IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., C.P. PHARMACEUTICAL S INTERNATIONAL C.V., PF PRISM C.V., PBG PUERTO RICO LLC, and PF PRISM IMB B.V., Plaintiffs, v. SINOTHERAPEUTICS INC., Defendant.	C.A. No. 21-1427-GBW

MEMORANDUM OPINION

Before the Court is Defendant Sinotherapeutics Inc.'s ("Defendant" or "Sinotherapeutics") Motion for Judgment on the Pleadings (the "Motion") contending that Sinotherapeutics does not infringe any claims of U.S. Patent No. 9,937,181 ("the '181 patent") either literally or under the doctrine of equivalents. D.I. 15. The Motion has been fully briefed. D.I. 15, 22, 26. For the following reasons, the Motion is denied.

I. BACKGROUND

Plaintiffs Pfizer Inc., C.P. Pharmaceuticals International C.V., PF PRISM C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively "Plaintiffs" or "Pfizer") sued Sinotherapeutics for infringement of the '181 patent based on Sinotherapeutics' filing of Abbreviated New Drug Application ("ANDA") No. 216001 seeking FDA approval to sell generic copies of Pfizer's 11 mg Xeljanz® XR (tofacitinib citrate extended-release tablets) prior to the

'181 patent's expiration. D.I. 1 ¶ 1-2.[1] Pfizer's 11 mg Xeljanz XR tablets are approved for the treatment of rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. *Id.* ¶ 19.

The active ingredient in Pfizer's Xeljanz® XR product is tofacitinib citrate. *Id.* ¶ 16. Xeljanz® XR contains tofacitinib citrate in an amount equivalent to 11 mg of tofacitinib base in extended release tablets formulated for once-daily administration. *Id.* According to Pfizer, Sinotherapeutics' proposed ANDA product purportedly contains "extended release oral tablets containing 11 mg of tofacitinib citrate." *Id.* ¶ 29. However, Sinotherapeutics avers that its "proposed ANDA product will not have 11 mg of tofacitinib in a core," which Sinotherapeutics explains the '181 patent requires. D.I. 11 ¶ 28, 56-57.

After answering Pfizer's complaint and asserting counterclaims of non-infringement and invalidity, D.I. 11, Sinotherapeutics filed the instant Motion, D.I. 15. Sinotherapeutics maintains that it does not literally infringe the '181 patent because its ANDA product does not meet the "a core comprising 11 mg of tofacitinib, or an equivalent amount of [a tofacitinib salt]" limitation that is required for all claims of the '181 patent. Sinotherapeutics also argues that Pfizer cannot rely on the doctrine of equivalents to "bridge the wide gap" due to amendment-based prosecution history estoppel. D.I. 15 at 4.

II. LEGAL STANDARD

Pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, a party may move for judgment on the pleadings "[a]fter pleadings are closed – but early enough not to delay trial." FED. R. CIV. P. 12(c). When evaluating a motion for judgment on the pleadings, the Court must "view

[1] The instant case arises under the Hatch-Waxman Act, more formally known as the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The '181 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Xeljanz XR 11 mg. D.I. 1 ¶ 19-22.

the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290-91 (3d Cir. 1988)).

"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). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory*, 114 F.3d at 1420. Ultimately, a motion for judgment on the pleadings can be granted "only if no relief could be afforded under any set of facts that could be proved." *Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991).

III. DISCUSSION

Because Pfizer does not dispute that Sinotherapeutics' ANDA product cannot literally infringe the claims of the '181 patent, *see generally* D.I. 22, the Court turns to whether Pfizer may assert infringement under the doctrine of equivalents. Sinotherapeutics argues Pfizer is estopped from doing so based on amendment-based prosecution history estoppel. D.I. 15 at 4.

"[E]quivalents remain a firmly entrenched part of the settled rights protected by the patent." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1363 (Fed. Cir. 2020) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002) ("*Festo I*")). "There are certain limitations, however, on a patentee's ability to obtain an infringement verdict under the doctrine of equivalents. One such limitation is prosecution history estoppel." *Bio-Rad*, 967 F.3d at

1363 (Fed. Cir. 2020) (citing *Festo I*, 535 U.S. at 737-40). "Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution." *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013). "Prosecution history estoppel can occur in two ways: "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019) (quoting *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006)).

Amendment-based prosecution history estoppel arises "when a patent applicant narrows the scope of his claims during prosecution for a reason 'substantial[ly] . . . relating to patentability.'" *Bio-Rad*, 967 F.3d at 1363 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003) (en banc) ("*Festo II*"). "A narrowing amendment is presumed to be a surrender of all equivalents within 'the territory between the original claim and the amended claim.'" *Id.* at 1364 (citing *Festo I*, 535 U.S. at 740). "This presumption can be overcome if the patentee can [satisfy an exception to prosecution history estoppel that] . . . the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question." *Id.* (citing *Festo I* at 740–41). "The crux of the tangentiality inquiry remains 'the patentee's objectively apparent reason for the narrowing amendment . . . [as] discernible from the prosecution history record.'" *Id.* at 1365 (quoting *Festo II*, 344 F.3d at 1369)

"[W]hether prosecution history estoppel applies, and hence whether the doctrine of equivalents may be available for a particular claim limitation, presents a question of law." *Id.* (quoting *Festo II*, 344 F.3d at 1367–68). In making this determination, the Court must "'look to

the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made.'" *Id.* (quoting *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010)).

Based on the record before it, the Court does not find prosecution history estoppel amenable to resolution in this litigation's early stage. "Hatch-Waxman trials are almost always bench trials, so the Court may choose in any particular Hatch-Waxman case (and likely the vast majority of them) to evaluate prosecution history estoppel at trial, as the Court will usually make a better decision when it has a full evidentiary record and the opportunity to consider at length all aspects of the parties' disputes." *Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443, 451 (D. Del. 2021).

A full record will improve the "case-specific analysis" required here. *Bio-Rad*, 967 F.3d at 1366. While Sinotherapeutics argues that Pfizer narrowed its claims to eventually contain the "core comprising 11 mg tofacitinib" element to overcome patentability rejections based on lack of written description, D.I. 15 at 12; D.I. 26 at 1, Pfizer maintains that its patentability arguments did not concern "the necessity of all 11 mg of tofacitinib being in the core" but rather were "related to the PK and dissolution profiles and how there was an established correlation between the excipients and structure of the osmotic formulation and the recited PK/dissolution profiles," D.I. 22 at 13-15. Pfizer also maintains that, even if the Court were to find that Pfizer added the 11 mg dose to the claims for reasons related to patentability, Pfizer's rationale for its claim amendments bears no more than a tangential relation to Sinotherapeutics' Generic XR Tablets—an argument Sinotherapeutics rejects as having "no force." D.I. 22 at 15-16; D.I. 26 at 5-6. Sinotherapeutics does not dispute that expert testimony from those skilled in the art as to the interpretation of the

prosecution history may help the Court understand the amendments and statements made during prosecution.[2]

While Sinotherapeutics argues that "prosecution history estoppel must apply" " to compel a finding of noninfringement," D.I. 26 at 5, it cannot be seriously disputed that "the Court has discretion to deny a Rule 12(c) motion." *Almirall*, 548 F. Supp. 3d at 451 (citing Wright & Miller, 5C Federal Practice and Procedure § 1367 (3d ed. Apr. 2021) (noting that Court may postpone determination of Rule 12(c) motion until trial)). Indeed, other courts have denied Rule 12(c) motions to defer resolving amendment-based prosecution history estoppel upon the development of a full record.[3] Sinotherapeutics cites to no authority compelling a different result.

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[2] The Court has discretion to consider such testimony. *Compare Festo II*, 344 F.3d at 1370 ("[W]hether the patentee has established a merely tangential reason for a narrowing amendment is for the court to determine from the prosecution history record without the introduction of additional evidence, except, when necessary, testimony from those skilled in the art as to the interpretation of that record."); *Silvergate Pharms., Inc. v. Bionpharma Inc.*, C.A. No. 18-1962-LPS, 2021 WL 1751148, at *14 (D. Del. Apr. 29, 2021), *aff'd sub nom. Azurity Pharms., Inc. v. BionPharma Inc.*, C.A. No. 2021-1926, 2022 WL 703903 (Fed. Cir. Mar. 9, 2022) (considering expert testimony as whether amendment was narrowing and tangential when evaluating amendment-based estoppel); *Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 729 (D. Del. 2012), *aff'd sub nom. Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App'x 961 (Fed. Cir. 2014) ("[E]vidence from the prosecution history coupled with testimony adduced at trial indicating that 0.20% impurity in a compound would be viewed by organic chemists as insignificant and, often, undetectable, leads the court to conclude that the applicants did not surrender their equivalence argument and prosecution history estoppel does not apply in this case."), *with Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1355 (Fed. Cir. 2003) (declining to consider attorney declaration explaining reasoning for adding limitation when evaluating if amendment was related to patentability); *Noven Pharms., Inc. v. Actavis Lab'ys UT, Inc.*, C.A. No. 15-249-LPS, 2017 WL 6619330, at *22 (D. Del. Dec. 22, 2017) (declining to rely upon in–house patent attorney testimony to try to prove that reason for amendment was "only tangential to the alleged equivalent").

[3] *See, e.g.*, *Amgen Inc. v. Alkem Lab'ys Ltd.*, C.A. No. 17-815-GMS, 2017 WL 6493150, at *2 (D. Del. Dec. 19, 2017) (declining to consider amendment-based prosecution history estoppel on Rule 12(c) motion); *accord Lighthouse Consulting Grp., LLC v. BB&T Corp.*, 476 F. Supp. 3d 532, 538 (W.D. Tex. 2020) (declining to bar infringement action under amendment-based prosecution history estoppel on Rule 12(c) motion); *see also Noven Pharms., Inc. v. Amneal Pharms. LLC*, C.A. No. 18-699-LPS, 2020 WL 11191445, at *28 (D. Del. Sept. 4, 2020) (deciding amendment-based prosecution history estoppel and tangentiality requirement after trial); *Noven*

Therefore, the Court declines to decide at this time whether amendment-based prosecution history estoppel applies and, if so, the extent of any such estoppel. Those questions may be resolved, if appropriate, at a later stage of the litigation, after the development of a full evidentiary record.[4]

IV. CONCLUSION

For the foregoing reasons, the Court denies Defendant's Motion.

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WHEREFORE, at Wilmington this 29th day of December, 2022, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion for Judgment on the Pleadings Pursuant to FRCP 12(c) (D.I. 15) is **DENIED**.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pharms., Inc. v. Actavis Lab'ys UT, Inc., C.A. No. 15-249-LPS, 2017 WL 6619330, at *20 (D. Del. Dec. 22, 2017) (deciding amendment-based prosecution history estoppel after trial).

[4] This Order does not alter Paragraph 12 of the Scheduling Order (D.I. 38) requiring "prior approval from the Court" to hear case dispositive motions.