech, Inc. (collectively, "Plaintiffs") filed this patent infringement action against Norwich on February 13, 2023, alleging infringement of eight patents covering XOFLUZA®, a drug used for the treatment of influenza. (D.I. 1 at ¶¶ 1, 36-38) XOFLUZA® contains baloxavir marboxil,

[1] For non-dispositive motions, such as a motion for leave to amend, the court reviews findings of fact for clear error and conclusions of law *de novo*. *Zogenix, Inc. v. Apotex Inc.*, C.A. No. 21-1252-RGA, 2023 WL 5835828, at *6 (D. Del. Sept. 8, 2023). When a motion for leave to amend is denied on the basis of futility, the dispositive standard of Rule 12(b)(6) applies. *Id.* (quoting *Great W. Mining & Min. Co. v. Fox Rothschild, LLP*, 615 F.3d 159, 175 (3d Cir. 2010)). Because the determination of whether a claim survives a Rule 12(b)(6) motion is a "purely legal question," the decision of a magistrate judge is reviewed *de novo* pursuant to 28 U.S.C. § 636(b)(1)(B) and Fed. R. Civ. P. 72(b)(1). *Id.*

which inhibits the growth activity of the influenza virus. (*Id.*) Norwich filed Abbreviated New Drug Application ("ANDA") No. 217449, seeking approval to market generic versions of 40 mg and 80 mg XOFLUZA® prior to the expiration of the patents-in-suit. (*Id.* at ¶ 1)

2. Norwich moves for leave to amend its responsive pleading to add affirmative defenses and counterclaims that asserted U.S. Patent No. 10,392,406 ("the '406 patent") is unenforceable due to Plaintiffs' inequitable conduct and unclean hands. (D.I. 87 at 1) Specifically, Norwich contends that Plaintiffs withheld critical data from the U.S. Patent and Trademark Office ("PTO") about an alleged error in a prior art patent, U.S. Patent No. 8,987,441 ("the '441 patent"), which should have been corrected during prosecution of the '406 patent. (*Id.*)

3. The '441 patent, which issued in 2015, is directed to a class of chemical compounds having antiviral activities, especially inhibiting the growth activity of the influenza virus. ('441 patent, Abstract) The '441 patent discloses six anti-influenza compounds and reported inhibitory activity data for one of those compounds, identified as Reference Example 682. (D.I. 87 at 1) Later, however, inventor Makoto Kawai performed an x-ray structural analysis and discovered that the inhibitory activity data for Reference Example 682 had been switched with another of the six compounds, Reference Example 684. (D.I. 87, Ex. 2 at 174:3-175:11; 183:3-19) Table 34 of the '441 patent lists the inhibitory activity data for Reference Example 684 as being the inhibitory activity data for Reference Example 682, and includes no inhibitory activity data at all for Reference Example 684:

TABLE 34

Reference example No.	CEN IC_{50} (μM)
666	0.00336
668	0.0126
682	0.0197
686	0.0151

('441 patent, col. 808:52-60; *see also* D.I. 87, Ex. 1 at ¶ 371)

4. The '406 patent, which issued in 2019, has a single claim reciting the formula for baloxavir marboxil. ('406 patent, col. 186:40-58) Norwich represents that Plaintiffs sought several corrections to the '441 patent during prosecution of the '406 patent, but the mistake regarding the inhibitory activity data for Reference Examples 682 and 684 in the '441 patent was never raised with the Examiner prior to the '406 patent's issuance. (D.I. 87 at 1) According to Norwich, this failure to correct amounts to inequitable conduct because the correct data for Reference Example 684 is the closest prior art compound to baloxavir, the active portion of baloxavir marboxil claimed in the '406 patent. (*Id.*)

5. In contrast, Plaintiffs corrected the mistake between Reference Examples 682 and 684 in six patent prosecutions for foreign counterparts of the '406 patent so that accurate inhibitory activity data for all six Reference Examples would be disclosed. (D.I. 87 at 1-2) During these foreign prosecutions where the correct data was disclosed, the examiners allowed the foreign counterparts to the '406 patent based on improvements to inhibitory activity compared to the '441 patent. (*Id.*, Ex. 1 at ¶¶ 594-98)

6. There is no dispute that the U.S. Examiner considered the '441 patent and, more specifically, Reference Examples 682 and 684, during prosecution of the '406 patent. (D.I. 88, Ex. C at 2) The Examiner concluded that the '441 patent "teaches a very large genus and does not expressly teach or fairly suggest compounds that are structurally analogous to the compounds of the instant claims and therefore, does not provide motivation to one of ordinary skill in the art to arrive at the compounds of the instant claims." (*Id.*)

7. Correspondence between the parties on January 9, 2024 confirms that Norwich was aware of the corrections made to Reference Examples 682 and 684 in the foreign patent

proceedings and had publicly available documents from those proceedings. (D.I. 88, Ex. D) However, Norwich first received information regarding Dr. Kawai's x-ray structural analysis of Reference Examples 682 and 684 on June 10, 2024. (D.I. 87, Ex. 5 at 1-3) Based on this newly received information, Norwich provided its first draft of the proposed amended answer and counterclaims on July 12, 2024, five days before the July 17 deadline for amended pleadings. (*Id.*, Ex. 3; D.I. 18) The proposed amendments add claims for inequitable conduct and unclean hands based on Norwich's argument that Plaintiffs made a deliberate decision to withhold material information about Reference Example 684 so the '406 patent would be allowed. (*Id.*, Ex. 1)

8. Legal standard. Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that the court should freely give leave to amend the pleadings 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). 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. Futility is measured under the same standard applicable to a Rule 12(b)(6) motion to dismiss: "If the complaint, as amended, would not survive a motion to dismiss, leave to amend may be denied as futile." *VLSI Tech. LLC v. Intel Corp.*, C.A. No. 18-966-CFC, 2020 WL 3488584, at *2 (D. Del. June 26, 2020) (quoting *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. , 2016 WL 720977, at *7 (D. Del. Feb. 23, 2016)).

9. Analysis. Plaintiffs oppose Norwich's motion for leave to amend for two reasons. First, Plaintiffs argue that the proposed amendment should be denied as untimely. Second,

Plaintiffs contend that the proposed amendment would be futile because it fails to satisfy the Rule 12(b)(6) standard. For the following reasons, I recommend that the court DENY Norwich's motion without prejudice.

10. ***Timeliness.*** Norwich argues its motion is timely because it sought leave to amend its answer and counterclaims on July 12, 2024, about a month after Plaintiffs produced the relevant fact discovery from the foreign patent prosecutions that supports the proposed amendments. (D.I. 87 at 2-3) According to Norwich, the delay was necessitated by Plaintiffs' failure to produce Dr. Kawai's x-ray structural analysis until May 31, 2024 and their failure to confirm until June 10, 2024 that there was no separate x-ray analysis reflecting Reference Examples 682 and 684. (*Id.*) Norwich also contends that it did not learn how the mistake between Reference Examples 682 and 684 in the '441 patent was discovered, who identified the error, and who was informed of the mistake until Dr. Kawai's deposition in March of 2024. (*Id.* at 2) Plaintiffs respond that Norwich's motion should be denied as untimely because foreign patent prosecution documents correcting the error have been publicly available since 2018, and Plaintiffs produced those same documents in this litigation in early January of 2024. (D.I. 88 at 4)

11. On this record, the "good cause" standard of Rule 16(b) does not apply because Norwich sought leave to amend the pleading prior to the expiration of the deadline for amended pleadings in the operative scheduling order. (D.I. 18) But Rule 15(a)(2) also requires an assessment of undue delay or dilatory motives on the part of the moving party. "[T]he question of undue delay requires [that the court] focus on the movant's reasons for not amending sooner." *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. 13-2108-RGA *et al.*, 2016 WL 720977, at

*7 (D. Del. Feb. 23, 2016) (quoting *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001)).

12. A review of the proposed amended pleading confirms that Norwich relied on evidence produced only a month before it brought its proposed amended pleading bringing claims for inequitable conduct and unclean hands. *See Lipocine Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 19-622-WCB, 2020 WL 4794576, at *3 (D. Del. Aug. 18, 2020) ("Because it is often the case that the critical evidence necessary to prove inequitable conduct can be obtained only from the patentee, it is common for claims of inequitable conduct to arise only after discovery has been conducted."). Here, the factual allegations in the proposed amendments are supported by citations to Dr. Kawai's deposition in March of 2024 and his x-ray analysis, which was produced in June of 2024. (*See, e.g.*, D.I. 87, Ex. 1 at ¶¶ 576-79) Norwich relies on this evidence to support its position regarding when and how Dr. Kawai learned that Reference Example 684 had significantly better inhibitory activity than Reference Example 682. (*Id.*)

13. Plaintiffs argue that Norwich's newly-alleged counterclaims and defenses are largely based on documents from foreign patent proceedings that have been available to Norwich since at least January of 2024. (D.I. 88 at 4) At this juncture, however, the court cannot "make a definitive determination as to whether the evidence of inequitable conduct in [Norwich's] hands" as of January of 2024 "was so compelling that [Norwich] was required to amend its answer by that date." *Lipocine*, 2020 WL 4794576, at *4. Because inequitable conduct requires proof of specific intent to deceive by the applicants or their representatives, it was reasonable for Norwich to wait until after it had deposed Dr. Kawai and obtained the documents discussed by Dr. Kawai during his deposition. *Id.* (explaining that the defendant "was justified in postponing its motion

to amend until after it was able to conduct depositions of the inventors[.]"). Consequently, Norwich's motion to amend is not untimely.

14. ***Futility.*** Plaintiffs raise no allegations of prejudice or bad faith regarding Norwich's proposed amended pleading. (D.I. 87 at 4) The only remaining dispute is whether Norwich's proposed defenses and counterclaims for inequitable conduct, infectious unenforceability, and unclean hands would be futile in this case under the Rule 12(b)(6) standard. To state a claim for inequitable conduct, the pleading must satisfy the heightened pleading requirements of Rule 9(b) by stating with particularity the circumstances constituting fraud. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). Accordingly, "the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission" by identifying a specific individual who "(1) knew of the withheld information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328-29.

15. I recommend that the court DENY Norwich's proposed inequitable conduct allegations as futile. This is not a typical inequitable conduct case in which the counterclaimant alleges the patentee withheld a relevant prior art reference during prosecution. There is no dispute that the Examiner considered the '441 patent during prosecution of the application leading to the issuance of the '406 patent. (D.I. 88, Ex. C) In fact, the Examiner considered the two specific Reference Examples in the 800-plus column specification of the '441 patent that form the basis of Norwich's inequitable conduct claim. (*Id.*) Norwich argues Plaintiffs intentionally misled the Examiner by failing to disclose and correct the erroneous transposition of a single data point between those two Reference Examples in the prior art '441 patent. However, the amended pleading does not plausibly allege that the error in Reference Examples

682 and 684 was but-for material to the issuance of the '406 patent, or that any specific individual had the requisite intent to mislead the PTO.

16. Norwich does not plausibly plead that the '406 patent would not have issued but for the errors in Reference Examples 682 and 684 of the prior art '441 patent. A review of the prosecution history for the '406 patent confirms that the Examiner considered Reference Examples 682 and 684 and concluded that neither was material to the issuance of the '406 patent. The proposed amended pleading quotes the Notice of Allowance for the '406 patent where the Examiner concluded that the '441 patent taught "a very large genus and does not expressly teach or fairly suggest compounds that are structurally analogous to the compounds of the instant claims," nor did it "provide motivation to one of ordinary skill in the art to arrive at the compounds of the instant claims." (D.I. 87, Ex. 1 at ¶ 140; D.I. 88, Ex. C at 2) There is nothing to plausibly suggest that the outcome would have been different if the Examiner knew the inhibitory activity data for Reference Example 682 had been switched with the data for Reference Example 684.

17. To factually support its averment that the Examiner would have rejected the '406 patent if the correct data for Reference Example 684 had been disclosed, Norwich states at least three foreign patent offices recognized that altering the 10-chloro substituent of Reference Example 684 to a 7,8-difluoro substituent of the '406 patent would have been obvious to a person of ordinary skill. (D.I. 87, Ex. 1 at ¶¶ 585-88) Norwich also alleges that other Reference Examples in the '441 patent disclosure similarly teach that switching from a 10-chloro substituent to a 7,8-difluoro substituent to increase inhibitory activity would be obvious to a person of ordinary skill. (*Id.*, Ex. 1 at ¶¶ 589-93) Here, however, the Examiner highlighted the difference between the 10-chloro substituent of Reference Example 684 and the 7,8-difluoro

substituent of the '406 patent before concluding that the '441 patent "teaches a very large genus and does not expressly teach or fairly suggest compounds that are structurally analogous to the compounds of instant claims[.]" (D.I. 88, Ex. C at 2) Norwich does not plead that this difference in structure would be impacted by corrections to the stereochemistry of Reference Example 684.

18. The proposed amended pleading also alleges that several foreign patent offices identified corrected Reference Example 684 as "one of the closest compounds to baloxavir" and asserts in a conclusory fashion that the PTO "would have recognized that modifying promising compounds to obtain improved inhibitory activity is not only expected, but would have been obvious based on the teachings of the '441 patent." (D.I. 87, Ex. 1 at ¶¶ 556, 594-98) But Norwich's proposed amended pleading expressly acknowledges that all foreign counterparts to the '406 patent were allowed by their respective patent offices, despite their consideration of corrected disclosures in Reference Examples 682 and 684 and despite the alleged similarities of those disclosures to the asserted claim of the '406 patent. (*Id.*, Ex. 1 at ¶¶ 594-98) Norwich stresses that examinations in these foreign patent offices apply different laws with more lenient obviousness standards than those applied in U.S. patent prosecutions. (*Id.* at 4) Nonetheless, the fact that all foreign counterparts to the '406 patent were allowed over corrected Reference Example 684 undercuts Norwich's position that corrected data in the '441 patent specification would have led to a different result in the prosecution of the '406 patent before the PTO.

19. Nothing in this recommendation precludes Norwich from pursuing obviousness arguments based on the '441 patent and, more specifically, the correct inhibitory activity data of Reference Example 684.

20. Norwich also fails to identify with specificity an individual who allegedly engaged in misconduct before the PTO. Norwich cites Dr. Kawai's deposition testimony in which he represented that he informed the "IP Department" about the error in the inhibitory activity data for Reference Example 684 but did not know why the IP Department took no action to correct the '441 patent specification with the PTO. (D.I. 87, Ex. 1 at ¶¶ 607-12) The proposed amended pleading confirms that the IP Department was responsible for patent strategy, but it more broadly attributes the failure to disclose to "Shionogi." (*Id.*, Ex. 1 at ¶¶ 449-50, 607, 618) However, Norwich does not identify a specific individual within Shionogi or the IP Department who deliberately decided to withhold the corrected data. Although 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." *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009). Norwich's proposed amended counterclaim does not satisfy this standard.

21. Because Norwich has failed to plausibly plead an inequitable conduct counterclaim, Norwich's theory of infections unenforceabilitiy for later-issued patents also fails. *See Int'l Bus. Machines Corp. v. Priceline Grp. Inc.*, C.A. No. 15-137-LPS-CJB, 2017 WL 1349175, at *21 (D. Del. Apr. 10, 2017) (explaining that, where court found no inequitable conduct associated with one asserted patent, it could not infer infectious unenforceability with respect to patents having an immediate and necessary relation to that patent). Absent a predicate act of inequitable conduct, there is no plausible basis for a claim of infectious unenforceability. *See Correct Craft IP Holdings, LLC v. Malibu Boats, LLC*, 2010 WL 598693, at *5 (M.D. Fla. Feb. 17, 2010)

("Because [the defendant] fails to state a claim for inequitable conduct in the prosecution of the [asserted patent], the doctrine of infectious unenforceability does not apply to the Patents-In-Suit.").[2]

22. To the extent that Norwich's affirmative defense of unclean hands is based on the same allegations as its inequitable conduct allegations, those averments do not meet the pleading standard. *See Equil IP Holdings LLC v. Akamai Techs., Inc.*, C.A. No. 22-677-RGA, 2024 WL 964204, at *5 (D. Del. Mar. 6, 2024). Norwich also alleges that Plaintiffs have unclean hands due to their purported efforts to evade discovery into the mix-up between Reference Examples 682 and 684 in the '441 patent. (D.I. 87 at 4) But the facts pleaded in support of this averment do not plausibly support a claim for unclean hands, even under the Rule 8 notice pleading standard. *See Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, 636 F. Supp. 3d 483, 488-89 (D. Del. 2022) (applying Rule 8 to assess the sufficiency of unclean hands counterclaim based on alleged litigation misconduct). Plaintiffs' response to Interrogatory No. 11, which is the primary focus of the amended pleading's allegations on litigation misconduct, expressly concedes that "[l]ater-conducted X-ray analysis indicated that the relative stereochemistry of [Reference Examples 682 and 684] was transposed in the initial analysis and in the drawings" of the '441

[2] Plaintiffs argue that the doctrine of infectious unenforceability cannot apply to patents from separate, unrelated patent families. (D.I. 88 at 4) In support, Plaintiffs cite *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007), which states that "inequitable conduct with respect to one or more patents in a family *can* infect related applications." But the Federal Circuit did not suggest that a familial relationship among patents is a prerequisite for infectious unenforceability. Case authority from this district suggests that patents may satisfy the "immediate and necessary relation" test for purposes of infectious unenforceability if those patents have similar specifications, claims, and subject matter. *See Guardant Health, Inc. v. Foundation Medicine, Inc.*, C.A. No.17-1616-LPS-CJB *et al.*, 2020 WL 2477522, at *8-9 (D. Del. Jan. 7, 2020).

patent. (D.I. 87, Ex. 1 at ¶¶ 746-48; Ex. 7 at 5) This response contradicts Norwich's assertion that Plaintiffs tried to conceal the mistake in their discovery responses.

23. Conclusion. For the foregoing reasons, I recommend that the court DENY without prejudice Norwich's motion for leave to file the amended answer and counterclaims. (D.I. 85) IT IS ORDERED that the teleconference set in this matter for September 24, 2024 at 3:00 p.m. is CANCELLED.

24. Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version by no later than **September 30, 2024**, for review by the court, along with a motion supported by a declaration. Any argument that portions of the Report and Recommendation should be sealed must be supported by "a particularized showing of the need for continued secrecy" sufficient to overcome the strong presumption of public access to court records. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672, 675 n.10 (3d Cir. 2019) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 166 (3d Cir. 1993) (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 fourteen (14) days of the date the Report and Recommendation issued.

25. This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and

Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to four (4) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

26. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge