IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC. and ABBVIE, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 23-272-RGA
	)	
MANKIND PHARMA LTD.,	)	[redacted]
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently before the court in this patent infringement action is the partial motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), filed by defendant Mankind Pharma Limited ("Mankind Pharma").[1] (D.I. 20) For the following reasons, I recommend that the court DENY Mankind Pharma's motion for judgment on the pleadings.

I. BACKGROUND[2]

Plaintiff Abbvie, Inc. ("Abbvie") is a global biopharmaceutical company that wholly owns Allergan, Inc. ("Allergan;" together with Abbvie, "Plaintiffs"). (D.I. 1 at ¶ 10) Abbvie holds New Drug Application ("NDA") No. 22184 for the brand drug LUMIGAN® 0.01%, which is used for the treatment of open angle glaucoma and ocular hypertension. (*Id.* at ¶¶ 4, 11) The Food and Drug Administration ("FDA") approved LUMIGAN® 0.01% pursuant to NDA No. 22184 on August 31, 2010. (*Id.* at ¶ 5) Allergan is the assignee of United States Patent No.

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[1] The briefing and associated filings relating to the motion for judgment on the pleadings are found at D.I. 1, D.I. 21, D.I. 38, D.I. 41, D.I. 42, D.I. 45, and D.I. 49.

[2] In accordance with the legal standard governing a Rule 12(c) motion for judgment on the pleadings, which requires the court to view all factual allegations in the pleadings in the light most favorable to the non-moving party, this summary of the facts is based on the allegations in Plaintiff's pleadings. (D.I. 1; D.I. 19); *see EMSI Acquisition, Inc. v. RSUI Indem. Co.*, 306 F. Supp. 3d 647, 652 (D. Del. 2018).

7,851,504 ("the '504 patent") entitled "Enhanced Bimatoprost Ophthalmic Solution," which expires on June 13, 2027. (*Id.* at ¶¶ 12, 26) The '504 patent is among twelve patents that are listed alongside LUMIGAN® 0.01% and NDA No. 22184 in the Orange Book. (*Id.* at ¶ 8)

Mankind Pharma manufactures and sells generic pharmaceuticals. (*Id.* at ¶ 14) On December 9, 2022, Mankind Pharma filed Abbreviated New Drug Application ("ANDA") No. 218196 requesting FDA approval of a generic version of LUMIGAN® 0.01% (the "ANDA Product"). (*Id.* at ¶ 2; D.I. 19 at ¶ 9) The ANDA includes a comparison chart of the excipients in LUMIGAN® and those in the ANDA Product, which shows that LUMIGAN® includes a phosphate buffering agent, [redacted].[3] (D.I. 9, Ex. C at § 3.2.P.1, Table 6) Mankind Pharma sent a Paragraph IV notice letter (the "Notice Letter") to Plaintiffs on January 27, 2023, alleging that the '504 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the ANDA Product. (D.I. 1 at ¶ 30)

On March 13, 2023, Plaintiffs brought this suit alleging that Mankind Pharma infringes the '504 patent either literally or under the doctrine of equivalents. (*Id.* at ¶ 34) The complaint does not allege infringement of the other eleven patents listed in the Orange Book for LUMIGAN®. (*Id.*) Those patents are scheduled to expire on March 16, 2025, before the 2027 expiration date of the '504 patent. (*Id.* at ¶ 8)

[3] The court may consider Mankind Pharma's ANDA on a Rule 12(c) motion because it is "integral to or expressly relied upon in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *see Azurity Pharms., Inc. v. Alkem Labs. Ltd.*, 582 F. Supp. 3d 192, 196 (D. Del. 2022) (citing *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012)); *Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, C.A. No. 22-1395-RGA, 2023 WL 6387975, at *4 (D. Del. Sept. 29, 2023) ("[W]here such filings provide the basis for the complaint, ANDA or NDA filings are 'integral' to the pleadings and can be relied upon in deciding a motion for judgment on the pleadings.").

On March 27, 2023, Mankind Pharma answered the complaint, asserted counterclaims against Plaintiffs, and produced its ANDA. (D.I. 9) Plaintiffs answered Mankind Pharma's counterclaims on April 25, 2023. (D.I. 19) The pleadings are now closed. On April 27, 2023, Mankind Pharma filed the pending Motion for Judgment on the Pleadings under Fed. R. Civ. P. 12(c). (D.I. 20)

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter the pleadings are closed – but early enough not to delay trial." Fed. R. Civ. P. 12(c). The movant will not prevail unless it is clearly established that "no material issue of fact remains to be resolved and that [the movant] is entitled to judgment as a matter of law." *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290-91 (3d Cir. 1988). Because a Rule 12(c) motion is analyzed under the same standards that apply to a Rule 12(b)(6) motion, the court must "view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the non-moving party." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008).

III. DISCUSSION

A. Literal Infringement

Mankind Pharma asserts that its ANDA Product cannot literally infringe because it has a [redacted] and therefore does not meet the phosphate buffer limitation recited in all three claims of the '504 patent:

> **1.** A composition having a pH of about 7.3 which consists essentially of about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, a phosphate buffer, NaCl, and water, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.
>
> **2.** A composition having a pH of about 7.3 which comprises about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, citric acid monohydrate, a phosphate buffer, and NaCl wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.
>
> **3.** A composition having a pH of about 7.3 which comprises about 0.01% bimatoprost, 200 ppm benzalkonium chloride, about 0.014 citric acid monohydrate, a phosphate buffer, NaCl, and water wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

(D.I. 21 at 5, 10) (quoting '504 patent, col. 6:16-30). According to Mankind Pharma, the ANDA specification controls the infringement inquiry, and the lack of any ingredient including phosphorous in the ANDA specification directly establishes that there is no literal infringement. (*Id.* at 6-8; D.I. 41 at 2-3) Plaintiffs respond that discovery is needed to determine whether the ANDA Product lacks a compound with the element phosphorous, and granting judgment on the pleadings as to literal infringement is therefore premature. (D.I. 38 at 13)

I recommend that the court deny Mankind Pharma's Rule 12(c) motion as it pertains to Plaintiffs' claim for literal infringement of the '504 patent. Mankind Pharma insists that the ANDA specification controls the infringement inquiry. (D.I. 41 at 3) However, the case law cited by Mankind Pharma in support of this proposition explains that the infringement inquiry is based not only on the ANDA filing, but also on "other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties." *Abbott Lab'ys v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). The Federal Circuit explained "[i]t is . . . possible, at least in theory, that other evidence may directly contradict the clear representations of the ANDA and create a dispute of material fact[,]" even if "[s]uch circumstances [are] unlikely to arise in

practice[.]" *Id.* Consistent with this recitation of the applicable standard, each case cited by Mankind Pharma was decided on a fully developed record, either on summary judgment or following a bench trial. *See Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022) (decision issued following a bench trial); *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1186-87 (Fed. Cir. 2014) (same); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569-70 (Fed. Cir. 1997) (same); *Intendis GmbH v. Glenmark Pharms., Inc.*, 822 F.3d 1355, 1362 (Fed. Cir. 2016) (same); *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279-80 (Fed. Cir. 2013) (decided on motion for summary judgment); *Bayer AG v. Elan Pharm. Res. Corp.*, 212 F.3d 1241, 1248-50 (Fed. Cir. 2000) (same).

The court finds more persuasive two recent cases from this district denying motions for judgment on the pleadings in ANDA cases. In *InfoRLife SA v. Sun Pharmaceutical Industries Ltd.*, the court determined that factual disputes existed regarding "whether the innermost layer of the plastic bag in [the] accused product comprises" ethylene-vinyl acetate ("EVA") copolymer. C.A. No. 21-1740-WCB, D.I. 153 at 4-5 (D. Del. Nov. 21, 2022). Although the asserted patent required the presence of EVA in the inner layer of the bag, the ANDA did not expressly disclose EVA in the innermost layer. *Id.* at 2-4. The court held that "the absence of such a statement in the ANDA does not conclusively establish" judgment as a matter of law of no literal infringement. *Id.* at 5. Similarly, Mankind Pharma's ANDA does not expressly recite a phosphate buffer. Although the ANDA specifies that the ANDA Product [redacted].

(D.I. 9, Ex. C at MAN-BIM_00033674, MAN-BIM_00038676)

Likewise, the court denied a Rule 12(c) motion in *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd.* based on a lack of "sufficient information to decide the broader

question of infringement at this stage of the litigation." C.A. No. 22-1395-RGA, 2023 WL 6387975, at *5 (D. Del. Sept. 29, 2023).[4] In *Novartis*, the court addressed whether the ANDA precluded a claim of literal infringement where the asserted patent recited an "amorphous" form of a compound and the ANDA required a crystalline form. *Id.* at *4. Stressing that "an infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence," the court found it was plausible that the ANDA products "may contain an amount of infringing material sufficient to raise an infringement theory[.]" *Id.* at *5 (quoting *Par Pharma., Inc. v. Hospira Inc.*, 2018 WL 3343238, at *3 (D. Del. May 11, 2018)).

The court's reasoning in *Novartis* rested on the Federal Circuit's decision in *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005), which affirmed the district court's judgment of infringement following a bench trial. In *SmithKline*, the asserted patent claim covered PHC hemihydrate, whereas the accused ANDA products were PHC anhydrate tablets. *Id.* The Federal Circuit upheld the district court's factual finding of infringement based on evidence showing that the generic PHC anhydrate tablets would contain trace amounts of the claimed PHC hemihydrate. *Id.* This analysis is consistent with Plaintiffs' position that the testing of samples of the ANDA Product is needed to confirm whether or not the ANDA Product satisfies the "phosphate buffer" limitation in the '504 patent. (D.I. 38 at 13) Consequently, I recommend that the court deny Mankind Pharma's motion for judgment on the pleadings regarding Plaintiffs' claim for literal infringement of the '504 patent.

[4] The court's decision in *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd.* issued after the completion of briefing on the pending Rule 12(c) motion.

B. Infringement Under the Doctrine of Equivalents

Plaintiffs' theory of infringement under the doctrine of equivalents is based on their position that the borate buffer in Mankind Pharma's ANDA Product is equivalent to the phosphate buffer claimed in the '504 patent. Mankind Pharma argues that the disclosure-dedication rule bars Plaintiffs from asserting infringement under the doctrine of equivalents. (D.I. 21 at 11)

The disclosure-dedication rule precludes a finding of infringement that is based on subject matter disclosed, but not claimed, in the written description. *See ViiV Healthcare Co. v. Gilead Scis., Inc.*, 437 F. Supp. 3d 395, 399 (D. Del. 2020). In other words, "when a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public." *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). If a person of ordinary skill in the art "can understand the unclaimed disclosed teaching upon reading the written description," the teaching is considered disclosed. *Eli Lilly and Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019) (quoting *PSC Comput. Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)). The Federal Circuit has explained that the doctrine of equivalents cannot be used to recapture subject matter left unclaimed because this practice would "conflict with the primacy of the claims in defining the scope of the patentee's exclusive right." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997).

Quoting the following language from the '504 patent specification, Mankind Pharma argues [redacted] is disclosed, but not claimed, in the '504 patent:

> As is known in the art, buffers are commonly used to adjust the pH to a desirable range for ophthalmic use. Generally, a pH of around 6-8 is desired, and in certain compositions a pH of 7.4 is desired. Many buffers including salts of inorganic acids such as phosphate, borate, and sulfate are known.

(D.I. 21 at 2, 11; D.I. 1, Ex. B at 2:36-30) Plaintiffs respond that the [redacted] in the '504 patent specification is too general to trigger the disclosure-dedication rule, and a skilled artisan would not recognize [redacted] as a disclosed alternative to the claimed phosphate buffer.[5] (D.I. 38 at 6, 9-11)

I recommend that the court deny Mankind Pharma's motion as it pertains to Plaintiffs' theory of infringement under the doctrine of equivalents because a factual dispute exists as to whether a person of ordinary skill would derive from the '504 patent specification the disclosure of [redacted]. Although the '504 patent specification discloses phosphate, borate, and sulfate as known salts of inorganic acids, it does not disclose [redacted]. (D.I. 1, Ex. B at 2:36-30) It would be premature to hold that the specification's generic disclosure of broad classes of unclaimed buffers, which are not specifically identified as alternatives to the "phosphate buffer" claim limitation, would sufficiently inform a person of ordinary skill and trigger the application of the disclosure-dedication rule. *See Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1378-79 (Fed. Cir. 2005) ("[T]he public notice function of patents suggests that before unclaimed subject matter is

[5] Plaintiffs also argue that a pending patent application filed by Mankind Pharma (U.S. 2022/0125801 A1), which claims a borate buffer, necessarily contradicts Mankind Pharma's assertion that the '504 patent discloses a borate buffer. (D.I. 38 at 7-8) The parties' citation to this pending patent application and a June 27 preliminary amendment to the application were the subject of a post-briefing letter campaign. (D.I. 45; D.I. 49) While Mankind Pharma's pending patent application is a matter of public record, Plaintiffs did not refer to it in their complaint, which is the subject of Mankind Pharma's Rule 12(c) motion. (D.I. 20) Consideration of Mankind Pharma's pending patent application and its associated prosecution history is not necessary or permissible to resolve the motion for judgment on the pleadings in Plaintiffs' favor. *Cf. InfoRLife SA*, C.A. No. 21-1740-WCB, D.I. 153 at 2 n.2 (explaining that a patent and its file history may be considered when those documents are referenced in the complaint and are therefore part of the pleadings).

deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation."); *see also Sun Pharm. Indus. Ltd. v. Saptalis Pharms., LLC*, C.A. No. 18-648-WCB, 2019 WL 13153693, at *11 (D. Del. Aug. 26, 2019) (rejecting application of disclosure-dedication rule where specification "contains no example formulations that use [sulfate and/or borate buffers] as an alternative to" the claimed phosphate buffer).

As with Mankind Pharma's arguments on literal infringement, nearly all the cited case authorities applying the disclosure-dedication rule were decided on a complete record following discovery. *See, e.g.*, *PSC Comput.*, 355 F.3d at 1360 (decided on a motion for summary judgment); *Johnson & Johnston*, 285 F.3d at 1054 (decided following a jury trial). Two cases applying the disclosure-dedication rule at the pleadings stage are distinguishable. In *Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC*, the Federal Circuit upheld a decision to grant judgment of non-infringement on the pleadings based on the application of the disclosure-dedication rule because the patents themselves established the rule's applicability. 958 F.3d 1171, 1177 (Fed. Cir. 2020). The asserted patent claim described a "pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol ['PG']" as a component of the claimed composition. *Id.* at 1174. However, the specification repeatedly described "preferred pharmaceutically accepted fluids" as including PG or ethanol and disclosed both as preferred alternatives in an embodiment of the invention. *Id.* Based on this disclosure, the Federal Circuit concluded "the only reasonable inference that can be made from the patent disclosures is that a skilled artisan would understand the patents to disclose ethanol as an alternative to the claimed PG." *Id.* at 1178. Here, in contrast, the '504 patent specification refers

generally to a borate buffer on one occasion, without expressly identifying it as an alternative to a phosphate buffer in any preferred embodiment or specific example.

The court's decision in *In re Bendamustine* is not binding and is factually distinguishable. C.A. No. 13-2046-GMS, 2015 WL 1951399, at *2-3 (D. Del. Apr. 29, 2015). The specification of the asserted patents in *In re Bendamustine* identified a list of organic solvents that were expressly identified as alternatives to the claimed tertiary butanol. *Id.* at *2. The court determined that this recitation was sufficiently precise to inform a person of ordinary skill of the disclosed subject matter. *Id.* However, the written description of the '504 patent does not describe borate buffers as alternatives to phosphate buffers or otherwise describe how a borate buffer would be a viable substitute for the claimed phosphate buffer. Because this inquiry involves unresolved issues of fact regarding the understanding of a person of ordinary skill in the art, I recommend that the court deny Mankind Pharma's motion for judgment on the pleadings.

IV. CONCLUSION

For the foregoing reasons, I recommend that the court deny without prejudice Mankind Pharma's motion for judgment on the pleadings pursuant to Rule 12(c). (D.I. 20)

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 **January __, 2024**, 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 fourteen (14) days of the date the Report and Recommendation issued.

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 ten (10) 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).

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, http://www.ded.uscourts.gov.

Dated: December 21, 2023

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE