

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

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC,

Plaintiffs,

v.

Civil Action No. 23-00358-GBW

BAXTER HEALTHCARE CORPORATION,

Defendant.

Kaan Ekiner, W. Blake Coblentz, Aaron S. Lukas, Kerry B. McTigue, Keri L. Schaubert, and
Madison McNutly, COZEN O'CONNOR.

Counsel for Plaintiffs

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MEMORANDUM OPINION

March 12, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

This matter is before the Court on the Report and Recommendation (the “Report”) (D.I. 52) of Magistrate Judge Fallon on: (1) Plaintiffs’¹ Motion for Preliminary Injunction and Temporary Restraining Order (“TRO”); and (2) Defendant’s² Motion for Judgment on the Pleadings. Judge Fallon recommended that the Court deny both motions and, on November 17, 2023, Defendant filed an objection to the Magistrate Judge’s recommendation that the Court deny Defendant’s Motion for Judgment on the Pleadings. D.I.69. Plaintiffs filed their response in opposition to Defendant’s Objection on December 1, 2023. D.I. 77. For the reasons discussed below, the Court overrules Defendant’s objection and adopts Judge Fallon’s Report in its entirety.

I. LEGAL STANDARD

The product of a magistrate judge, following a referral of a dispositive matter, is often called a “report and recommendation.” *EEOC v. City of Long Branch*, 866 F.3d 93, 99-100 (3d Cir. 2017). “Parties ‘may serve and file specific written objections to the proposed findings and recommendations’ within 14 days of being served with a copy of the magistrate judge’s report and recommendation.” *Id.* (quoting Fed. R. Civ. P. 72(b)(2)). “If no party objects to the magistrate judge’s order regarding a non-dispositive matter, the magistrate judge’s order becomes binding ‘unless the district court takes some action to overrule it.’” *EEOC*, 866 F.3d at 99 (internal quotations omitted). “If a party objects timely to a magistrate judge’s report and recommendation, the district court must ‘make a *de novo* determination of those portions of the report or specified

¹ Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively “Plaintiffs”).

² Baxter Healthcare Corporation’s (“Baxter” or “Defendant”).

proposed findings or recommendations to which objection is made.” *Id.* (quoting 28 U.S.C. § 636(b)(1)).

II. DISCUSSION

1. Plaintiffs’ Motion for Injunctive Relief

Plaintiffs have raised no objections to the Magistrate Judge’s recommendation that the Court deny Plaintiffs’ Motion for Preliminary Injunction and TRO (hereinafter, “Motion for Injunctive Relief”). The Court, having reviewed the record in this case and the Report, agrees with the Magistrate Judge’s findings. A preliminary injunction is an “extraordinary remedy” that is granted only in “limited circumstances.” *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). Here, Plaintiffs failed to show that their infringement claims under the doctrine of equivalents are likely to succeed on the merits and failed to show that, minus injunctive relief, irreparable harm would result. *See* D.I. 52 at 7-18. Accordingly, the Report’s recommendation that the Court deny Plaintiffs’ Motion for Injunctive Relief is adopted.

2. Defendant’s Motion for Judgment on the Pleadings

“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); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir.1997) (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion). Thus, the Court will not grant a Motion for Judgment on the Pleadings “unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.” *Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 290–91 (3d Cir.1988) (internal quotations omitted).

Here, Judge Fallon found that Plaintiffs “plausibly state a claim for infringement under the doctrine of equivalents, and material issues of disputed fact preclude the entry of judgment on the pleadings.” D.I. 52 at 19. Thus, the Report recommends that Defendant’s Motion be denied. *Id.* at 19-20. Defendant challenges this recommendation on the ground that the recommendation contradicts Judge Fallon’s earlier findings regarding Plaintiffs’ Motion for Injunctive Relief. D.I. 69 at 3. Defendant also contends that Judge Fallon erred in finding that disputed issues of fact preclude the Court from granting Defendant’s Motion for Judgment on the Pleadings. *Id.* at 4-6. Following a *de novo* review of the Report and all relevant briefing, the Court disagrees with Defendant on both grounds and adopts the Report’s recommendation to deny Defendant’s Motion for Judgment on the Pleadings.

i. The Court finds no contradictions in Judge Fallon’s Report.

The parties dispute whether Plaintiffs can overcome the presumption of prosecution history estoppel by proving that the narrowing amendments to the Asserted Patents³ were “tangential” to the equivalence alleged between an acetate buffer and a lactate buffer. D.I. 69 at 6-7; D.I. 77 at 5.

Judge Fallon recommended that, “[u]nder these circumstances, testimony from a person skilled in the art is necessary to interpret the prosecution history and provide evidence on whether the narrowing amendment was made for a tangential reason.” D.I. 52 at 20-21. Defendant objects to the Report and contends that Judge Fallon’s recommendation to deny Defendant’s Motion for Judgment on the Pleadings contradicts her “previous findings that the amendments made during prosecution were directly related to the identity of the buffer.” D.I. 69 at 6. The Court disagrees.

³ U.S. Patent Nos. 9,993,520, 11,135,265, and 11,207,372 (collectively “the Asserted Patents”).

In recommending that the Court deny Plaintiffs' Motion for Injunctive Relief, Judge Fallon found "no dispute that a *presumption* of prosecution history estoppel applies." D.I. 52 at 9. Plaintiffs attempted to overcome this presumption by raising the tangential relation exception to prosecution history estoppel and, in support of their claim, cited the Federal Circuit's decision in *Eli Lilly Co. v. Hospira, Inc.*, 933 F.3d 1320 (Fed. Cir. 2019). *See id.* at 12. Judge Fallon was not persuaded by Plaintiffs' arguments and found that this matter was distinguishable from *Eli Lilly* because Plaintiffs' amendments "were not made to overcome a particular prior art reference" but, instead, were made "because the written description of the Asserted Patents only provided support for acetate buffers." *Id.*

Ultimately, after recognizing that the tangential relation exception is "very narrow," Judge Fallon determined that Plaintiffs failed to show *a strong likelihood* that they will prevail on the tangential relation exception. *Id.* at 13. In recommending that the Court deny Plaintiffs' Motion, however, Judge Fallon did not, as Defendant implies, "make[] conclusive findings based on a review of the file history of the [Asserted Patents]" or hold that Plaintiffs are precluded from asserting the tangential relation exception as a matter of law. *See* D.I. 69 at 5. Judge Fallon also did not find that Plaintiffs could not succeed in proving that the amendments were made for some reason unrelated to the lactate buffer asserted in this matter. Rather, Judge Fallon recognized that some evidence "support[s] Defendant's position that limiting the claimed buffer specifically to an acetate buffer was crucial to allowability." D.I. 52 at 12. Thus, Judge Fallon concluded that Plaintiffs had not met their burden of proving their entitlement to pre-trial injunctive relief.

On the other hand, in recommending that the Court deny Defendant's Motion for Judgment on the Pleadings, Judge Fallon noted that "[p]rosecution history estoppel, including the tangentiality inquiry, is always a case-specific analysis." *See id.* at 20 (citing *Bio-Rad Labs., Inc.*

v. 10X Genomics Inc., 967 F.3d 1353, 1366). Judge Fallon explained that Defendant’s Motion called for a different legal standard and required the Court to view all disputed evidence and reasonable inferences in Plaintiffs’ favor. *Id.* at 19. After doing so, Judge Fallon found that Defendant failed to meet its burden of proving that all issues of fact could be resolved on the pleading. *Id.* Specifically, Judge Fallon found that a genuine and material dispute remained “regarding the proper interpretation of the Asserted Patents’ prosecution history” and whether it supported Plaintiffs’ claim that the narrowing amendments from “any buffer” to an “acetate buffer” were made for tangential reasons. *Id.* at 20.

Given the differences in the legal standards and burdens applicable to Plaintiffs’ Motion for Injunctive Relief and Defendant’s Motion for Judgment on the Pleadings, the Court finds that Judge Fallon was not, as Defendant claims, inconsistent in recommending that both motions be denied.

ii. The Court’s de novo review of the prosecution history supports Judge Fallon’s finding that there remains a factual dispute that must be resolved concerning the tangential relation exception.

“[W]hether an amendment was merely tangential to an alleged equivalent necessarily requires focus on the context in which the amendment was made; hence the resort to the prosecution history.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1370 (Fed. Cir. 2003). “If the amendment was not narrowing, then prosecution history estoppel does not apply.” *Id.* However, if the amendment was a narrowing amendment, “then the second question is whether the reason for that amendment was a substantial one relating to patentability.” *Id.* If the patent holder can show that the amendment was made for a reason tangential to patentability, prosecution history estoppel will not apply. *Id.* A claim that the amendment was made for a tangential purpose will fail, however, where it is clear that “the amendment was made

to avoid prior art.” *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003); *Sextant Avionique, S.A. v. Analog Devices, Inc.*, 172 F.3d 817, 826 (Fed. Cir. 1999) (internal citations omitted) (finding prosecution history estoppel is applicable where “a substantive change” is made to a claim “that clearly responds to an examiner’s rejection of that claim as unpatentable over prior art”).

Here, it is undisputed that the amendments narrowed the claims of the Asserted Patents. However, this fact alone does not establish that the tangential relation exception does not apply. *See Festo-Corp.*, 344 F.3d at 1370. In determining the applicability of the tangential relation exception, the Court must consider whether the amendments to the Asserted Patents were made for reasons substantially related to the non-acetate equivalent buffer alleged by Defendant. *Id.* Judge Fallon’s Report recommends that this issue not be resolved on the pleadings, since the prosecution history for each of the Asserted Patents “was not limited to the identity of the claimed buffer” but also “addressed the pH of the formulation and buffer concentration.” D.I. 52 at 20. The Court agrees.

While the amendments “include[d] a limitation of an acetate buffer,” the Court agrees with Judge Fallon that it is not clear from the prosecution history whether the amendments were made for reasons substantially related to the non-acetate equivalent buffer in Defendant’s accused product. That is, “the prosecution history across the three Asserted Patents indicates that the examiner’s § 112(a) rejection for lack of written description addressed ‘the pH of the formulation and buffer concentration.’” *Id.*

In an office action issued in response to the ’520 patent application, for instance, the examiner explained that the application was rejected under § 112(a) because “one of ordinary skill in the art would not conclude that Applicant was in possession of a vasopressin formulation *at any*

pH or buffer concentration that can be used in the claim methods as a diluted unit dosage form that be stored prior to use.” D.I. 8, Ex. A at A.15 (emphasis added). After the patent application was amended to limit the pH of the formulation, the buffer concentration, and the identity of the claimed buffer, the examiner issued a Notice of Allowance. The Notice of Allowance provided the two (2) grounds for the examiner’s determination that the amended claims were “novel and unobvious” over the Vasostrict® Label prior art reference: (1) Plaintiffs’ amended claims allowed vasopressin to be stored in its “diluted form for at least 24 hours” while Vasostrict® Label teaches away from this step by requiring that “the vasopressin must be discarded 18 hours after dilution if kept at room temperature or 24 hours if refrigerated;” and (2) the amended claims disclosed a “unit dosage form has an estimated shelf like [sic] at 5 °C of about 16.1 months and at 25 °C of about 8 months.” *Id.* at A.35. Yet, the examiner’s Notice of Allowance did not directly address the amendment to the identity of the claimed buffer or consider the equivalency of a lactate buffer.⁴ D.I. 52 at 20.

Viewing the evidence in the light most favorable to Plaintiffs, the Court agrees with Judge Fallon that, at this stage of the pleading, the Court cannot determine whether the amendments limiting the identity of the claimed buffers were made for reasons tangential to the requirement of an acetate buffer as opposed to Defendant’s alleged equivalent buffer. *Id.* at 21. The Court similarly agrees that testimony from a person of ordinary skill in the art would assist the Court in interpreting the prosecution history and determining whether the amendments to only an “acetate buffer” were substantially related to the issue of patentability. *Id.* at 20. Accordingly, the Court

⁴ The same is true with regard to the two (2) remaining Asserted Patents. The Notice of Allowance issued for each again highlighted the pH and dilution concentrations as characteristics distinguishing the Asserted Patents from the Vasostrict® Label and other prior art and failed to discuss the identity of the disclosed acetate buffer or whether the claimed acetate buffer was equivalent to lactate or any similar buffers. *See generally* D.I. 8, Ex. B-C.

adopts Judge Fallon's recommendation to deny Defendant's Motion for Judgment on the Pleadings.

III. CONCLUSION

Upon the Court's *de novo* review of Judge Fallon's Report, (D.I. 52), Defendant's Objections, (D.I. 69), and Plaintiffs' Response, (D.I. 77), it is hereby **ORDERED** that:

1. Judge Fallon's Report and Recommendation dated November 3, 2023, (D.I. 52), is **ADOPTED** in its entirety;
2. Defendant's Objections, (D.I. 69), are **OVERRULED**;
3. Defendant's Motion for Judgment on the Pleadings, (D.I. 17), is **DENIED**; and
4. Plaintiffs' Motion for Injunctive Relief, (D.I. 22), is **DENIED**.

Date: March 12, 2024