NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON MEDICINES LLC and NUVO PHARMACEUTICAL (IRELAND) DESIGNATED ACTIVITY COMPANY, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, Defendants.	**Civil Action No. 15-3324 (SRC)** **OPINION & ORDER** (consolidated for discovery purposes with Civil Action Nos. 16-4918, 15-3327, 16-4921, 15-3326, and 16-4920)

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for summary judgment of various issues by Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL.") Plaintiffs Horizon Medicines LLC and Nuvo Pharmaceutical (Ireland) Designated Activity Company (collectively, "Horizon") have opposed the motion. For the reasons that follow, the motion will be granted in part.

These consolidated cases arise from Hatch-Waxman litigation regarding patents related to the drug Vimovo®. Plaintiff Nuvo owns the patents, Plaintiff Horizon is a licensee, and Defendants are pharmaceutical companies which have filed ANDA applications to produce generic versions. The first round of litigation involved U.S. Patent Nos. 6,926,907 and 8,557,285.[1] Those patents have been found to be invalid for failure to satisfy the written

[1] This round of litigation involved Civil Action Nos. 11-2317, 11-4275, 13-91, and 13-4022.

description requirement. Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1371 (Fed. Cir. 2019).

During the first round of litigation, nine additional patents related to Vimovo® issued and were listed in the Orange Book, and the instant cases arose. The two patents presently at issue descend from U.S. Patent No. 6,926,907: U.S. Patent Nos. 8,858,996 (the "'996 patent") and 9,161,920 (the "'920 patent"). Presently at issue are claims 1, 4, 5, 12, and 15 of the '996 patent and claims 1, 4, 5, 11, and 14 of the '920 patent (the "Asserted claims.")

DRL previously moved for summary judgment of invalidity of the Asserted claims in the '996 and '920 patents for lack of adequate written description pursuant to § 112, ¶ 1; that motion was denied. DRL now moves again for summary judgment on several issues, including invalidity on the basis of issue preclusion, and claim preclusion.

I. ISSUE PRECLUSION

As to the argument based on issue preclusion, the parties agree on the fundamental legal principles: the issue preclusion analysis is governed by Third Circuit law, except for substantive matters of patent law; and, under Third Circuit law, the party seeking to effectuate the estoppel bears the burden of establishing the four standard requirements, one of which is that the identical issue was previously adjudicated. "'Identity of the issue is established by showing that the same general legal rules govern both cases and that the facts of both cases are indistinguishable as measured by those rules.'" Suppan v. Dadonna, 203 F.3d 228, 233 (3d Cir. 2000) (quoting 18 Wright et al., Federal Practice & Procedure § 4425, at 253 (1981)).

DRL contends that the identical issue of invalidity for lack of adequate written description was litigated and decided in Nuvo: "the same written description issue that doomed

the Invalidated Claims in Nuvo is presented by the Asserted Claims of the patents-in-suit." (Defs.' Br. 14.) At issue in Nuvo were claims 5, 15, 52, and 53 of the '907 patent and claims 1-4 of the '285 patent (the "Invalidated claims" or the "Nuvo claims.") 923 F.3d at 1374. In that previous litigation, DRL argued that "[t]he '907 and '285 patents claim uncoated PPI effective to raise the gastric pH to at least 3.5" and that "the claimed effectiveness of uncoated PPI" is not supported by adequate written description. Id. at 1377. As to the claim elements at issue, the Federal Circuit stated:

> In sum, the parties appear to have assumed before the district court that the claims require a therapeutically effective amount of uncoated PPI that can raise the gastric pH to at least 3.5. We see no reason to change course on appeal. Because the parties' assumption at the trial court is a fair reading of the claim language, we will proceed as everyone did before the district court and search the specification for written description support for the efficacy of uncoated PPI.

Id. at 1379. Thus, the issue decided in Nuvo is: the claim requirement of a therapeutically effective amount of uncoated PPI that can raise the gastric pH to at least 3.5 is not supported by adequate written description. In the Nuvo opinion, the Court often employed the shorthand phrase, "effectiveness of uncoated PPI." See, e.g., id. at 1376, 1384.

DRL argues that, for the claims asserted in the instant case, the issue of invalidity for lack of written description is identical. DRL's argument relies on three undisputed propositions: 1) the parties do not dispute that, for the purposes of this motion, the Nuvo patents and the patents at issue have materially identical specifications (Pls.' Resp. 56.1 Stmt. ¶ 26); 2) at claim construction, this Court construed "all claims at issue to require esomeprazole which is effective to raise gastric pH to at least 3.5" (Horizon Meds. LLC v. Dr. Reddy's Labs., Inc., 2020 U.S. Dist. LEXIS 147768, at *66 (D.N.J. Aug. 14, 2020)); and 3) esomeprazole is a species in the genus of PPIs (proton pump inhibitors). DRL argues that, given these undisputed propositions,

the issue preclusion question turns on whether the esomeprazole disclosed in the claims at issue is materially the same as the uncoated PPI of the Nuvo claims, for purposes of the written description issue. In other words, does the effective esomeprazole required by the claims at issue materially differ from the effective uncoated PPI, as understood in Nuvo, in the context of the written description analysis?

Because the key issue here concerns the question of a coating (or lack thereof) for the PPI, it is useful to distinguish two groups of claims at issue: those that expressly require a "non-enteric film coating," and those that do not contain that phrase. Four claims in the instant case require a "non-enteric film coating" and fall into the first group. In the '996 patent:

> 12. A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising: a core layer comprising naproxen, wherein said core layer has a coating that inhibits release of said naproxen from said core layer unless said dosage form is in a medium with a pH of 3.5 or higher; and a layer comprising esomeprazole, wherein said layer is has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient.
>
> 15. The pharmaceutical composition of claim 12, wherein naproxen is present in said unit dosage form in an amount of between 200-600 mg and esomeprazole in an amount of from 5 to 100 mg per unit dosage form.

In the '920 patent:

> 11. A method of reducing the incidence of NSAID-associated gastric ulcers in a patient requiring chronic NSAID treatment and who is at risk of developing an NSAID-associated ulcer, wherein the method comprises administering to said patient in need thereof a pharmaceutical composition in unit dose form in the form of a tablet, said composition comprising: a core layer comprising naproxen, wherein said core layer has a coating that inhibits release of said naproxen from said core layer unless said dosage form is in a medium with a pH of 3.5 or higher; and a layer comprising esomeprazole, wherein said layer is has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient.
>
> 14. The method of claim 11, wherein naproxen is present in said unit dosage form

> in an amount of between 200-600 mg and esomeprazole in an amount of from 5 to 100 mg per unit dosage form.

DRL points out that the "non-enteric film coating" language in the '920 and '996 claims at issue is very similar to language in claim 15 of the '907 patent (which depends on claim 14), invalidated for lack of written description support in Nuvo:

> 14. The pharmaceutical composition of claim 13, wherein said unit dosage form is a bilayer tablet having an outer layer of said acid inhibitor and an inner core of said NSAID and wherein said outer layer of said tablet is surrounded by a non-enteric film coating that releases said acid inhibitor upon ingestion by patient.
>
> 15. The pharmaceutical composition of any one of claims 1 or 7-14, wherein said acid inhibitor is a proton pump inhibitor.

All four claims in the first group contain the phrase, "wherein said layer is has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient." The corresponding claim in Nuvo contains a highly similar phrase, "wherein said outer layer of said tablet is surrounded by a non-enteric film coating that releases said acid inhibitor upon ingestion by patient." This Court does not discern any substantial difference between these phrases. They appear to be materially the same.

This point addresses a concern that this Court had expressed when it denied DRL's first motion for summary judgment on this issue: how could requiring a "non-enteric film coating" be materially the same as "uncoated?" Horizon Meds. LLC v. Reddy's Labs., Inc., 2021 U.S. Dist. LEXIS 29223, at *9 (D.N.J. Feb. 17, 2021.) DRL has pointed out that, in Nuvo, the parties agreed that the claims which require a "non-enteric film coating" may be described as "uncoated," and the Federal Circuit characterized that as a "fair reading" of the claim language. 923 F.3d at 1379. Plaintiffs have not argued that the claims presently at issue should be construed differently.

It is also worth noting that "uncoated" appears to be a shorthand expression for the Nuvo Court, not claim language. The word "uncoated" does not appear in the '907 or '285 patents – anywhere. It appears in Nuvo as a description of a concept, a common property of the claims at issue in that case. The key concept appears to be that the claims required that the acid inhibitor have no *enteric* coating – not no coating of any kind. There is no material difference between that requirement and the requirement of a non-enteric coating. Supporting this view is the fact that the parties stipulated to the following: "The Asserted Claims, as construed, recite at least some amount of immediate-release, non-enteric-coated esomeprazole that is effective to raise gastric pH to at least 3.5." (Stipulation filed 10/12/21, Docket Entry No. 422.) The parties thus agreed that all the claims at issue require that the esomeprazole have no enteric coating. The claims in Nuvo required no enteric coating, which is what the Nuvo Court meant by "uncoated." There is no material difference on this point.

The second group of claims are the remaining claims at issue, claims 1, 4, and 5 in the '996 patent, and claims 1, 4, and 5 in the '920 patent. Claims 4 and 5 in both patents depend on independent claim 1. All these remaining claims at issue share a common phrase about the timing of the release of the esomeprazole. In the '996 patent:

> 1. A pharmaceutical composition in unit dosage form in the form of a tablet, said composition comprising: naproxen in an amount of 200-600 mg per unit dosage form; and esomeprazole in an amount of from 5 to 100 mg per unit dosage form, **wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium**, and release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.

In the '920 patent:

> 1. A method of reducing the incidence of NSAID-associated gastric ulcers in a patient requiring chronic NSAID treatment and who is at risk of

> developing an NSAID-associated ulcer, wherein the method comprises administering to said patient in need thereof a pharmaceutical composition in unit dose form in the form of a tablet, said composition comprising: naproxen in an amount of 200-600 mg per unit dosage form; and esomeprazole in an amount of from 5 to 100 mg per unit dosage form, **wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium**, and release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher.

The common phrase of interest in these six claims is: "wherein upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium." Compare this language to the two claims quoted as representative by the Federal Circuit in Nuvo. As to the '285 patent:

> 1. A pharmaceutical composition in unit dosage form comprising therapeutically effective amounts of:
>   (a) esomeprazole, **wherein at least a portion of said esomeprazole is not surrounded by an enteric coating**; and
>   (b) naproxen surrounded by a coating that inhibits its release from said unit dosage form unless said dosage form is in a medium with a pH of 3.5 or higher;
>
> **wherein said unit dosage form provides for release of said esomeprazole such that upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium.**

As to the '907 patent:

> 1. A pharmaceutical composition in unit dose form suitable for oral administration to a patient, comprising:
>   (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
>   (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;
>
> and wherein said unit dosage form provides for coordinated release such that: i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any

> NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher; ii) **at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.**

These claims both contain an express requirement that is absent from the six claims in the second group at issue: the Nuvo claims require that at least a portion of the acid inhibitor is not surrounded by an enteric coating, while the six present claims under discussion contain no language about coating. Nonetheless, because the parties stipulated that all of the claims presently at issue require non-enteric-coated esomeprazole, there is no material difference on this point. (Stipulation filed 10/12/21, Docket Entry No. 422.)

In addition to the requirement of no enteric coating, these two representative Nuvo claims share a very similar phrase: upon introduction/ingestion, at least a portion of the acid inhibitor is released regardless of the pH of the medium. The six claims presently under consideration share highly similar requirements: upon introduction, at least a portion of the esomeprazole is released regardless of the pH of the medium.

Thus, this Court finds that the six claims at issue in the second group contain requirements that appear materially identical to the two claims in Nuvo that the Federal Circuit described as representative. The four claims at issue in the first group contain requirements that appear materially identical to claim 15 of the '907 patent in Nuvo.

Nonetheless, there are clear differences. All the claims presently at issue require esomeprazole, whereas the claims in Nuvo variously require esomeprazole, an acid inhibitor, or a proton pump inhibitor. Plaintiffs have not asserted that this is constitutes any material difference. Plaintiffs do, however, contend that the claims presently at issue are narrower and

require more specific formulations, whereas the claims in Nuvo are broader and more general. Plaintiffs point to two bases for this assertion: 1) specific dosage ranges; and 2) specific dosage form of a tablet. In reply, DRL points out that Plaintiffs merely selected Nuvo claims for comparison that show a difference, rather than claims that show sameness. Nuvo claim 4 of the '285 patent contains the same dosage ranges as in the claims presently at issue. Claim 4 of the '285 patent states:

> 4. The pharmaceutical composition of claim 1, wherein naproxen is present in said unit dosage form in an amount of between 200-600 mg and esomeprazole in an amount of from 5 to 100 mg per unit dosage form.

Indeed, these specific ingredients and dosage ranges in claim 4 of the '285 patent are identical to those stated in claim 1 of the '920 patent and claim 1 of the '996 patent. Claim 14 of the '907 patent requires the specific dosage form of a tablet. There is no material difference in scope between the narrowest Nuvo claims and the narrowest Asserted claims.

Moreover, this specific dosage range for esomeprazole appears in the common specification as well as in claim 4 of the '285 patent. In the Detailed Description of the Invention, the specification of the '285 patent states that typical amounts of esomeprazole are "5-100 mg, with about 40 mg being preferred." '285 patent, col.8 ll.9-10. The Nuvo Court described how Dr. Williams specifically pointed to that disclosure in his testimony about specification support, and then stated:

> The Generics argue that the parts of the specification Dr. Williams identified are not enough to satisfy the written description requirement. They argue that the specification provides only typical dosage amounts of uncoated PPI and the use of uncoated PPI in a drug formulation, but it never discusses or explains its efficacy. We agree with the Generics that Dr. Williams's testimony does not identify parts of the specification sufficient to satisfy the written description requirement. The statements he points to recite the claim limitation by simply calling generally for effective amounts of uncoated PPI, but our precedent clearly establishes that is

not enough.

923 F.3d at 1380. The Federal Circuit squarely rejected the argument that "calling generally for effective amounts of uncoated PPI" is enough to satisfy the written description requirement. Id. The Nuvo Court fully considered the disclosures in the '285 patent of formulations with 5-100 mg of esomeprazole, and found insufficient written description support.

Plaintiffs offer factually incorrect assertions to support their contention that the Asserted claims are truly narrower in scope. Plaintiffs state: "In contrast, the claims analyzed by the Federal Circuit in Nuvo did not require any particular dosage form, did not require any particular amount of any active ingredient." (Pls.' Opp. Br. 10-11.) As just discussed, Nuvo claim 4 of the '285 patent shows this statement to be incorrect. Plaintiffs state: "And going the other way, the Nuvo claims included limitations relating to a 'coating' and an 'enteric coating' that are not found in claims of the '996 and '920 patents." (Pls.' Opp. Br. 11.) With regard to "coating," Plaintiffs point only to the language in the Nuvo claims that requires that the naproxen or NSAID be surrounded by a coating that inhibits or prevents its release. The patents presently at issue use very slightly different language to say substantially the same thing: e.g., "release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher." '920 patent, claim 1. Plaintiffs have not even argued that there is any material difference as to the naproxen and its coating. Moreover, as to "enteric coating," the Nuvo claims require no enteric coating, and Plaintiffs have stipulated that all the claims presently at issue require no enteric coating. Plaintiffs have not persuaded this Court that there is any material difference between the Nuvo claims and the Asserted claims relevant to the written description analysis.

Plaintiffs offer the conclusory assertion that the contrary conclusions of their experts are

sufficient to raise a factual dispute. Yet Plaintiffs' brief cites no particular expert statement in regard to any particular factual dispute. Plaintiffs offer merely a citation to fourteen pages of expert reports. Rule 56(c)(1) states: "A party asserting that a fact cannot be or is genuinely disputed must support the assertion by: (A) citing to particular parts of materials in the record . . ." Without particulars, Plaintiffs do no more than attempt to pass off the legal conclusions of experts as evidence of facts. The Court need not credit conclusory statements by experts and need not find such statements sufficient to raise material factual disputes. "We have repeatedly held that such cursory conclusions will not withstand summary judgment." Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1365 (Fed. Cir. 2007).

In support of the argument that they have raised a factual dispute sufficient to defeat the motion for summary judgment, Plaintiffs quote from a district court case in which a party used expert testimony about claim differences to defeat a motion for summary judgment on issue preclusion, GREE, Inc. v. Supercell Oy, 2021 WL 1160413, at *2 (E.D. Tex. Feb. 9, 2021): "GREE puts forth expert testimony rebutting Supercell's argument, which at least creates a fact issue as to whether the claims are materially the same." This Court has no doubt that there can be cases in which such factual disputes may arise, but this is not one of them. This Court found no factual questions as it considered the parties' arguments and compared the claims presently at issue to the Nuvo claims, nor have Plaintiffs supported their assertion of factual disputes with particular evidence.

DRL is persuasive that Plaintiffs' assertion that the present claims at issue, as a whole, are narrower and more specific than the claims in Nuvo, is unsupported; it is incorrect. This assertion is fundamental to Plaintiffs' argument, and the determination that it is incorrect leaves

Plaintiffs with no case that the Nuvo claims and the Asserted claims materially differ. This Court finds that Plaintiffs point to no valid basis to materially differentiate the claims presently at issue from those at issue in Nuvo. Plaintiffs argue: "There are limitations in these claims not present in those in Nuvo, and there are limitations in the claims in Nuvo not present here." (Pls.' Opp. Br. 10.) To the contrary, this Court has examined the two sets of claims, as construed, and finds that, while there are minor differences in wording, there are no relevant limitations in the present claims that are not present in some claims in Nuvo. Plaintiffs have failed to persuade that there is a way to materially differentiate the two groups of claims. It appears that, as in Willow Wood, "these patents use slightly different language to describe substantially the same invention." Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

Plaintiffs offer other arguments in opposition, but identifying what point they oppose is made more challenging by the fact that the opposition brief does not consistently distinguish between issue preclusion and claim preclusion. Sometimes it does, but often, it only refers to "preclusion." DRL, in reply, points this out and asserts that Plaintiffs have conflated the two. Perhaps they have, or perhaps they decided to address them together but wrote it all up in a confusing way. In any case, none of their arguments succeed under the law of either issue preclusion or claim preclusion, and Plaintiffs fail to point out any material distinctions in the patent claims.

For example, Plaintiffs' brief next offers an argument based on SimpleAir, but fails to note that SimpleAir deals with claim preclusion, not issue preclusion. Plaintiffs point to this quote from SimpleAir: "where different patents are asserted in a first and second suit, a judgment

in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same." SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1167 (Fed. Cir. 2018). Plaintiffs do not explain how this is relevant to issue preclusion.

Plaintiffs then turn back to issue preclusion:

> Because the only claims analyzed in Nuvo differ in scope from the claims here, the issue presented here—whether the specification describes the narrower, picture claims of the '996 and '920 patents—was not actually litigated in Nuvo. And because it was not actually litigated, issue preclusion cannot apply.

(Pls.' Opp. Br. 14.) As already discussed, this relies on the incorrect premise that claim 4 of the 285 patent – which contains the same dosage range limitations that Plaintiffs characterize as a narrow, picture claim – was not before the Nuvo Court, despite the express statement in the opinion that it was. 923 F.3d at 1374. Moreover, Plaintiffs overlook that, according to the Federal Circuit, Plaintiffs did not dispute "that the claims require a therapeutically effective amount of uncoated PPI that can raise the gastric pH to at least 3.5." 923 F.3d at 1379. If the claims presently at issue contain the materially identical claim elements, and a materially identical specification, the same written description issue was actually litigated and decided in Nuvo. Plaintiffs' arguments to the contrary are meritless.

Plaintiffs assert, correctly, that "the same-issue question comes down to whether the difference in claim language changes the written description analysis." (Pls.' Opp. Br. 15.) The problem for Plaintiffs is that they have not shown that the slight differences in claim language have such an impact.

Plaintiffs attempt to demonstrate this when they argue that the "'effective to raise gastric pH to 3.5' property in the construed claims is necessarily inherent in the claimed formulations." (Pls.' Opp. Br. 21.) This is an attempt to relitigate an issue fully litigated in Nuvo; as already

established, the Asserted claims contain formulations already presented in Nuvo, and a materially identical specification. Plaintiffs presented the same argument to the Federal Circuit, which rejected it:

> [T]here is no written disclosure that in any way relates to the efficacy of immediately released PPI. Neither party has identified any evidence in the record that uncoated PPI necessarily is effective in a certain amount, consistent with the specification, to raise the gastric pH to 3.5 or higher. Nor can we find any evidence in the record demonstrating the inherency of the claimed feature. That failure of proof thus dooms Nuvo's inherency argument.

923 F.3d at 1383. Plaintiffs have failed to persuade that the law entitles them to relitigate this issue.

Plaintiffs also repeat their argument, offered in opposition to the prior motion for summary judgment, that DRL waived its preclusion arguments by failing to adequately plead them, which this Court considered and rejected. As the Court explained, the Third Circuit does not apply a bright-line rule, but has stated: "Waiver is appropriate if the party raising the defense did not do so at a pragmatically sufficient time and if the opposing party would be prejudiced if the defense were allowed." United States v. CITGO Asphalt Ref. Co. (In re Frescati Shipping Co.), 886 F.3d 291, 313 (3d Cir. 2018). Horizon argues that it has been prejudiced because, had DRL raised these defenses earlier, "the last two years of this case could have been avoided." (Pls.' Opp. Br. 3-4.) This Court is not persuaded that DRL failed to raise these defenses at a pragmatically sufficient time, nor that Plaintiffs were significantly prejudice by the timing.

Plaintiffs also repeat their previously-made argument that DRL should be judicially estopped from prevailing on issue preclusion because DRL argues a position contradictory to its position at claim construction. In brief, Plaintiffs argue that DRL prevailed at claim construction with the argument that the specification discloses esomeprazole effective to raise

the pH to at least 3.5, and it should not be allowed to argue the opposite now. In response, DRL distinguishes the positions persuasively: at claim construction, it argued that the specification held out the claim that the inventor had invented immediate-release esomeprazole which was effective to raise gastric pH to at least 3.5, whereas the issue now is different. The issue now is whether the specification demonstrates that the inventor actually possessed what the specification claimed he invented. DRL argues: "there is nothing 'inconsistent' with DRL simultaneously arguing that the specification limits the Asserted Claims to compositions with PPI effective to raise gastric pH to 3.5, but that the specification does not show the applicant actually possessed that invention." (DRL Reply Br. at 5.) DRL distinguishes the two issues persuasively.

Under Third Circuit law:

> The standard requirements for collateral estoppel, more generally termed issue preclusion, [are] (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.

Szehinskyj v. AG of the United States, 432 F.3d 253, 255 (3d Cir. 2005). The parties have disputed only the first of these four elements, the proposition that the identical issue was previously adjudicated in Nuvo. The Federal Circuit has held:

> [W]e apply our own precedent to those aspects of such a determination that involve substantive issues of patent law. . . If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.

Willow Wood, 735 F.3d at 1342. The parties do not dispute that the specifications of the patents at issue do not differ materially from those of the adjudicated patents for the purposes of this motion, and that, in short, the Nuvo Court determined that those specifications do not

provide adequate written description support for the claim elements of effective uncoated PPI. DRL has made a demonstration that the unadjudicated patent claims require effective uncoated esomeprazole, and that there are no material differences between the patents presently at issue and the adjudicated Nuvo patents that would impact the written description inquiry. DRL argues that, therefore, it is entitled to judgment of invalidity for failure to meet the written description requirement, on the basis of issue preclusion, as a matter of law. The summary judgment burden then shifts to Plaintiffs. This Court finds that Plaintiffs have neither demonstrated any material difference between the sets of patents that could change the written description analysis, nor have they raised any material factual dispute as to whether there is any material difference between the sets of patents. "The party asserting issue preclusion . . . bears the burden of proving its applicability to the case at hand." Dici v. Pennsylvania, 91 F.3d 542, 548 (3d Cir. 1996). DRL has sustained that burden. Plaintiffs have failed to defeat DRL's motion for summary judgment, which will be granted.

These circumstances resemble those in Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1343 (Fed. Cir. 2013), in which the Federal Circuit reviewed a grant of summary judgment that plaintiff-appellant OWW was collaterally estopped from challenging the validity of certain patent claims. Id. at 1337. The Federal Circuit stated the issue on appeal as follows:

> OWW seeks reversal on appeal by arguing that the mere existence of different language in the adjudicated claims of the '182 patent and unadjudicated claims of the '237 patent is sufficient to overcome collateral estoppel. We disagree. Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply. If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.

Id. at 1342 (citations omitted). The Federal Circuit compared the previously-adjudicated claims

with the unadjudicated claims and stated:

> these patents use slightly different language to describe substantially the same invention. . . Thus, the mere use of different words in these portions of the claims does not create a new issue of invalidity.
> . . .
> Since [summary judgment non-movant] OWW failed to explain how the 'block copolymer' limitation changes the invalidity analysis, OWW has not met its burden of opposing summary judgment based on this distinction.

Id. at 1342-43. As in Willow Wood, the key question before this Court is whether the differences between the unadjudicated patent claims and adjudicated patent claims materially alter the question of invalidity. DRL has made a demonstration that the patents use slightly different language to describe substantially the same invention. Plaintiffs, the summary judgment non-movants, have failed to explain how any differences in claim wording change the invalidity analysis. As a result, the motion for summary judgment of invalidity based on issue preclusion will be granted.

II. CLAIM PRECLUSION

DRL also moves for summary judgment of claim preclusion, based on Nuvo. Like issue preclusion, the Federal Circuit applies the law of the regional circuit to issues of claim preclusion. The Third Circuit has held:

> Claim preclusion requires: (1) a final judgment on the merits in a prior suit involving; (2) the same parties or their privities; and (3) a subsequent suit based on the same cause of action. If these three factors are present, a claim that was or could have been raised previously must be dismissed as precluded.

Corestates Bank, N.A. v. Huls Am., Inc., 176 F.3d 187, 194 (3d Cir. 1999) (citation omitted). There is no dispute that the first two elements are present. The sole question is whether the instant suit is based on the same cause of action as Nuvo was.

In a patent case, the inquiry into "same cause of action" is a matter of Federal Circuit

law:

> "[W]hether a particular cause of action in a patent case is the same as or different from another cause of action has special application to patent cases, and we therefore apply our own law to that issue." *Senju*, 746 F.3d at 1348. . . In a patent suit, essential transactional facts include both the asserted patents and the accused activity. If the overlap between the transactional facts of the suits is substantial, the later action should ordinarily be precluded.

SimpleAir, 884 F.3d at 1165. The inquiry into the overlap of transactional facts often requires a comparison of claims:

> As the accused activity between two cases must be "essentially the same" for claim preclusion to apply, we adopt that standard for comparison of the claims between asserted patents as well. Thus, where different patents are asserted in a first and second suit, a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same. In applying that standard to the particular context here, we conclude that claims which are patentably indistinct are essentially the same.

Id. at 1167.

DRL contends that claim preclusion bars all the present claims: "The Asserted Claims present the same cause of action that already was litigated to a final judgment in Nuvo." (Defs.' Br. 28.) At the outset, the Court observes that, although neither party has raised the point, claim preclusion cannot apply to Counts II and IV in the Third Amended Complaint, which allege patent infringement based on the launch at risk of a generic product in February of 2020, well after the Nuvo litigation had terminated. Counts II and IV, for later infringement, could not have been raised in the earlier case and cannot be subject to claim preclusion on that basis. Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.3d 1275, 1298 (Fed. Cir. 2017) ("claim preclusion does not bar later infringement allegations with respect to accused products that were not in existence at the time of the previous actions.") Only Counts I and III can be subject to claim preclusion based on Nuvo. DRL overlooks this.

Because Counts II and IV cannot be barred by claim preclusion, and because this Court has concluded that all claims *are* barred by issue preclusion, the Court need not further address the claim preclusion arguments.

CONCLUSION

DRL has shown that it is entitled to judgment as a matter of law on the issue of invalidity for lack of adequate written description, on the basis of issue preclusion, as to all the patent claims for which Plaintiffs have sued it for infringement. This produces several results. First, as to the four counts of infringement asserted in the Third Amended Complaint, DRL is entitled to judgment as a matter of law on its affirmative defense of patent invalidity, and judgment on the four counts of patent infringement will be entered in favor of DRL. Second, as to DRL's Third Counterclaim, seeking a declaratory judgment of the invalidity of the claims in the patents-in-suit asserted against it, judgment shall be entered in favor of DRL, and that declaratory judgment shall be issued; this moots the remaining Counterclaims, which will be dismissed.

This resolves all claims in the Third Amended Complaint, as well as counterclaims in the Amended Answer. All pending unresolved motions will be denied as moot.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: February 24, 2022