IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff/Counterclaim-Defendant, v. MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, MSN PHARMACEUTICALS INC., NOVADOZ PHARMACEUTICALS, LLC, Defendants/Counterclaim-Plaintiffs.	Civil Action No. 25-cv-81-RGA

MEMORANDUM OPINION

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January 21, 2026

/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before me are Plaintiff Novartis' Motion for Summary Judgment on Validity, Partial Summary Judgment on Infringement, and to Preclude Defendants from Relitigating Claim Construction on the Basis of Issue Preclusion and/or Claim Preclusion (D.I. 83)[1] and the parties' Joint Claim Construction arguments (D.I. 114). I have considered the parties' briefing on summary judgment (D.I. 84, 100, 111) and claim construction (D.I. 114). I heard oral argument on December 12, 2025. For the reasons stated below, Novartis' motion for summary judgment (D.I. 83) is GRANTED.

I. BACKGROUND

This case is part of the multi-district litigation of patent infringement claims regarding Entresto® (sacubitril/valsartan). *In re Entresto (Sacubitril/Valsartan) Patent Litigation*, C.A. No. 20-md-2930 ("*In re Entresto*"). In a previous case, I entered final judgment that Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited's Abbreviated New Drug Application No. 213748 ("MSN's ANDA") infringed claims 1–4 of Plaintiff Novartis's U.S. Patent No. 8,101,659 ("the '659 Patent"). (C.A. No. 19-2053, D.I. 508).[2]

In the current case, Novartis argues Defendants MSN Laboratories, MSN Life Sciences, MSN Pharmaceuticals, and Novadoz Pharmaceuticals[3] (collectively, "MSN") infringed the '659 patent by importing MSN's ANDA product, importing sacubitril/valsartan (the active ingredients

[1] Citations are to the docket in No. 25-cv-81 unless otherwise indicated.
[2] Nearly two years earlier, I had entered a final judgment to the same effect in regard to MSN's infringement, but also finding the asserted claims invalid for lack of written description. (C.A. No. 19-2053, D.I. 406). On appeal, the written description finding was reversed.
[3] Novadoz Pharmaceuticals was not named as a party in the previous litigation. The application of this opinion to Defendant Novadoz is discussed below.

in MSN's ANDA product), and offering to sell the ANDA product. (D.I. 84 at 4). MSN answered by asserting various affirmative defenses and counterclaims. (D.I. 5). Novartis now moves to preclude MSN from relitigating claim construction, for summary judgment on MSN's Third Affirmative Defense (invalidity) and Second Counterclaim (invalidity), partial summary judgment on Novartis' infringement claim, and partial summary judgment on MSN's First Counterclaim (non-infringement). (D.I. 84 at 1; *see* D.I. 5).

II. LEGAL STANDARD

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Id.* The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex,* 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored

information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." FED. R. CIV. P. 56(c)(1). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams*, 891 F.2d at 460–61.

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Claim Preclusion

"Under the doctrine of claim preclusion, a prior final judgment forecloses successive litigation of the very same claim." *In re Adams*, 151 F.4th 144, 153 (3d Cir. 2025) (internal quotations omitted). Claim preclusion, or res judicata, applies when there is "(1) a final judgment on the merits in a prior suit involving (2) the same parties or their privies and (3) a subsequent suit based on the same cause of action." *Senju Pharm. Co., Ltd v. Apotex, Inc.*, 746 F.3d 1344, 1348 (Fed. Cir. 2014) (applying Third Circuit law); *Ndungu v. Att'y Gen. United States*, 126 F.4th 150, 165 (3d Cir. 2025). The party asserting claim preclusion has the burden of proof. *Taylor v. Sturgell*, 553 U.S. 880, 907 (2008).

Federal Circuit law governs "whether a particular cause of action in a patent case is the same as or different from another cause of action." *Senju Pharm.*, 746 F.3d at 1348. For claim preclusion to apply to invalidity arguments in patent cases, the Federal Circuit requires that the

current and prior cases involve the same accused devices. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1300 (Fed. Cir. 2017). I believe the *Mentor Graphics* rule would require that the current and prior cases involve the same accused products.

C. Issue Preclusion

"Issue preclusion, on the other hand, bars successive litigation of an issue of fact or law that was actually litigated, resolved in a valid court determination, and essential to that prior judgment, even if the issue recurs in the context of a different claim." *In re Adams*, 151 F.4th at 153 (internal quotations omitted and quote cleaned up). Issue preclusion, also referred to as collateral estoppel, applies when "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotation omitted). "The party seeking to effectuate an estoppel has the burden of demonstrating the propriety of its application." *Suppan v. Dadonna*, 203 F.3d 228, 233 (3d Cir. 2000).

While Third Circuit law governs the application of issue preclusion generally, Federal Circuit law governs those aspects of issue preclusion "that may have special or unique application to patent cases." *Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1382 (Fed. Cir. 2018).

III. DISCUSSION

A. Issue Preclusion Bars the Parties from Relitigating Claim Construction

Novartis argues that issue preclusion bars MSN from relitigating the claim construction of the "wherein" clause[4] because the term was construed in a previous case between the parties. (D.I. 84 at 13–15). MSN responds that claim construction has not been fully litigated because construction of the term has not been addressed since the Federal Circuit's ruling. (D.I. 100 at 7–9). MSN argues that, based on principles of fairness, the Court should use its discretion to deny issue preclusion. (*Id.* at 10–11).

The Federal Circuit has confirmed that "where a determination of the scope of patent claims was made in a prior case, and the determination was essential to the judgment there on the issue of infringement, there is collateral estoppel in a later case on the scope of such claims, i.e., the determined scope cannot be changed." *Molinaro v. Fannon/Courier Corp.*, 745 F.3d 651, 655 (Fed. Cir. 1984); *see Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1324 (Fed. Cir. 1987).

1. The Identical Claim Construction Issue Was Previously Adjudicated

The exact same "wherein" clause was construed in the prior litigation between the parties; the term is from the same patent and has not been expanded or narrowed since its prior construction. (D.I. 114 at 2 (Joint Claim Construction Brief); C.A. No. 19-2053, D.I. 136 at 3–43 (Joint Claim Construction Brief in prior case)). In the prior case, after the parties fully briefed the term (C.A. No. 19-2053, D.I. 136 at 3–43), and the Court held a *Markman* hearing on the term

[4] The full "wherein" clause appears in claim 1 of the '659 patent and reads: "wherein said (i) AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor [sacubitril] or [sacubitrilat] or a pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio." ('659 patent, col. 16, lines 26–33; *see also* D.I. 114 at 2 (Joint Claim Construction Brief)).

(C.A. No. 19-2053, D.I. 149 at 14:13–63:19), the Court "explicitly interpreted the phrase," *In re Freeman*, 30 F.3d 1459, 1466 (Fed. Cir. 1994), to have its "plain and ordinary meaning" (C.A. No. 20-2930, D.I. 294 at 5–7). "It is eminently clear, therefore, that the identical issue, the interpretation of the phrase . . . is also present in the [present] proceeding. *Freeman*, 30 F.3d at 1466.

The Federal Circuit's decision reversing the written description holding did not create new, unlitigated, issues. MSN argues otherwise, pointing to a footnote in the opinion:

> To the extent MSN maintains that the claims were construed to *claim* valsartan-sacubitril complexes (*i.e.*, to the extent MSN alleges that its stipulation of infringement was made on that basis), that construction would have been error. . . . Because valsartan-sacubitril complexes were undisputedly unknown at the time of the invention, the '659 patent could not have been construed as claiming those complexes as a matter of law.

Novartis Pharms. Corp. v. Torrent Pharma Inc. (In re Entresto (Sacubitril/Valsartan)), 125 F.4th 1090, 1099 n.5 (Fed. Cir. 2025) (internal citation omitted). The footnote did not change the claim construction; the opinion stated that it "would have been error," not that there was error. *Id.* The term was originally construed to have its plain and ordinary meaning. Nothing in the "plain and ordinary meaning" construction claims complexes. The parties were free to use the plain and ordinary meaning—that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)—to argue whether MSN's complexed ANDA product was covered by the term. *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985).[5]

[5] "[C]laims are not construed 'to cover' or 'not to cover' the accused [product]. That procedure would make infringement a matter of judicial whim. It is only after the claims have been construed without reference to the accused [product] that the claims, as so construed, are applied to the accused [product] to determine infringement." *SRI Int'l*, 775 F.2d at 1118. The disputed term is, essentially, "valsartan . . . and . . . sacubitril . . . in combination." The term does not claim a complex. That the accused product is a valsartan and sacubitril complex does not mean that it is

Thus, I find that the identical claim term at issue was previously adjudicated.[6]

2. Claim Construction of the Term Was Actually and Fully Litigated

The "wherein clause" was fully litigated in the prior case. The parties submitted forty-one pages of claim constuction briefing in the earlier case (C.A. No. 19-2053, D.I. 136 at 3–43) and the transcript from the *Markman* hearing reflects approximately an hour of argument on the "wherein" clause (C.A. No. 19-2053, D.I. 149 at 14:13–63:19). The record demonstrates that "[t]he court[] in the earlier litigation gave full and careful consideration to the issues raised." *Molinaro*, 745 F.3d at 655.

The prior case came to a "final and valid judgment" on both the relevant issues and the overall merits of the case. *AMTRAK v. Pa. PUC*, 288 F.3d 519, 525 (3d Cir. 2002). Along with the record showing claim construction of the "wherein" clause was fully argued and considered, "[t]he district court also resolved the meaning of this claim phrase . . . . Therefore, it is clear that the issue—the meaning of the phrase [the 'wherein clause']—was actually decided." *In re Freeman*, 30 F.3d at 1466. Beyond resolving claim construction, the prior case resulted in a final judgment that relied on the claim construction.[7] (C.A. No. 19-2053, D.I. 508).

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not also valsartan and sacubritil "in combination." This, however, is a question for an infringement analysis, not a question for claim construction.

[6] At oral argument, MSN conceded this point. (D.I. 133 at 19:4–8).

[7] There were various arguments raised in the parties' briefing and at oral argument about the impact MSN's pending writ of certiorari had on the finality and fairness of preclusion. As of the Supreme Court's December 15th, 2025, order denying the petition, these arguments are moot. (Order List (12/15/2025) at 3 (denying certiorari for *MSN Pharms. v. Novartis Pharms. Corp.*, No. 25-225). Even without this order, "the pendency of an appeal does not affect the potential for res judicata flowing from an otherwise-valid judgment." *United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009). The Federal Circuit has confirmed that "the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding" in a patent dispute. *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999).

Therefore, I find that claim construction of the "wherein" clause was actually litigated in the prior case.[8]

3. Claim Construction Was Necessary to the Resolution of the Prior Case

Issue preclusion applies only to aspects of the previous litigation which the parties had "actually deem important, and not on incidental matters." *Jean Alexander Cosmetics*, 458 F.3d at 250. The Federal Circuit has held that "prior claim interpretation has issue preclusive effect in the present case insofar as it was necessary to the judgment of noninfringement in the previous case." *Pfaff v. Wells Elecs., Inc.*, 5 F.3d 514, 518 (Fed. Cir. 1993). The Federal Circuit has also held that claim construction is preclusive in subsequent suits when the previous "determination of [claim] scope was essential to a final judgment on the question of validity." *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 704 (Fed. Cir. 1983).

The prior case addressed an allegation of infringement of independent claims 1 and dependent claims 2–4 of the '659 patent (C.A. No. 19-2053, D.I. 508), and the "wherein" clause is part of independent claim 1 ('659 patent, col. 16, lines 26–33) and therefore part of claims 2–4. The prior case also involved the invalidity defenses of lack of written description, non-enablement, and obviousness. (C.A. No. 19-2053, D.I. 508 at 2). As written description and enablement rest on the claims and their constructions, the Court's claim construction was necessary to the final adjudication on validity. *Novartis Pharms.*, 125 F.4th at 1098–110. Thus, the claim construction of the term at issue was a necessary part of the overall resolution of the previous case. (C.A. No. 19-2053, D.I. 508 at 1).

Nor does the final judgment's reliance on a stipulation prevent claim preclusion from applying. As the Third Circuit has stated: "The fact that the case was tried upon stipulation of fact

[8] At oral argument, Defendants conceded this point. (D.I. 133 at 19:13–15).

does not make it any the less a final adjudication of the plaintiff's claim." *Williamson v. Columbia Gas & Elec. Corp*, 186 F.2d 464, 466–67 (3d Cir. 1950). The stipulation does not dispute or change the "wherein" clause as construed by the Court;[9] rather, the stipulation to infringement necessarily[10] builds upon the Court's construction. *Id.* The stipulation was then used alongside the trial findings to come to a final ruling. (C.A. No. 19-2053, D.I. 508). Like claim construction, the stipulation was necessary to the final adjudication of the case.

Therefore, I find that the claim construction of the "wherein" clause was necessary to the final resolution of the prior case.[11]

4. The Defendants Were Fully Represented in the Prior Case

MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited were parties to the litigation throughout the entire prior case. (C.A. No. 19-2053, D.I. 508). These three defendants were also represented by counsel throughout the proceedings. *Seborowski v. Pittsburgh Press Co.*, 188 F.3d 163, 171–72 (3d Cir. 1999). As discussed above, the defendants in the prior case fully argued the claim construction issue through their briefing and oral argument. (C.A. No. 19-2053, D.I. 136 at 3–43; *id*. at D.I. 149 at 14:13–63:19). Thus, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited were fully represented in the prior case.

[9] Claim construction was decided by this Court on July 8, 2021. (C.A. No. 20-2930, D.I. 294). It was not until March 31, 2022, that the stipulation of infringement was entered. (C.A. No. 19-2053, D.I. 234).

[10] The stipulation is silent on claim construction. However, a finding of infringement is based on the claim elements. Thus, without support to the contrary in the stipulation or record, the stipulation of infringement must have been based on the claim elements, including the terms as construed by the Court.

[11] At oral argument, Defendants conceded this point. (D.I. 133 at 16–21).

The present case adds a new defendant, Novadoz Pharmaceuticals ("Novadoz"). However, "[i]ssue preclusion does not require identical parties; preclusion may be invoked in a case involving the same plaintiff and either a party or a non-party to the first action." *Innovad, Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334 (Fed. Cir. 2001). For issue preclusion to apply to a non-party in a patent case, the non-party must have "been in privity with a party to the prior adjudication." *Uniloc*, 52 F.4th at 1346 n.4. The Third Circuit has held that:

> A nonparty will be found to be in privity with a party to a proceeding where:
>
> 1) the nonparty agrees to be bound by the determination of issues in an action between others;
> 2) a substantive legal relationship—i.e.[,] traditional privity—exists that binds the nonparty;
> 3) the nonparty was "adequately represented by someone with the same interests who [wa]s a party";
> 4) the nonparty assumes control over the litigation in which the judgment is rendered;
> 5) the nonparty attempts to bring suit as the designated representative of someone who was a party in the prior litigation; [or],
> 6) the nonparty falls under a special statutory scheme that "expressly foreclos[es] successive litigation by nonlitigants."

Doe v. Hesketh, 828 F.3d 159, 172 (3d Cir. 2016) (citing *Taylor v. Sturgell*, 553 U.S. 880, 894–95 (2008)). Novadoz is in privity with MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited based on a substantive legal relationship and adequate representation by a party with the same interests. Novartis points to many factors that support this finding, none of which Defendants object to. (D.I. 84 at 9–11). These include Novadoz "hold[ing] itself out as 'An MSN Company,'" Novadoz's representation that "'Novadoz®' is a registered trademark of MSN," and, among other examples Novartis identifies, Novadoz's representations that "it is a wholly owned subsidiary of MSN with its purpose being to sell MSN's generic products in the U.S." (*Id.* at 10). Based on these factors, Novadzo is in privity with the prior MSN defendants based on a substantive legal relationship representation in the prior

litigation by a party with the same interests. *See Hart Steel Co. v. Railroad Supply Co.*, 244 U.S. 294, 298 (1917). Therefore, issue preclusion applies to Novadoz.[12]

Thus, I find that all Defendants in the current case were fully represented in the prior case.[13]

5. Considerations of Fairness Do Not Prohibit Issue Preclusion

MSN argues that the Court should exercise its discretion to deny Novartis' motion due to concerns over fairness.[14] MSN correctly notes that the Supreme Court has urged relitigation "if there is reason to doubt the quality, extensiveness, or fairness of procedures followed in prior litigation." *Montana v. United States*, 440 U.S. 146, 164 n.11 (1979). The holding applies to patent cases. *Innovad*, 260 F.3d at 1334. However, MSN has not identified any issues of quality, extensiveness, or fairness.

Contrary to MSN's arguments (D.I. 100 at 10), the Federal Circuit's reversal of one invalidity ruling did not change the construction of the "wherein" clause. At most, the Federal Circuit merely clarified that a construction that claimed complexes would have been incorrect. *Novartis*, 125 F.4th at 1099 n.5. MSN also argues that its previous litigation was improperly based on "an understanding that complexes were within the plain and ordinary meaning." (D.I. 100 at 10–11). As I have previously explained, nothing in the Federal Circuit's opinion changed the claim construction; any of MSN's misunderstandings which were clarified by the Federal Circuit's opinion do not warrant reconsideration of extensively litigated issues. It would be contrary to the interests of the judicial system and the purpose of the ANDA process to relitigate every issue that a party comes to better understand after the case has been fully litigated.

[12] At oral argument, Defendants conceded that any resolution regarding MSN applied equally to Novadoz. (D.I. 133 at 3).
[13] At oral argument, Defendants conceded this point. (D.I. 133 at 19:22–24).
[14] At oral argument, Defendants denied that this was their argument. (D.I. 133 at 19:25–20:24).

MSN argues that it is only fair to relitigate claim construction because they based their invalidity arguments, and ultimately their stipulation of infringement, on the understanding that complexes were included in the construction. (*Id.* at 10–11). However, the *Markman* opinion was released on July 8, 2021. (C.A. 20-2930, D.I. 294). About eight months later, the stipulation of infringement was entered. (C.A. No. 19-2053, D.I. 234). Approximately half a year later there was a trial on validity. (C.A. No. 19-2053, D.I. 371–73). MSN did not rush into its decision to stipulate to infringement after claim construction, and MSN had more than enough time to fully think through its validity strategy before trial.

Nothing about the proceedings in the prior case raise concerns about quality or extensiveness. As previously addressed, the parties in the prior litigation were given many opportunities to argue claim construction and plenty of time to develop arguments around claim construction. MSN had the opportunity to appeal the Court's claim construction ruling but chose not to. Thus, precluding more claim construction of the "wherein" clause does not raise any issue of fairness.

As all four factors are met, and issue preclusion would not raise any concerns over fairness, I GRANT Novartis' motion to prevent relitigating the claim construction of the "wherein" clause based on issue preclusion. The "wherein" clause is the only term in the parties' joint motion for claim construction. (D.I. 114). Thus, since resolution of the only disputed claim construction is resolved by issue preclusion, there is no need for any claim construction in this case.

B. Summary Judgment of Validity Is Granted

Novartis raises two theories to support its argument for summary judgment of validity: claim preclusion (D.I. 84 at 17–19) and issue preclusion (*id.* at 6–13).

1. Claim Preclusion Prohibits Arguments on Validity

Novartis argues that claim preclusion should prevent MSN from making invalidity arguments based on any theory. (D.I. 84 at 17–19). MSN responds by arguing that claim preclusion does not apply because invalidity is not a claim,[15] but rather a defense, to which claim preclusion does not attach. (D.I. 100 at 19–20).

a. Claim preclusion requirements are met

As set forth earlier, there are four requirements for claim preclusion to apply to invalidity arguments.

To satisfy the first requirement for claim preclusion, there must be a final judgment in the prior case. *Senju Pharm.*, 746 F.3d at 1348. This first requirement is met. (*See* C.A. No. 19-2053, D.I. 508). For the second requirement, the same parties or their privities must be involved in the current and prior cases. *Senju Pharm.*, 746 F.3d at 1348. As addressed above, the second requirement is met because the parties in the current case were all parties to the prior case or in privity with a party. The third requirement mandates that the current case be "based on the same cause of action' as the cause of action in the prior case. *Id.* To determine this in a patent case, the Federal Circuit has held that a court must look at whether (1) there is "overlap of *the product or process* accused in the instant action with *the product or process* accused in the prior action," and (2) "whether the *same patents* are involved in both suits." *Senju Pharm.*, 746 F.3d at 1349. There is no need for elaborate discussion of these factors; both the current case and the prior case involve the same accused product, MSN's ANDA product, and both cases involve the '659 patent. The

[15] As used here, "claim" refers to the cause of action which would serve as the basis of claim preclusion. This type of claim should not be confused with a claim of the patent, particularly because the same patent claim is relevant to both the current dispute and the prior case. *See Senju Pharm.*, 746 F.3d at 1349 (discussing the distinction between patent claims and the cause of action claims).

fourth requirement, that the accused products are essentially the same, is met; both the current case and the prior case involve MSN's ANDA product.

b. Claim preclusion can properly apply to validity

Nothing prohibits claim preclusion from applying to validity in this case. MSN cites *Foster*, 947 F.2d at 479, for the statement: "An assertion of invalidity of a patent by an alleged infringer is not a 'claim' but a defense to the patent owner's 'claim.'" (D.I. 100 at 19). However, *Foster* held that:

> "In a declaratory judgment action, invalidity is but an anticipatory defense, and the 'claim' of the declaratory judgment suit is based on the facts related to the patent owner's charge of infringement. Thus, claim preclusion applies in this case only if [the patentee]'s infringement claim rests on the same transactional facts as in *Foster I.*"

Foster, 947 F.2d at 479. Unlike *Foster*, the prior case related to this dispute was not a declaratory judgment presenting invalidity as an anticipatory defense. It was a patent holder primarily seeking injunctive relief. (*See* C.A. No. 19-2053, D.I. 1, at 60–61). Instead, the facts of this case align more closely to those of *Hallco Mfg. Co. v. Foster*, 256 F.3d 1290 (Fed. Cir. 2001), a later dispute between the same parties as in *Foster*. In this later case, defendant sought claim preclusion based on counterclaims brought during the earlier action. The Federal Circuit held:

> In the present case, the infringement action against the [defendant's] device was terminated by a . . . judgment on the merits. Accordingly, under basic claim preclusion rules, [plaintiff] is precluded from bringing another suit for infringement regarding the [defendant's product]. As a corollary principle, [defendant] now is similarly precluded from challenging validity in a suit for infringement of any device that is the same as the [device in the previous litigation], because invalidity was a defense that was or could have been raised in the prior litigation.

Id. at 1297. The ruling in *Hallco* relies on the Federal Circuit's long-established principle that after there is a "judgment covering infringement by the [accused product], any issue relating to the claim of infringement by that device, including the validity of the [disputed] patent, . . . is barred

in future litigation between the parties." *Epic Metals Corp. v. H.H. Robertson Co.*, 870 F.2d 1574, 1577 (Fed. Cir. 1989) (applying Third Circuit law).

In the current dispute, the prior case came to a final judgment involving both validity and infringement. (C.A. No. 19-2053, D.I. 508 at 2–3). Because "[a]ny judgment declaring the ['659] patent infringed by [MSN's ANDA product] would include, as a matter of law, a determination that the ['659] patent is valid and enforceable[,] the validity of the '659 patent . . . is barred in future litigation." *Epic Metals Corp.*, 870 F.2d at 1577. Additionally, in the prior case, MSN asserted both invalidity defenses (C.A. No. 19-2053, D.I. 27 at 16–17) and invalidity counterclaims (*id.* at 27–28). Therefore, the prior litigation involved more than "an anticipatory defense." *Foster*, 947 F.2d at 479.

Thus, claim preclusion prohibits MSN from arguing any theories of invalidity.

2. Novartis' Issue Preclusion Argument Is Moot

Novartis argues that issue preclusion bars MSN from relitigating the issue of invalidity, or in the alternative, should prevent MSN from arguing the specific issues of obviousness, enablement, written description, and indefiniteness. (D.I. 84 at 6–13). As I find claim preclusion bars all relitigation of validity issues, Novartis' issue preclusion arguments are moot.

As claim preclusion prevents any arguments challenging the validity of the '659 patent, there are no disputed issues of material fact. Thus, summary judgment of validity is GRANTED.

C. Summary Judgment of Infringement by MSN's ANDA Product Is Granted

Novartis argues that partial summary judgment of infringement[16] should be granted because issue preclusion bars MSN from arguing that their ANDA product so not infringes the

[16] The motion is "partial" because it only seeks to resolve one issue—whether MSN's ANDA product meets the claim limitations of the '659 patent. Thus, any references to "infringement" in this section only refer to that one issue. Nothing about this discussion relates to other actions

’659 patent. (D.I. 84 at 15–17). MSN responds by arguing that the requirements for issue preclusion are met. (D.I. 100 at 11–15).

1. The Identical Issue of Infringement by MSN’s ANDA Product Was Adjudicated

MSN argues that infringement under 35 U.S.C. § 271(a–c) was not at issue in the prior case. (D.I. 100 at 14). Although this is a correct—the final judgment found MSN’s filing of ANDA No. 213748 “infringed the Asserted Claims of the ’659 Patent under 35 U.S.C. § 271(e)(2)” (C.A. No. 19-2053, D.I. 508 at 2)—MSN’s argument is ultimately irrelevant. Novartis only moves for summary judgment of MSN’s ANDA product meeting the claim elements of the ’659 patent. (D.I. 84 at 15–17; D.I. 111 at 9).

There is no dispute that both the current and the prior cases involve an issue of whether MSN’s ANDA product meets the claim elements of the ’659 patent. The prior case dealt with whether MSN’s actions filing ANDA No. 213748 infringed the ’659 patent, among other patents. (C.A. No. 19-2053, D.I. 1 at 39–44 (original complaint); C.A. No. 19-2053, D.I. 234 at 2 (stipulation MSN’s ANDA product, if approved, would infringe the ’659 patent); C.A. No. 19-2053, D.I. 508 at 2 (final judgment including infringement of the ’659 patent)). Although different underlying infringement actions were in dispute in the prior case, the infringement claims in both cases depend on whether MSN’s ANDA product meets the claim elements of the ’659 patent.

Thus, I find the first factor for issue preclusion is met.

(importation, advertising, sale, etc.) that Novartis must show for an overall finding of infringement based on 35 U.S.C. § 271(a–c). And, by granting the motion, I do not foreclose MSN from any defenses or counterclaims that are based on other issues, including, for example, lack of specific intent to indirectly infringe.

2. Infringement Was Actually and Fully Litigated in the Prior Case

MSN presents three arguments for why infringement was not actually litigated in the prior case. (D.I. 100 at 11–14).[17]

a. The stipulation of infringement was part of the final judgment

First, MSN argues the final judgment of infringement was not actually litigated because it was based on a stipulation that is not binding in this case. (*Id.* at 11–13). The Federal Circuit has held that a stipulated judgment in a patent case can serve as the grounds for issue preclusion. *Hartley v. Mentor Corp.*, 869 F.2d 1469, 1471–76 (Fed. Cir. 1989). The Federal Circuit's rationale in *Hartley* was based on the rule that settlement agreements can serve as the grounds for claim preclusion. *Id.* at 1472. This is a rule that the Third Circuit has consistently upheld. *See Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 281 (3d Cir. 2014). The reason for the rule is that "it is a well-recognized rule of law that valid stipulations entered into freely and fairly, and approved by the court, should not be lightly set aside." *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998). The Federal Circuit has similarly held, "A stipulation of fact that is fairly entered into is controlling on the parties and the court is generally bound to enforce it." *Ring & Pinion Serv. Inc. v. ARB Corp. Ltd.*, 743 F.3d 831, 836 (Fed. Cir. 2014).

Third Circuit law supports the notion that a stipulation should have preclusive effect if the stipulation is valid and "entered into freely and fairly." *Waldorf*, 142 F.3d at 616. Here, the stipulation is valid and was accepted by the Court. (C.A. No. 19-2053, D.I. 234). There is no evidence the stipulation was not entered freely and fairly. The evidence is that both parties were represented by sophisticated counsel and there was no pressure from the Court to stipulate. The

[17] MSN argues that the elements of infringement under 35 U.S.C. § 271(a–c) were not actually litigated. (D.I. 100 at 14–15). Based on the scope of the motion, only the actual litigation of whether MSN's ANDA product met the claim elements of the '659 patent is relevant.

intent-based requirements presented in *Foster*[18] are also met. The stipulation in this case is a clear and unambiguous "agreement manifesting an intention to be bound." *Foster*, 947 F.2d at 480. First, the stipulation was entered into in an ANDA case. The main point of ANDA cases is to resolve infringement and invalidity issues before the defendant's ANDA product is on the market. Any pharmaceutical company knows the outcome of the ANDA case will be binding on it. Second, the stipulation has forward looking langauge[19] indicating the parties' intent for the agreement to apply to future conduct. *Foster*, 947 F.2d at 480–81.

MSN does not have grounds to argue it is unfair to be held to its stipulation in a subsequent case. MSN argues that in negotiations over the stipulation, it sought to limit the agreement to the current claim construction. (D.I. 100 at 11–12). MSN argues that the stipulation should be considered vague and unenforceable. (*Id.* at 12). The argument makes little sense to me. It is what the parties agreed to that counts, not what a party asked for but did not get. As a legal matter, there is no reason to consider evidence of negotiations, which would be extrinsic evidence. As a principle of contract interpretation, extrinsic evidence is only relevant if the agreement is ambiguous. Here, the terms of the stipulation, as negotiated by the parties and ultimately agreed

[18] *Foster v. Hallco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991), analyzed the role of consent judments—not stipulations—for applying issue preclusion in later cases. It is not clear if the Federal Circuit would extend this "intent" requirement to stipulations.

[19] Two portions of the stipulation indicate a forward-looking effect:

> 2. MSN's ANDA Products, if approved by FDA, will infringe the Asserted Claims of the '659 patent, including during the extension of patent term for the '659 patent pursuant to 35 U.S.C. § 156, however, MSN maintains all rights to defend, and counterclaim, on the basis that the Asserted Claim(s) of the '659 patent are invalid.
> . . .
> 4. For the avoidance of doubt, if one or more, but not all, of the Asserted Claims of the '659 or '331 patents are held invalid in a judgment from which no appeal has been or can be taken, the above stipulations of infringement for the remaining Asserted Claims of the '659 and '331 patents will remain in place.

(C.A. No. 19-2053, D.I. 234 at 3).

to by MSN, are clear. "Parties are charged with knowledge of the law and, particularly in the case of a sophisticated litigant like [MSN], are presumed to know background legal principles like collateral estoppel," and thus should be held to the outcomes of the parties' court-approved agreements. *Uniloc USA Inc. v. Motorola Mobility LLC*, 52 F.4th 1340, 1350 (Fed. Cir. 2022).

b. The parties spent considerable time litigating the issue

Second, MSN argues infringement was not actually litigated because Novartis did not spend a considerable amount of effort litigating the issue of infringement. (D.I. 100 at 13). This argument is misguided. Novartis' complaint alleged that MSN's ANDA product infringed the '659 patent. (C.A. No. 19-2053, D.I. 1 at 39–40, 43–44). For nearly two and a half years, it was an issue that Novartis had to prove to make its case. After Novartis submitted an expert report on infringement (*see* D.I. 84 at 16),[20] MSN entered into a stipulation of infringement. (C.A. No. 19-2053, D.I. 234).

Novartis had advanced its infringement case through litigation. When MSN had to choose to meet the infringement case, presumably by submitting an expert report explaining why it did not infringe, it chose to stipulate to infringement. The Third Circuit has stated: "If an issue is raised and the party who has the burden fails in his proof and the issue is decided against him, he is just as much bound by collateral estoppel as though he had presented a barrel of testimony." *United States v. Silliman*, 167 F.2d 607, 617 (3d Cir. 1948). Before entering the stipulation, MSN had plenty of time to evaluate Novartis' expert report and the facts supplied through discovery.

[20] While the expert reports are not in the record, MSN does not dispute that Novartis submitted an expert report. (D.I. 100 at 13). Additionally, it is not clear from the briefing whether Novartis submitted one or more expert reports on infringement. In its briefing, Novartis first states the stipulation was entered after "expert reports," but then writes "Novartis's expert report." (D.I. 84 at 16). As MSN chose to stipulate to infringement after at least one of Novartis' expert reports, it is irrelevant how many expert reports Novartis submitted on the issue.

As an ANDA case is the type with clear impact on subsequent suits, MSN also had more than enough motivation to litigate this case and the particular issue of infringement. *Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 977 (3d Cir. 1975).

c. There is no new law from which to argue non-infringement

Third, MSN argues that that infringement was not litigated after the Federal Circuit's opinion. (D.I. 100 at 13–14). As previously addressed, the Federal Circuit's decision did not change the law. There is nothing new to litigate. Any arguments related to whether MSN's ANDA product met the claim elements of the '659 patent were available to make in the prior case.

As explained above, the parties actually and fully litigated the issue of whether MSN's ANDA product met the claim elements of the '659 patent.

3. Infringement Was Necessary in the Prior Case

For MSN's filing of their ANDA to infringe the '659 patent under 35 U.S.C. § 271(e)(2), the underlying ANDA product must have met the elements of the asserted patent claims. Thus, resolution of the issue was necessary in the prior case.

4. MSN Was Fully Represented in the Prior Case

For the reasons addressed above, MSN was fully represented in the prior case. Thus, the fourth factor for issue preclusion is met.

5. There Are No Issues of Fairness that Prevent Issue Preclusion

MSN argues that, even if the requirements for issue preclusion are met, the Court should allow new arguments on non-infringement because it would be unfair to hold MSN to its failure to make those arguments, which were based on a misunderstanding of the plain and ordinary

meaning of the "wherein" clause. (D.I. 100 at 19).[21] Once again, the claim construction in the prior case never changed, and issue preclusion extends the same construction of the "wherein' clause to the current case. MSN's recent understanding of the term's construction does not negate the extensive litigation in the prior case. It would defeat the purposes of preclusion to allow MSN to relitigate their previously argued non-infringement theories because it has since decided that other arguments may have been stronger.

Based on the factors discussed above, issue preclusion prevents the parties from relitigating whether MSN's ANDA product infringes the '659 patent. Therefore, there are no disputed issues of material fact on whether the ANDA product meets the limitations of the asserted claims. Thus, I GRANT partial summary judgment that MSN's ANDA product meets the claim elements of the '659 patent.

IV. CONCLUSION

An appropriate order will issue.

[21] MSN presents these fairness arguments against issue preclusion for both invalidity and infringement. (D.I. 100 at 18–19). As the arguments are the same for both issues, and claim preclusion bars relitigation of validity, I only address the fairness arguments here.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff/Counterclaim-Defendant, v. MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, MSN PHARMACEUTICALS INC., NOVADOZ PHARMACEUTICALS, LLC, Defendants/Counterclaim-Plaintiffs.	Civil Action No. 25-cv-81-RGA

ORDER

For the reasons stated in the accompanying Memorandum Opinion, Novartis Pharmaceuticals Corporation's Motion for Summary Judgment on Validity, Partial Summary Judgment on Infringement, and to Preclude Defendants from Relitigating Claim Construction on the Basis of Issue Preclusion and/or Claim Preclusion (D.I. 83) is GRANTED.

IT IS SO ORDERED.

Entered this 21st day of January, 2026

/s/ Richard G. Andrews
United States District Judge