NOT FOR PUBLICATION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 invalidity 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 denied.

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").

DRL moves 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. DRL makes two arguments based on the Federal Circuit's decision in Nuvo. First, DRL argues that the claims at issue are invalid under the doctrine of issue preclusion. Second, DRL argues, in the alternative, that, even in the absence of a finding of issue preclusion, this Court's claim construction of the claims at issue, viewed in the light of Nuvo, warrants a grant of judgment of invalidity as a matter of law in favor of DRL.

As to the argument based on issue preclusion, the parties agree on the fundamental legal principles:[2] the issue preclusion analysis is governed by Third Circuit law, except for substantive matters of patent law;[3] 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

[2] In an exchange of footnotes, the parties debate the question of whether DRL, never having pled the affirmative defense of collateral estoppel, waived it. The Third Circuit does not apply such 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 has not argued that this standard has been met.

[3] "Whether a claim satisfies the written description requirement is a question of fact." Nuvo, 923 F.3d at 1376.

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's moving brief does not reference the Suppan standard just quoted, nor does it argue that this standard has been met. It does not appear likely that the parties would dispute whether the same general legal rules govern both cases, but the parties' briefs do not consider the question of whether the facts of both cases are indistinguishable as measured by those rules.

Moreover, DRL's arguments to establish identity of issues are not only insufficient under the Suppan standard but seriously flawed. DRL states: "this Court construed the '996 and '920 Patents to require the same effective uncoated esomeprazole limitation as the '907 and '285 Patents . . ." (Defs.' MSJ Br. 9-10.) This assertion has no basis in reality. The claim construction decision has no discussion about uncoated anything, because that was not the issue. No issues about "coating" were ever considered or determined: in this Court's claim construction Opinion and Order, filed August 14, 2020, the word "uncoated" appears *only* in a quote from Nuvo. Horizon Meds. LLC v. Dr. Reddy's Labs., Inc., 2020 U.S. Dist. LEXIS 147768, at *38 (D.N.J. Aug. 14, 2020). This Court stated its claim construction conclusion as follows:

> The Court concludes that the Specification describes the features of the "present invention" as a whole, and that description is expressly and consistently limited to compositions which contain an acid inhibitor effective to raise gastric pH to at least 3.5. This description limits the scope of the claims.

Id. at *65-*66. DRL has not supported its insertion of the word "uncoated" into this Court's

claim construction.[4]

DRL also argues for identity of issues by asserting that any differences in claim language between the instant claims and the Nuvo claims are "immaterial." (Defs.' MSJ Br. 11.) There are several problems with DRL's support for this assertion. First, DRL does not support this assertion with any analysis. Second, the differences in the wording of the claims merit, at least, some inquiry into the impact on the written description determination. As Horizon notes, there are many variations in claim scope, and the assertion that such differences have no material impact on the written description determination remains to be demonstrated. Independent claim 11 of the '920 patent and claim 12 of the '996 patent both expressly require that the esomeprazole layer has a coating, while the Nuvo decision focuses on uncoated PPI. Perhaps DRL can demonstrate that such differences indeed have no material impact on the written description analysis – but such a demonstration remains to be attempted.

Third, instead of presenting an analysis of the differences in claim language, and a demonstration that the differences have no impact on the written description inquiry, DRL relies largely on a discussion of 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.

[4] Had this Court construed the claims at issue to require effective uncoated esomeprazole, it would have been very peculiar, given that claim 11 of the '920 patent and claim 12 of the '996 patent both expressly require that the esomeprazole layer has a coating.

> 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. Thus, in Willow Wood, the Federal Circuit considered a challenge to a grant of summary judgment of collateral estoppel and held that the plaintiff-appellant had failed to defeat the motion. The Federal Circuit was not presented with a question about the movant's burden of proof, but about the opponent's burden to defeat the motion.

In terms of the instant case, this is putting the cart before the horse: at the moment, DRL first needs to meet the movant's summary judgment burden of proof, before the adequacy of the non-movant's opposition is tested. DRL needs to show that it is entitled to judgment as a matter of law that Horizon is collaterally estopped from challenging validity. DRL asserts, without support, that the differences in claim language are immaterial and that there is identity of issues. This Court does not read Willow Wood to relieve DRL, as the movant for summary judgment of invalidity for lack of written description, asserting the collateral estoppel effect of a prior judgment, from the various burdens it must bear to prevail on that motion.

As to the collateral estoppel element of the identity of issues, DRL has failed to show that it is entitled to judgment as a matter of law. DRL having failed to make a sufficient showing as

to the first element of collateral estoppel under Third Circuit law, this Court need not reach the other three. Nor does this Court reach the question of whether Horizon has adequately defeated the motion under Willow Wood.[5]

DRL next argues that, in the alternative, even without relying on issue preclusion:

> DRL is entitled to judgment as a matter of law because there are no genuine issues of material fact. Given the outcome of Nuvo, there is no dispute on the controlling factual issue (what the common specification describes—or more precisely does not describe—concerning "effective" uncoated PPI).

(Defs.' MSJ Br. 15.) In the short argument that follows, DRL appears to have forgotten that it bears the burden of proof of invalidity at trial, by clear and convincing evidence. Vasudevan Software, Inc. v. MicroStrategy, Inc., 782 F.3d 671, 682 (Fed. Cir. 2015). "When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Prop., 941 F.2d 1428, 1438 (11th Cir. 1991)). DRL has not even attempted to make such a showing.

DRL's motion for summary judgment is denied. Should DRL wish to renew this motion, it must obtain leave from the Court.

For these reasons,

IT IS on this 17th day of February, 2021

[5] The Court notes, however, that it entirely rejects Horizon's argument that this Court's statements in the claim construction decision about what the inventor "actually invented" constitute a determination that "establishes that the specification provides written description supporting those claims." (Pls.' Opp. Br. 9.)

ORDERED that DRL's motion for summary judgment (Docket Entry No. 317) is **DENIED**.

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