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,	)	C.A. No. 23-358-GBW-SRF
v.	)	[redacted]
BAXTER HEALTHCARE CORPORATION,	)	
Defendants.	)	

REPORT AND RECOMMENDATION[1]

Presently before the court in this patent infringement action are the following motions: (1) the motion for a preliminary injunction and temporary restraining order ("TRO") filed by plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC ("Par Sterile"), and Endo Par Innovation Company, LLC ("Endo;" collectively, "Plaintiffs"), (D.I. 22);[2] and (2) the motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), filed by defendant Baxter Healthcare Corporation ("Defendant" or "Baxter"), (D.I. 17).[3] For the following reasons, I recommend that the court DENY Plaintiffs' motion for a preliminary injunction and TRO and DENY Baxter's Rule 12(c) motion for judgment on the pleadings.

[1] Pursuant to 28 U.S.C. § 636 and the referral order dated October 4, 2023 (D.I. 21), this decision is issued as a Report and Recommendation. *See Ali v. Howard*, C.A. No. 05-102-SLR-LPS, 2008 WL 4427209, at *1 n.5 (D. Del. Sept. 30, 2008) (explaining that the magistrate judge's authority with respect to a motion for TRO/PI is limited to issuing a Report and Recommendation).

[2] The briefing and filings associated with the pending motion for a TRO and PI are found at D.I. 23, D.I. 24, D.I. 29, D.I. 30, D.I. 31, D.I. 33, and D.I. 34.

[3] The briefing and filings associated with the pending Rule 12(c) motion for judgment on the pleadings are found at D.I. 18, D.I. 35, and D.I. 47.

I. BACKGROUND[4]

On September 25, 2012, Par Sterile's predecessor submitted New Drug Application ("NDA") No. 204485 to the Food and Drug Administration ("FDA") pursuant to § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. (D.I. 1 at ¶¶ 22-23) NDA No. 204485 sought FDA approval for a vasopressin injection product that could increase blood pressure in adults with vasodilatory shock. (*Id.* at ¶ 22) The FDA approved NDA No. 204485 for use in a clinical setting on April 17, 2014, and Plaintiffs began marketing the product as Vasostrict® to hospitals directly and through group purchasing organizations ("GPOs") and wholesalers. (*Id.* at ¶¶ 22, 26)

During the first quarter of 2022, several generic alternatives to Vasostrict® were launched, starting with a generic that was launched at risk and began shipping in January of 2022. (D.I. 31, Ex. 52 at 50; D.I. 24, Ex. 19 at 20) These launches have negatively impacted Plaintiffs' market share and product price for Vasostrict®. (*Id.*) Plaintiffs launched Vasostrict® in a ready-to-use ("RTU") bottle in February of 2022, and the RTU formulation "represents a meaningful portion of the overall vasopressin market." (D.I. 31, Ex. 52 at 50; D.I. 24, Ex. 19 at 55)

Following the launch of the generic alternatives, on August 16, 2022, Endo filed a voluntary Chapter 11 bankruptcy petition. (D.I. 24, Ex. 19 at F-13-14) In the proposed sale agreement filed in the bankruptcy case on November 23, 2022, Endo represented that, to its knowledge, "no Person is Infringing, in any material respect, any Intellectual Property owned by

[4] The facts set forth herein are primarily taken from the pleadings and documents incorporated by reference into the pleadings in accordance with the standard governing the Rule 12(c) motion for judgment on the pleadings. *See Mele v. Fed. Rsrv. Bank of New York*, 359 F.3d 251, 257 (3d Cir. 2004). Citations to documents outside the pleadings pertain only to the court's analysis of the motion for TRO and PI.

or exclusively licensed to the Endo Companies and included in the Transferred Assets[.]" (D.I. 30, Ex. 14 at 59-60) The bankruptcy proceedings are ongoing.

Baxter submitted NDA No. 217569 to the FDA under § 505(b)(2) on November 30, 2022 in connection with its own RTU vasopressin product.[5] (D.I. 13 at ¶ 87) On January 30, 2023, Baxter sent Plaintiffs a written notice that its NDA contained Paragraph IV certifications confirming that use of Baxter's product would not infringe Plaintiffs' patents listed in the Orange Book in connection with Plaintiffs' Vasostrict® product (the "Notice Letter"). (*Id.* at ¶ 90) Plaintiffs did not sue Baxter on any of the Orange Book-listed patents within the 45-day period under the Hatch-Waxman Act. (*Id.* at ¶ 95) As a result, there is no 30-month stay of the FDA's final approval of Baxter's NDA No. 217659. (*Id.*)

Plaintiffs filed their complaint in the instant action on March 29, 2023, alleging that Baxter infringes Plaintiffs' U.S. Patent Nos. 9,993,520 ("the '520 patent"), 11,135,265 ("the '265 patent"), and 11,207,372 ("the '372 patent;" collectively, the "Asserted Patents"). (D.I. 1) The Asserted Patents are directed to RTU vasopressin formulations that can be stored for extended periods of time. The Asserted Patents are not listed in the Orange Book in connection with the Vasostrict® product. (D.I. 13 at ¶ 95) Unlike the Orange Book-listed patents for Vasostrict®, the Asserted Patents do not require a dilution step.

Key to the parties' arguments on the pending motions is the claimed "buffer" in the Asserted Patents. During prosecution of the '520 patent, the examiner issued a rejection under 35 U.S.C. § 112(a) for lack of written description. (D.I. 8, Ex. A at A.14-15) The examiner instructed the patentee to "amend the claims to limit the pH of the formulation and buffer

[5] The 505(b)(2) pathway allows an applicant to submit an NDA for a change or modification to a reference listed drug found to be safe and effective by the FDA. 21 U.S.C. § 355(b)(2). The NDA must contain clinical data demonstrating the safety and effectiveness of the drug, but there is no requirement to include findings of therapeutic equivalence. *See id.*

concentration as set forth in Example 16." (*Id.*, Ex. A at A.15) To overcome the rejection, the patentee amended the claims to specify "about 1 mM to about 10 mM acetate buffer," consistent with the buffer used in Example 16 at the claimed pH and active concentration. (*Id.*, Ex. A at A.22) The examiner then allowed the claims. (*Id.*, Ex. A at 35) The '372 and '265 patent claims are consistent with the claims as allowed in the '520 patent. (*Id.*, Ex. B at B.2, B.14-15; Ex. C at C.77-78) Claim 1 of the '520 patent requires:

> a) providing a unit dosage form for intravenous administration, wherein the unit dosage form comprises:
> i) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) from about 1 mM to about 10 mM acetate buffer;
> iii) 0-2% vasopressin degradation products;
> iv) sodium chloride; and
> v) water[.]

(D.I. 1, Ex. A at 175:34-42) Claim 1 of the '265 patent recites:

> b) a unit dosage form contained in the drip-bag, wherein the unit dosage form comprises:
> i) vasopressin of a pharmaceutically-acceptable salt thereof at a concentration of about 0.1 units/mL to about 1 unit/mL;
> ii) from about 1 mM to about 10 mM acetate buffer;
> iii) dextrose, sodium chloride or a combination thereof; and
> iv) water[.]

(*Id.*, Ex. B at 179:6-14) Claim 1 of the '372 patent discloses:

> a unit dosage form, wherein the unit dosage form consists essentially of:
> a) from about 0.1 units mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> b) a pH-adjusting agent;
> c) an acetate buffer;
> d) about 0.9% NaCl; and
> e) water[.]

(*Id.*, Ex. C at 173:22-29)

Baxter answered the complaint and asserted counterclaims for noninfringement and invalidity of the Asserted Patents on August 14, 2023. (D.I. 8) In its pleading, Baxter lists the

ingredients in its NDA product and notes that it does not contain an acetate buffer. (*Id.* at ¶¶ 88-89) Rather, the buffer in Baxter's NDA product is [redacted] (*Id.* at ¶ 88) Baxter's pleading also alleges that the January 30 Notice Letter set forth its invalidity positions on various patents listed in the Orange Book in connection with Vasostrict®, and those Orange Book-listed patents are related to the Asserted Patents. (*Id.* at ¶¶ 42, 93) Plaintiffs filed their answer to Baxter's counterclaim on September 5, 2023. (D.I. 13)

The FDA approved Baxter's NDA on September 29, 2023. (D.I. 24, Ex. 1) On October 4, 2023, Plaintiffs filed the pending motion for a preliminary injunction and TRO seeking to delay Baxter's market launch. (D.I. 22) The hearing on Plaintiffs' motion for a preliminary injunction and TRO was held on October 27, 2023. At the hearing, Baxter represented tha[redacted] (10/27/2023 Tr.)

A sale hearing in Endo's bankruptcy case was scheduled to go forward on October 19, 2023 and Plaintiffs represent it has since been rescheduled to November of 2023. (D.I. 31, Ex. 60; 10/27/2023 Tr.)

II. DISCUSSION

A. Plaintiffs' Motion for a Preliminary Injunction and TRO

1. Legal standard

The decision to grant or deny a preliminary injunction is within the sound discretion of the district court. *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006). A preliminary injunction is "an extraordinary and drastic remedy . . . that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original) (internal quotation marks and citations omitted). However, the Patent Act expressly states that courts "may grant injunctions in accordance with

the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283.

To obtain a preliminary injunction, the movant "must establish that he is likely to succeed on the merits" and will "suffer irreparable harm in the absence of preliminary relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors[.]" *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis in original). If the movant meets its burden on the first two factors, the court considers the third and fourth factors, which require a showing that the balance of hardships tips in the movant's favor, and the injunction will have a favorable impact on the public interest. *Id.* "While granting a preliminary injunction requires analysis of all four factors, [ ] a trial court may . . . deny a motion based on a patentee's failure to show any one of the four factors—especially either of the first two—without analyzing the others[.]" *Jack Guttman, Inc. v. KopyKake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) (citations omitted). "[A]ll findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

The standard for a preliminary injunction applies equally to a motion for a TRO where, as here, the opposing party has notice of the motion. *See Genentech, Inc. v. Amgen Inc.*, C.A. No. 18-924-CFC, 2019 WL 3290167, at *2 (D. Del. July 18, 2019). Consequently, Plaintiffs' motion for a TRO rises and falls with its motion for a preliminary injunction.

2. Analysis

For the following reasons, Plaintiffs have failed to meet their burden of establishing the first two preliminary injunction factors: (1) a likelihood of success on the merits, and (2)

irreparable harm in the absence of a preliminary injunction. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Consequently, I recommend that the court deny Plaintiffs' motion for a preliminary injunction and TRO.

a. Likelihood of success on the merits[6]

A patentee seeking a preliminary injunction in an infringement suit "must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). To satisfy this standard, "the moving party must put forth evidence supporting its claims, and neither attorney argument nor the allegations in the complaints suffice." *Vertigo Media, Inc. v. Earbuds Inc.*, C.A. No. 21-120-MN, 2021 WL 4806410, at *5 (D. Del. Oct. 14, 2021). If the party opposing the motion for a preliminary injunction "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue."[7] *Amazon.com*, 239 F.3d at 1350-51.

Plaintiffs have not shown a strong likelihood of success on the merits of their infringement claims. They concede that Baxter's product does not literally infringe the Asserted Patents because it lacks the claimed acetate buffer. (D.I. 23 at 5) However, Plaintiffs argue that

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[6] Plaintiffs argue that, "[t]o satisfy the likelihood of success factor, Par need only show 'a reasonable chance, or probability, of winning' which need not be greater than 50%." (D.I. 23 at 7) (citing *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011)). Baxter challenges the accuracy of the standard as recited by Plaintiffs. (D.I. 29 at 6 n.4) "Because motions pursuant to 35 U.S.C. § 283 'involve[ ] substantive matters unique to patent law,' they are governed by the law of the Federal Circuit." *Nevro Corp. v. Stimwave Techs., Inc.*, C.A. No. 19-325-CFC, 2019 WL 3322368, at *3 n.2 (D. Del. July 24, 2019) (quoting *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988)). Thus, Plaintiffs' reliance on Third Circuit case law for the applicable standard is misplaced.

[7] Baxter maintains that Plaintiffs' failure to establish a likelihood of success on the merits of their infringement claims is fatal to their preliminary injunction motion and, for this reason, the court need not weigh the merits of Baxter's invalidity counterclaims. (10/27/2023 Tr.)

they are likely to prevail on their theory of infringement under the doctrine of equivalents because the claimed "acetate buffer" in the Asserted Patents is equivalent to the [redacted] buffer in Baxter's accused product. (*Id.*) Plaintiffs present expert declarations demonstrating that the formulation of Baxter's [redacted] buffer falls within an optimal pH range for stability over the product's shelf life, with results comparable to those of Plaintiffs' acetate buffer in reducing the degradation of vasopressin. (*Id.* at 8-11; D.I. 24, Ex. 11 at 18; Ex. 15 at ¶¶ 100-04, 133-37, 167-71)

Baxter responds that prosecution history estoppel precludes the application of the doctrine of equivalents in this case because Plaintiffs narrowed the claims during prosecution to recite an acetate buffer for purposes of overcoming a written description rejection under 35 U.S.C. § 112(a). (D.I. 29 at 7-9) Baxter further argues that Plaintiffs' equivalents theory fails on the merits because there are substantial differences between Baxter's [redacted] buffer and the acetate buffer recited in the Asserted Patents. (*Id.* at 10-11) Baxter contends that its product does not infringe under either the "function-way-result" test or the "insubstantial differences" test due to the many differences in the structural, physical, and chemical properties of the components of [redacted] and acetate buffers. (*Id.* at 10; D.I. 30, Ex. 1 at ¶¶ 47-55) Baxter refutes Plaintiffs' arguments regarding the comparable pH ranges of the acetate and [redacted] buffers, noting that, "[i]n assessing function for purposes of DOE . . . more is required than simply maintaining pH." (D.I. 29 at 10) (citing *Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS et al., 2021 WL 1751148, at *33 (D. Del. Apr. 29, 2021)).

The court cannot view the substance of Plaintiffs' doctrine of equivalents theory in isolation where, as here, there is no dispute that a presumption of prosecution history estoppel applies. On this record, Plaintiffs have not shown a likelihood of overcoming the multiple layers

of standards weighted against them (i.e., the limited application of the doctrine of equivalents, the presumption of prosecution history estoppel, and the narrow application of the tangential relation exception) sufficient to meet the likelihood of success factor. *See Mazurek*, 520 U.S. at 972.

Under the doctrine of equivalents, a product or process that does not literally infringe a patent claim may nevertheless infringe if it performs "substantially the same function in substantially the same way to obtain the same result," or if it is "substantially different from what is patented." *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017) (internal citations and quotation marks omitted). However, the doctrine of equivalents "cannot be used to effectively read out a claim limitation . . . because the public has a right to rely on the language of patent claims." *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) (internal citations omitted). The Federal Circuit has explained that "[a]pplication of the doctrine of equivalents is the exception . . . not the rule," and it should not be viewed as "simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims[.]" *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991).

The limited application of the doctrine of equivalents cuts against Plaintiffs' position that they have a strong likelihood of success on the merits of their infringement claims. At oral argument, Plaintiffs confirmed that they cannot provide the court with any case authority in which a preliminary injunction was granted solely on a doctrine of equivalents theory of infringement. (10/27/2023 Tr.) The Federal Circuit has recognized that granting a preliminary injunction based on the doctrine of equivalents is "unusual" because "equivalents cases are highly factual inquiries that rarely come clear on a premature record[,]" "the law on the doctrine

of equivalents as applied to chemical materials is not clear, and its misapplication can lead to unsound results." *Mylan*, 857 F.3d at 866; *see also Jeagr Ventures, LLC v. Does 1-54*, 2022 WL 1450384, at *5 (N.D. Ill. May 9, 2022) (explaining that "relying on the doctrine of equivalents is disfavored at the preliminary injunction stage" due to the factual nature of the inquiry and the difficulty resolving it "on a premature record.").

Moreover, Plaintiffs may be legally barred from prevailing on their doctrine of equivalents theory based on Baxter's assertion of prosecution history estoppel. (D.I. 29 at 7-9) The prosecution history of the Asserted Patents gives rise to a presumption that Plaintiffs will be estopped from succeeding on their infringement claims because Plaintiffs narrowed the claimed "buffer" to an "acetate buffer" in response to the examiner's rejection for lack of written description under 35 U.S.C. § 112(a). The Supreme Court has held that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). Specifically, a narrowing amendment made to comply with § 112 "creates a presumption that the patentee surrendered the territory between the original claims and the amended claims." *Glaxo Wellcome, Inc. v. Impax Lab'ys, Inc.*, 356 F.3d 1348, 1352 (Fed. Cir. 2004). Here, Plaintiffs do not dispute that the amendments limiting the claimed buffer in the Asserted Patents to an acetate buffer were narrowing amendments made for a substantial reason relating to patentability—namely, to overcome the examiner's § 112(a) rejection. (D.I. 23 at 12) Consequently, there is a presumption that Plaintiffs surrendered the claim scope encompassing Baxter's allegedly equivalent buffer.

Plaintiffs maintain that the presumption is overcome in this case because the narrowing amendments are tangential to the question of whether the claimed acetate buffer is equivalent to

Baxter's [redacted] buffer. (D.I. 23 at 12) A patentee may rebut the presumption of a surrender of claim scope during prosecution by demonstrating that "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003). However, "[t]he tangential relation exception is 'very narrow.'" *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (quoting *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007)). The Federal Circuit has explained that an amendment which narrows an existing claim element "evinces an intention to relinquish that claim scope" and "is a powerful indication that an amendment was not merely tangential." *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1333 (Fed. Cir. 2019).

Here, Plaintiffs argue that the focus of the examiner's rejections was on the pH of the formulation and the buffer concentration, as opposed to the specific type of buffer. (D.I. 23 at 12) But the examiner's rejections specifically directed the patentee to amend the claims in a manner consistent with Example 16 in the specification, which disclosed an acetate buffer, and the patentee amended the claims accordingly to include a limitation of an acetate buffer before the claims were allowed. (*See, e.g.*, D.I. 8, Ex. A at 15, 22, 25-26) During prosecution of the '372 patent, the examiner rejected claims reciting "any buffer, and a range of pH of 3.7 to 3.9" because the specification only supported "a pH range of 3.5 to 3.7 *and only in the buffer acetate*." (*Id.*, Ex. C at 11) (emphasis added). And when the patentee pursued a broader range of buffers, such as glycine, aspartate, and phosphate, the examiner referred to the high level of unpredictability in the art in finding that "the additional examples pointed to by Applicant are insufficient to support the amended genus of buffers with acidic pH." (*Id.*, Ex. C at 45)

These rejections support Baxter's position that limiting the claimed buffer specifically to an acetate buffer was crucial to allowability. *See Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS, 2021 WL 1751148, at *29 (D. Del. Apr. 29, 2021), *aff'd, Azurity Pharms., Inc. v. Bionpharma Inc.*, 2022 WL 703903 (Fed. Cir. Mar. 9, 2022) (concluding that the amendment bore more than a tangential relationship to the accused equivalent buffer where the prosecution history showed that both the identity and concentration of the claimed buffer were important to long-term stability of the composition). Plaintiffs have not shown a strong likelihood that they will prevail on the tangential relation exception where, as here, the applicant narrowed the scope of the claims to overcome a § 112 rejection based on an alleged lack of written description supporting a broader definition of "buffer."

Plaintiffs draw a comparison between the record before the court and the Federal Circuit's decision in *Eli Lilly Co. v. Hospira, Inc.* to support their argument that the tangential relation exception applies to the narrowing amendments made during prosecution of the Asserted Patents. (D.I. 23 at 12) In *Eli Lilly*, the patentee amended the claims to narrow "pemetrexel salts generally" to "pemetrexel disodium" to overcome the examiner's rejection based on a prior art reference claiming treatments using methotrexate. 933 F.3d at 1330-31. The Federal Circuit determined that the amendment did not preclude other pemetrexed salts because it was made for the limited purpose of avoiding methotrexate. *Id.* As a result, the Federal Circuit held that the amendments were tangential to the question of whether pemetrexel disodium was equivalent to ditromethamine salt. *Id.* at 1331. In the instant case, however, Plaintiffs' amendments were not made to overcome a particular prior art reference. Instead, the patentee limited the claimed buffer in the Asserted Patents to an acetate buffer to overcome the examiner's § 112(a) rejection because the written description of the Asserted Patents only provided support for acetate buffers.

(D.I. 8, Ex. C at C.72-73) Thus, Plaintiffs have failed to show a likelihood of success on the merits of their tangential relation exception argument sufficient to overcome the presumption of prosecution history estoppel.

Plaintiffs are unlikely to succeed on the merits of their infringement claims because application of the doctrine of equivalents is the exception, not the rule, *see London*, 946 F.2d at 1538; there is a presumption that Plaintiffs' doctrine of equivalents claims will be barred by prosecution history estoppel; and the tangential relation exception to that presumption is "very narrow," *Integrated Tech.*, 734 F.3d at 1358. In the overarching context of a request for an "extraordinary remedy that is not to be routinely granted," Plaintiffs have not satisfied their burden of persuasion on their likelihood of success on the merits. *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993).

b. Irreparable harm

Having determined that Plaintiffs did not make a sufficient showing of a likelihood of success on the merits, the court need not address the remaining preliminary injunction factors before recommending denial of Plaintiffs' motion. *See Jack Guttman*, 302 F.3d at 1356. For the sake of completeness, the court analyzes the irreparable harm factor.

To satisfy the irreparable harm factor, Plaintiffs must establish "a likelihood of substantial and immediate irreparable injury." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). This requires a showing that the injury suffered cannot be adequately compensated through monetary damages. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Moreover, Plaintiffs must demonstrate the existence of a causal nexus between the alleged harm and the alleged infringement. *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012).

As a preliminary matter, the timing of Plaintiffs' lawsuit and their motion for a preliminary injunction weighs slightly against a finding of irreparable harm. *See Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 714 (D. Del. 2019) ("Injunctive relief has been found to be inappropriate where a Plaintiff had no apparent urgency in requesting it."). Baxter submitted its Notice Letter on January 30, 2023, informing Plaintiffs that Baxter intended to market its NDA products before the Orange Book-listed patents for Vasostrict® expired. (D.I. 1 at ¶ 31) However, Plaintiffs did not sue for infringement of the Orange Book-listed patents within 45 days of the Notice Letter to trigger the 30-month stay of FDA approval. Instead, Plaintiffs filed this action two months after receiving the Notice Letter, asserting infringement of patents that are not listed in the Orange Book in connection with Vasostrict®. Thus, there is no dispute that FDA approval of Baxter's vasopressin product is not subject to a 30-month stay.

At oral argument, Plaintiffs confirmed that they anticipated an FDA decision on approval of Baxter's product sometime in September or October of 2023. (10/27/2023 Tr.) Yet Plaintiffs did not seek preliminary injunctive relief until days after the FDA approved Baxter's product for launch. (D.I. 22; D.I. 24, Ex. 1) Plaintiffs argue that the timing of their motion is appropriate because it was filed promptly after the FDA approved Baxter's NDA, and "there was no guarantee a motion would be needed at this juncture if Baxter had not obtained FDA approval, which was not a given." (D.I. 33 at 2) But Plaintiffs' own evidence establishes that the 505(b)(2) NDA pathway taken by Baxter has high "approval success rates . . . because safety and efficacy profiles of the drug substance are typically well-characterized." (D.I. 24, Ex. 20 at 47) Under these circumstances, Plaintiffs' delay in seeking the preliminary injunction "negates the idea of irreparability." *Genentech*, 2019 WL 3290167, at *2 (quoting *Pfizer*, 429 F.3d at 1382) (finding no irreparable harm where the plaintiff received a notice letter and was aware of the

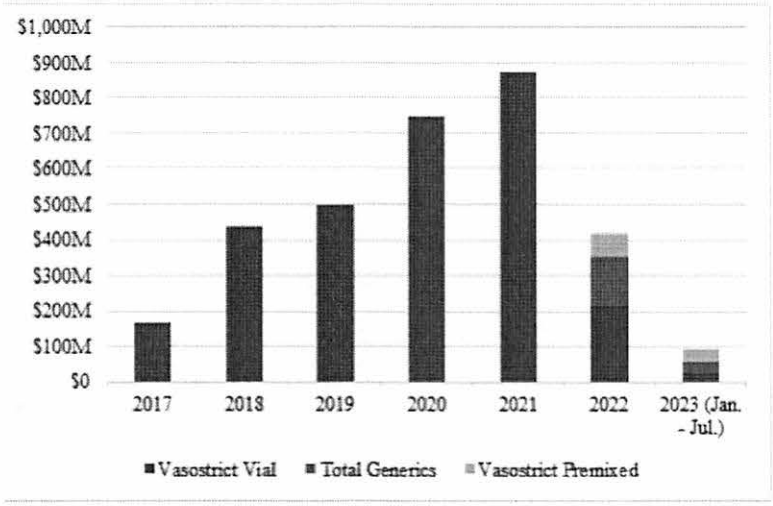
FDA's anticipated timeline for approving the defendant's product, but did not seek injunctive relief until after the defendant obtained FDA approval).

A finding of no irreparable harm is also supported by the balance of the record. Plaintiffs allege they will suffer irreparable harm in the form of price erosion, lost market share, reputational harm, and damage to their operations if Baxter begins marketing its product on October 30. (D.I. 23 at 14) "Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro*, 664 F.3d at 930. However, these harms are not categorically irreparable if they can be compensated by money damages, if the level of harm is exaggerated, and/or if the movant has a business plan in place to deal with the launch of a competing product. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009) (upholding district court's exercise of discretion in finding that harms of price erosion, loss of market share, loss of profits, loss of research opportunities, and possible layoffs were not irreparable).

Here, Baxter presents evidence that other generic versions of Vasostrict® were launched in 2022, and price erosion impacting Vasostrict® sales and market share were attributed to generic market entry. (D.I. 31, Ex. 52 at 50; D.I. 24, Ex. 19 at 20) Plaintiffs' evidence supporting their allegations on price erosion and lost market share does not directly address the impact of the other market participants on the analysis, nor does it consistently demonstrate the potential impact of Baxter's product on Vasostrict® Premix Bottles as opposed to the broader Vasostrict® market. (D.I. 24, Ex. 17 at ¶¶ 14-30; Ex. 18 at ¶¶ 23-46); *see Belden Techs. Inc. v. Superior Essex Commc'ns LP*, 802 F. Supp. 2d 555, 576-77 (D. Del. 2011) (finding no irreparable harm where other market competitors might be responsible for lost market share). For instance, the declaration of Scott Sims states that Baxter's launch will significantly impact

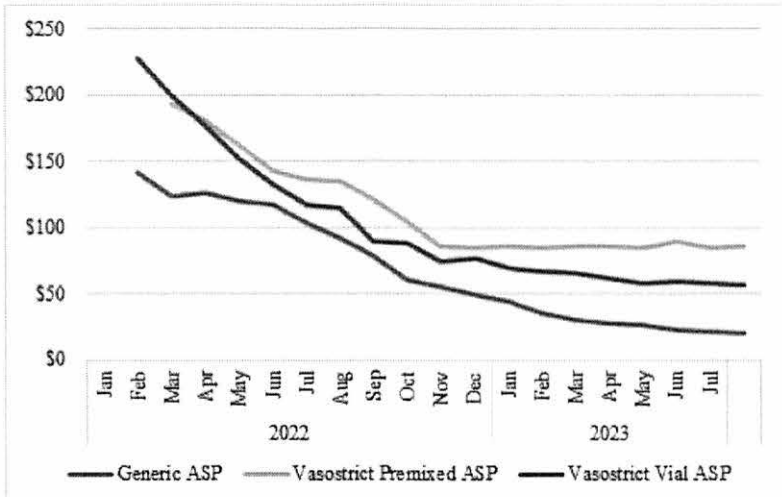
Plaintiffs' market share for Vasostrict® Premix Bottles, but they describe anticipated price erosion in the context of the entire vasopressin market consisting of Vasostrict® Premix Bottles, Vasostrict® Vials, and generic vasopressin vials. (*Id.*, Ex. 17 at ¶¶ 16, 18-19) In contrast, Baxter's evidence shows that Vasostrict® Premix Bottle sales and prices have already been impacted by other market forces prior to Baxter's entry, including competition from generic manufacturers:

Table 1: 2017- Jul. 2023 Vasopressin Revenues by Product[53]



(D.I. 30, Ex. 2 at ¶ 30)

Table 2: Vasopressin Market ASPs, Jan. 2022 – Jul. 2023[57]



(*Id.*, Ex. 2 at ¶ 31)

Moreover, the declarations submitted by Plaintiffs confirm that any price erosion and lost market share are calculable and can be compensated with monetary damages. Mr. Sims provides an estimate of the pricing for Baxter's product and Plaintiffs' Vasostrict® Premix Bottles based on competition from Vasostrict® Vials and generic vasopressin vials, noting that the price reductions will be apparent in GPO contracts. (D.I. 24, Ex. 17 at ¶ 19) And Plaintiffs' declarant, Steven Stanton, concedes that "Plaintiffs will ultimately be able to determine their decline in revenue and gross margin from its Vasostrict® Premix Bottles if Baxter is allowed to launch its vasopressin product[.]" (D.I. 34, Ex. 28 at ¶ 3) Mr. Stanton's declaration presents charts calculating the anticipated lost revenues and lost gross margin resulting from sales of Baxter's product. (D.I. 24, Ex. 18 at ¶¶ 33, 44)

Plaintiffs contend that Baxter's market entry will cause reputational harm and operational damages which are not readily calculable. (D.I. 23 at 16-17) But the evidence of these harms is speculative. *See Sunoco Partners Mktg & Terminals L.P. v. Powder Springs Logistics, LLC*, C.A. No. 17-1390-LPS-CJB, 2018 WL 395750, at *14 (D. Del. Jan. 8, 2018) (rejecting conclusory and speculative allegations as evidence of irreparable harm). Here, Mr. Sims suggests that Par Sterile "may suffer reputational harm if Baxter prematurely launches" the accused product, and the premature launch "will likely impair Par Sterile's ability to make the capital expenditures required to support the manufacture of existing and new life-saving sterile injectable projects[.]" (D.I. 24, Ex. 17 at ¶¶ 24, 28) Mr. Sims speculates that Par Sterile could be forced to stop manufacturing less profitable products, leading to drug shortages and reductions in its workforce. (*Id.*, Ex. 17 at ¶ 24) The Federal Circuit has cautioned against issuing an injunction "based solely upon allegations and conclusory affidavits submitted by plaintiff." *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1575 (Fed. Cir. 1990).

Baxter argues that there is no irreparable harm for the additional reason that the allegedly injured party, Par Sterile, has no standing due to its alleged lack of an ownership interest in the patents-in-suit. (D.I. 29 at 17-18) Having determined that Plaintiffs' evidence does not show non-speculative harm which cannot be compensated by monetary damages, the court need not reach the matter of Par Sterile's standing.

Because Plaintiffs have failed to show a likelihood of success on the merits or irreparable harm in the absence of a preliminary injunction, the court need not reach the remaining factors regarding the balance of hardships and the public interest. *See Jack Guttman*, 302 F.3d at 1356.

B. Baxter's Rule 12(c) Motion for Judgment on the Pleadings

Baxter's motion for judgment on the pleadings raises the same prosecution history estoppel argument discussed at § II.A.2.a, *supra*, in the context of Plaintiffs' likelihood of success on the merits for purposes of the preliminary injunction motion. (*Compare* D.I. 18 at 15-20 *with* D.I. 29 at 7) However, the standard Plaintiffs face for demonstrating a likelihood of success on the merits is far more demanding than the plausibility standard Plaintiffs must satisfy to survive a Rule 12(c) motion for judgment on the pleadings. *See Begin v. Lawn Beauticians, Inc.*, 2015 WL 9652679, at *3 (D.R.I. Nov. 3, 2015) (citing *Sepulveda-Villarini v. Dep't of Educ. of Puerto Rico*, 628 F.3d 25, 30 (1st Cir. 2010)). "To hold that plaintiffs' [pleading] is plausible . . . is not to suggest that plaintiffs are likely to succeed." *Calloway v. Green Tree Servicing, LLC*, 599 F. Supp. 2d 543, 546 n.2 (D. Del. 2009).

1. Legal standard

Under Federal Rule of Civil Procedure 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). A Rule 12(c) motion "will not be granted unless the movant clearly establishes that no

material issue of fact remains to be resolved and that [it] is entitled to judgment as a matter of law." *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988) (internal quotation marks and citation omitted). The standard governing a Rule 12(b)(6) motion to dismiss for failure to state a claim also applies to motions brought under Rule 12(c). Consequently, the court "must accept the truth of all factual allegations in the complaint and must draw all reasonable inferences in favor of the non-movant." *Revell v. Port Auth. of New York & New Jersey*, 598 F.3d 128, 134 (3d Cir. 2010).

"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). The court does not otherwise consider matters outside the pleadings on a Rule 12(c) motion. *Mele v. Fed. Rsrv. Bank of New York*, 359 F.3d 251, 257 (3d Cir. 2004).

2. Analysis

Here, Plaintiffs' pleadings 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. As a result, I recommend that the court deny Baxter's motion for judgment on the pleadings. This recommendation is not inconsistent with the recommended denial of the preliminary injunction motion due to the well-established differences in the applicable legal standards.

Baxter argues that judgment on the pleadings as a matter of law is appropriate in this case because there is no dispute that Baxter's product does not literally infringe the Asserted Patents, and prosecution history estoppel legally bars Plaintiffs from pursuing their doctrine of equivalents theory of infringement. (D.I. 18 at 15-20) Baxter maintains that further discovery is

unnecessary because the reasons for the claim amendments are apparent from the face of the file history of the Asserted Patents.

Plaintiffs respond that the claim amendments identifying the buffer as an acetate buffer bear no more than a tangential relation to the equivalence between an acetate buffer and a [redacted] buffer. (D.I. 35 at 11-12) According to Plaintiffs, the focus of the examiner's rejection was not on the identity of the claimed buffer, but rather on the pH of the formulation and buffer concentration. (*Id.* at 8, 12) Plaintiffs contend that disputed fact issues regarding the interpretation of the prosecution history and the equivalence of the acetate and [redacted] buffers preclude the entry of judgment on the pleadings. (*Id.* at 16-18)

I recommend that the court deny Baxter's motion for judgment on the pleadings because disputed issues of fact exist regarding the proper interpretation of the Asserted Patents' prosecution history. "Prosecution history estoppel, including the tangentiality inquiry, is always a case-specific analysis." *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1366 (Fed. Cir. 2020) (addressing tangential relation exception to prosecution history estoppel on post-verdict motions). Here, 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," and it was not limited to the identity of the claimed buffer. (D.I. 8, Ex. A at A.15) The examiner did not consider any prior art references having a [redacted] buffer, and nothing in the prosecution history expressly relinquishes buffers that may be functionally equivalent to the claimed acetate buffer. *Cf. Amgen Inc. v. Coherus Biosciences Inc.*, 931 F.3d 1154, 1159-60 (Fed. Cir. 2019) (affirming district court's dismissal of a complaint based on prosecution history estoppel where the patentee made a clear and unmistakable surrender of claim scope). Under 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. *See Festo*, 344 F.3d at 1370 (explaining that testimony from those skilled in the art may be necessary to interpret the prosecution history record).

The cases cited by both parties confirm that resolution of Plaintiffs' prosecution history estoppel argument on the pleadings is premature. In *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, the Federal Circuit affirmed the district court's finding of prosecution history estoppel on summary judgment. 356 F.3d 1348 (Fed. Cir. 2004). In considering the applicability of the foreseeability exception to prosecution history estoppel, the court considered evidence regarding sustained release hydrogel-forming polymers that were known in the art at the time the claim amendments were made. *Id.* at 1355. The procedural posture of other cases relied on by the parties similarly demonstrates that resolution of a prosecution history estoppel argument generally occurs on a fully developed record. *See Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1330-31 (Fed. Cir. 2019) (resolving appeal of prosecution history estoppel issue following summary judgment and bench trial); *Abraxis Biosci., Inc. v. Mayne Pharma.*, 467 F.3d 1370, 1381-82 (Fed. Cir. 2006) (reviewing judgment of infringement under the doctrine of equivalents, made after eleven-day bench trial).

Because the prosecution histories of the Asserted Patents show that the claim amendments were made to clarify the pH of the formulation and buffer concentration, in addition to the identity of the buffer, the court cannot assess the applicability of the tangential relation exception to Baxter's prosecution history estoppel argument on the pleadings alone. *See Sun Pharm. Indus. Ltd. v. Saptalis Pharms., LLC*, C.A. No. 18-648-WCB, 2019 WL 13153693, at *17 (D. Del. Aug. 26, 2019) (acknowledging that "factual issues [may] arise in the course of the

district court's consideration of the application of prosecution history" estoppel). Consequently, I recommend that the court deny Baxter's motion for judgment on the pleadings.

III. CONCLUSION

For the foregoing reasons, I recommend that the court DENY Plaintiffs' motion for a preliminary injunction and TRO, (D.I. 22), and DENY Baxter's motion for judgment on the pleadings, (D.I. 17).

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 **November 13, 2023**, 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: November 3, 2023

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE