NOT FOR PUBLICATION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** (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 this Court on the motion for a preliminary injunction by Plaintiffs Horizon Medicines LLC and Nuvo Pharmaceutical (Ireland) Designated Activity Company (collectively, "Plaintiffs"). Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") oppose the motion. The Court held a hearing on this motion on December 11, 2019. For the reasons that follow, the motion will be denied.

These 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.[1] The first round of litigation involved U.S. Patent Nos. 6,926,907 and 8,557,285.[2] Those patents

[1] DRL has filed ANDA No. 202461 ("ANDA I") and ANDA No. 204206 ("ANDA II.") The parties have stipulated that this preliminary injunction motion shall be briefed and argued as to ANDA I only, but that the outcome shall apply to both ANDA I and ANDA II.

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

have been found to be invalid for failure to satisfy the written 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").

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

"The grant of a preliminary injunction under 35 U.S.C. § 283 is within the discretion of the district court." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 129 S. Ct. 365, 374 (2008). The Supreme Court has held that injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Id. at 376.

As to the requirement that the movant establish that he is likely to succeed on the merits, the Federal Circuit has held:

> [T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent. In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. . . .

Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) (citation

omitted). "To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability." Mylan Institutional LLC v. Aurobindo Pharma Ltd., 857 F.3d 858, 866 (Fed. Cir. 2017). "An accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity or infringement." Trebro Mfg. v. FireFly Equip., LLC, 748 F.3d 1159, 1165 (Fed. Cir. 2014); Tinnus Enters., LLC v. Telebrands Corp., 846 F.3d 1190, 1202 (Fed. Cir. 2017).

ANALYSIS

I. Plaintiffs have not demonstrated that they are likely to succeed on the merits.

Plaintiffs move for injunctive relief on the ground that they expect that DRL will soon launch at risk a generic product that will infringe claims in the '996 and '920 patents. At the hearing, DRL confirmed that it plans to launch its generic product at risk as soon as it receives final FDA approval to do so, which could occur at any time. Plaintiffs assert claims 1-19 of the '996 patent and claims 1-5, 7-9, and 11-14 of the '920 patent. DRL does not dispute infringement on this motion. Plaintiffs argue that injunctive relief should be granted because: 1) DRL's proposed generic product will infringe, and DRL's validity defenses will fail, and thus Plaintiffs are likely to succeed on the merits; 2) Plaintiffs will suffer irreparable harm absent an injunction; 3) the balance of hardships supports injunctive relief; and 4) the public interest favors a grant of injunctive relief to maintain the *status quo*.

DRL opposes the preliminary injunction motion by challenging the validity of the '996 and '920 patents. Specifically, *inter alia*, DRL argues that the asserted claims lack adequate written description.

As noted, in May of 2019, the Federal Circuit decided Nuvo and invalidated the '907 and '285 patents for failure to meet the written description requirement. 923 F.3d 1368. The '907 patent states an application number of 10/158,216. In the "Related U.S. Application Data" section of the '285 patent, it states that the '285 patent is descended from that same application, 10/158,216. In the "Related U.S. Application Data" section of the '920 patent, it states that the '920 patent is descended from that same application, 10/158,216. In the "Related U.S. Application Data" section of the '996 patent, it states that the '996 patent is descended from that same application, 10/158,216. Thus, the application that resulted in the '907 patent is a parent application that the '285, '996, and '920 patents all descended from.

In August of 2019, DRL moved for summary judgment, and this Court decided that motion in the Opinion and Order entered November 8, 2019. In brief, DRL moved for summary judgment of invalidity of the '996 and '920 patents, as well as other patents which Plaintiffs have since withdrawn from this litigation, on the grounds of issue preclusion and claim preclusion, in view of the Nuvo decision. This Court denied the motion, stating, *inter alia*, that the Federal Circuit's decision in Nuvo had relied on the fact that the plain language of the claims at issue in that case required effectiveness of an uncoated proton pump inhibitor ("PPI"), but that the plain language of the asserted claims in this case did not.[3] (Opinion and Order of November 8, 2019 at 3-4.) This important difference, among others, prevented finding that the same issue had

[3] In Nuvo, the Federal Circuit stated:

> At trial, the parties and the district court understood that the plain words of the patents claim effectiveness of uncoated PPI. Beyond the plain language of the claims, the district court was not asked to define further the effectiveness limitation.

923 F.3d at 1377. In the '996 and '920 patents, the plain language of the claims at issue does

already been litigated. (Id.)

DRL opposes the instant preliminary injunction motion principally on the ground that the asserted claims are invalid for lack of written description, as in Nuvo. Now, however, DRL argues that this Court should construe the asserted claims to require effective uncoated esomeprazole, and that the asserted claims, thus construed, fail to meet the written description requirement, for reasons similar to the Federal Circuit's reasoning in Nuvo. Plaintiffs, in their reply brief, contend that all claim language should have its ordinary meaning.

As to the likelihood of success on the merits, then, the present dispute turns on the question of whether the asserted claims should be construed to require effective uncoated esomeprazole. At this juncture, in the context of a preliminary injunction motion, this Court need not reach a conclusive resolution of this issue. The Federal Circuit has held:

> [T]he trial court has no obligation to interpret claim 1 conclusively and finally during a preliminary injunction proceeding. Under *Markman*, claim interpretation is a matter of law. However, *Markman* does not obligate the trial judge to conclusively interpret claims at an early stage in a case. A trial court may exercise its discretion to interpret the claims at a time when the parties have presented a full picture of the claimed invention and prior art. *Illinois Tool Works, Inc. v. Grip-Pak, Inc*., 906 F.2d 679, 681 (Fed. Cir. 1990)(referring to a preliminary injunction "hearing in which neither party was required to prove his case in full and in light of findings and conclusions not binding at trial." (emphasis added); *Atari Games Corp. v. Nintendo of Am., Inc*., 897 F.2d 1572, 1575 (Fed. Cir. 1990)("The district court need not make binding findings of fact, but at the very least, must find probabilities that the necessary facts can be proved.")

Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996) (citations omitted). The Federal Circuit has called this "rolling claim construction." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1359 (Fed. Cir. 2006). This Court now considers

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not require the effectiveness of uncoated PPI.

the parties' claim construction arguments not to conclusively construe all the claims, but to assess Plaintiffs' likelihood of success on the merits in view of the arguments and the record presently before the Court.

DRL proposes that this Court should construe the claims at issue to require effective uncoated esomeprazole, and thus to import a limitation from the specification. The '996 patent has two independent claims:

> 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.
>
> 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.

The '920 patent has two independent claims:

> 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.
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> 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.

Crucially, at oral argument, the parties agreed that the '920, '996, '907, and '285 patents share a common specification.

DRL begins its claim construction analysis by pointing to the statements in the specification which describe "the present invention" as having an effective acid inhibitor. The Abstract for both the '920 and '996 patents states:

> The present invention is directed to drug dosage forms that release an agent that raises the pH of a patient's gastrointestinal tract, followed by a non-steroidal anti-inflammatory drug. The dosage form is designed so that the NSAID is not released until the intragastric pH has been raised to a safe level.

The specification for both the '920 and '996 patents states:

- The present invention is directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID). '996 patent, col.1 ll.25-28.

- The present invention is based upon the discovery of a new method for reducing the risk of gastrointestinal side effects in people taking NSAIDs for pain relief and for other conditions, particularly during chronic treatment. The method involves the administration of a single, coordinated, unit-dose product that combines: a) an agent that actively raises intragastric pH to levels associated with less risk of NSAID-induced ulcers; and b) an NSAID that is specially formulated to be released in a coordinated way that minimizes the adverse effects of the NSAID on the gastroduodenal mucosa. '996 patent, col.3 ll.15-24.

- The present invention is based upon the discovery of improved pharmaceutical compositions for administering NSAIDs to patients. In addition to containing one or more NSAIDs, the compositions include acid inhibitors that are capable of raising the pH of the GI tract of patients. '996 patent, col.6 ll.23-27.

These statements support DRL's assertion that the specification repeatedly describes "the present invention" as containing an acid inhibitor that raises the pH of the GI tract prior to the release of the NSAID. DRL contends that, under Federal Circuit law, "such language bounds invention scope," which is overstatement: under Federal Circuit law, such language *may* bind claim scope. (Defs.' Opp. Br. 10.) In support, DRL cites Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1398 (Fed. Cir. 2008), in which the Federal Circuit held:

> We agree with Netcraft that use of the phrase "the present invention" does not "automatically" limit the meaning of claim terms in all circumstances, and that such language must be read in the context of the entire specification and prosecution history. For the reasons below, however, we agree with the district court that the common specification's repeated use of the phrase "the present invention" describes the invention as a whole, and, as will be discussed further below, that the prosecution history does not warrant a contrary result.

Id. (citation omitted). DRL's second citation offers firmer support for Defendants' characterization of Federal Circuit law: "When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention." Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed. Cir. 2007); see also Honeywell Int'l, Inc. v. ITT Indus., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (finding that repeated use of "the present invention" in the specification characterized the invention as a whole and limited a key claim term); Sony Corp. v. Iancu, 924 F.3d 1235, 1241 (Fed. Cir. 2019) (quoting Verizon.)

The specification also states: "In a more general sense, the invention includes methods of treating pain, inflammation and/or other conditions by orally administering an acid inhibitor at a dose effective to raise a patient's gastric pH to at least 3.5, preferably to at least 4 or and more preferably to at least 5." '996 patent, col.5 ll.36-40. This statement makes clear that the invention, in general, contains an acid inhibitor at a dose effective to raise a patient's gastric pH to at least 3.5.

The specification statement just mentioned is the clearest statement which ties together: 1) a broad view of the invention as a whole; and 2) the use of an acid inhibitor "at a dose *effective* to raise a patient's gastric pH to at least 3.5." '996 patent, col.5 ll.38-39 (italics added). Also already quoted is this statement: "the compositions include acid inhibitors that are *capable* of raising the pH of the GI tract of patients." '996 patent, col.6 ll.26-27 (italics added). Including the sentence that preceded it, that statement ties together: 1) a broad view of the invention as a whole; and 2) the use of an acid inhibitor that is *capable* of raising the pH of the GI tract of patients. While the words "effective" and "capable" are different words, in these contexts, they have a common meaning: they refer to the ability to produce a desired result, and the result is raising the pH of the GI tract of patients. In the context of the patent as a whole, it is clear that the desired result is not simply raising the pH of the GI tract of patients in any amount, but raising the pH of the GI tract of patients to at least 3.5.

This inference is supported by these statements in the "Summary of the Invention" section of the specification:

> In its first aspect, the invention is directed to a pharmaceutical composition in unit dosage form suitable for oral administration to a patient. The composition contains an acid inhibitor present in an amount *effective* to raise the gastric pH of a patient to at least 3.5, preferably to at least 4, and more preferably to at least 5, when one or more unit dosage forms are administered.

'996 patent, col.3 ll.31-37 (italics added). This quote expressly refers to an aspect of the invention, and not to the invention as a whole, but again we see the assertion that the composition contains an acid inhibitor in an amount *effective* to raise the gastric pH to at least 3.5. This supports the inference that the inventors understood that it was necessary that the acid inhibitor be present in amount that would have the ability to produce the result of raising the pH to at least 3.5. Although, in this instance, the statements do not refer to the invention as a

whole, other statements quoted make clear that this is a characteristic of the invention as a whole.

This Court agrees with DRL that these statements in the common specification of the '920 and '996 patents support the inference that the invention, as a whole, comprises an acid inhibitor in an amount effective to raise the pH of the GI tract, prior to the release of the NSAID, to at least 3.5.

DRL also points to the prosecution history of a parent patent, the '907 patent. The '920 and '996 patents descended from the application that produced the '907 patent, application number 10/158,216.[4] On April 22, 2004, in a non-final office action, all claims were rejected as either anticipated by the Goldman reference, or as anticipated by the Depui references, or as obvious over Depui in view of other references. (Office action of April 22, 2004, application number 10/158,216.) In response to these rejections, the applicants filed traversing arguments, including the following:

> All of Applicant's claims have requirements not only with respect to the type of active ingredients present in compositions or methods, but also with respect to the way in which active ingredients are delivered in relation to one another. Specifically, claim 1 requires that there be a single unit dosage form containing both an acid inhibitor and an NSAID and that, upon administration to a patient, the dosage form deliver these drugs in a coordinated fashion such that the acid inhibitor is released first and the NSAID is not released until after the gastric pH of the patient is 3.5 or higher. Applicant submits that these characteristics are not disclosed or suggested Goldman. [sic]

(Applicant Remarks filed 7/22/2004, application number 10/158,216.)

In the Final Office Action filed October 20, 2004, the examiner allowed certain claims and rejected others, for the reasons stated in the previous rejection, including anticipation by the

[4] DRL submitted exhibits with its opposition brief that included some, but not all, of the relevant documents from the file wrapper for the prosecution of the '907 patent. The entire file wrapper is publicly available on the PTO's website, and this Court has taken judicial notice of certain relevant documents from the file wrapper that DRL did not include as exhibits.

Depui reference. (Office action of October 20, 2004, application number 10/158,216.) In response, the applicants submitted amendments and remarks on November 22, 2004. In the remarks, the applicants distinguished Depui as follows:

> It should also be recognized that Depui's compositions would act in a very different way than those claimed by Applicant. Specifically, release of acid inhibitor in Depui's compositions would be delayed whereas acid inhibitor release from Applicant's compositions is immediate and only the release of NSAID is delayed. The basic concept of coating NSAIDs in a way that will prevent them from being released until the surrounding pH rises to at least 3.5 is entirely missing from the Depui reference.

(Amendment and Response under 37 C.F.R. § 1.116, filed November 22, 2004, Pollack Dec. Ex. 5.) On March 29, 2005, a notice of allowance was issued for all but two out of fifty-seven claims.

The prosecution history of a parent application, application number 10/158,216, shows that the applicants overcame a rejection in part by distinguishing the Depui reference as not having taught the following features of the inventive composition: immediate release of an acid inhibitor and delayed release of an NSAID until the gastric pH rises to at least 3.5. This does not appear to meaningfully differ from characterizing the invention as having an immediate release acid inhibitor effective to raise gastric pH to at least 3.5. The applicants overcame a rejection over the Depui reference by describing the invention as having an immediate release acid inhibitor and an NSAID that does not release until the gastric pH rises to at least 3.5. This constitutes further evidence supporting the inference that the applicants so understood the invention of the '920 and '996 patents as a whole.

The intrinsic evidence just reviewed supports the inference that what the inventors

actually invented[5] was a composition, as well as a treatment method using that composition, comprising naproxen and esomeprazole, which worked because uncoated esomeprazole was first released in the stomach, and then raised the pH of the stomach to at least 3.5, at which point the naproxen was released. The intrinsic evidence supporting this inference is quite strong.

DRL also points to statements made by the then-owners of the '996 patent, Horizon and Pozen, in the preliminary response they submitted in IPR2015-1344. In this response, the then-owners attempted to rebut an invalidity challenge involving a reference by Gimet with an argument that included this statement: "Gimet does not disclose a dosage form comprising an acid inhibitor in an amount effective to raise the gastric pH of a patient to at least 3.5." (Pollack Dec. Ex. 9 at 19.) This is not intrinsic evidence, but it is consistent with DRL's contention that the invention of the '996 patent, as a whole, comprises an acid inhibitor effective to raise the gastric pH to at least 3.5.

This Court finds that the evidence of record supports DRL's contention about the invention as a whole. Next, this Court considers the question of whether such evidence may, under Federal Circuit law, support the construction that DRL proposes, which imports a limitation from the specification. At oral argument, Plaintiffs argued principally that DRL's proposed construction did not comport with Federal Circuit law because the claim language contains no "hook." This Court understood this to refer to a case cited in Plaintiffs' reply brief, NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1310 (Fed. Cir. 2005), which states:

> Our case law requires a textual "hook" in the claim language for a limitation of this nature to be imposed. Generally, "a party wishing to use statements in the

[5] See Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.")

> written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements. Without any claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). In other words, there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction.

Plaintiffs' opening brief does not mention the hook argument. Plaintiffs' reply brief cites NTP only in support of its argument that the word "effective" does not appear in the specification quotes in DRL's opposition brief. (Pls.' Reply Br. 3.) The argument that Plaintiffs made at oral argument was that there was no hook for DRL's proposed construction in the claims, not the specification. The point is that the hook argument, as made at oral argument, was entirely new. Furthermore, the hook argument, as presented at oral argument, was little more than the assertion that there was no hook in the claims, without supporting explanation of the law or analysis of the claim language. This leaves this Court in the position of considering an argument that was not made in the briefs nor developed at oral argument.

Thus, while Plaintiffs argued at the hearing that the claims have no hook, they did not offer a definition of a hook, within the meaning of NTP and the Federal Circuit law of claim construction. Nor does NTP offer a definition of a hook, nor articulate how a court should decide whether or not a hook is present in claim language, beyond the statement that "there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction." NTP, 418 F.3d at 1310. These statements appear in the context of the Federal Circuit's review of the district court's claim construction decision which declined to impose a "separate and distinct" limitation on certain claims. Id. The Federal Circuit affirmed the district court's decision that a limitation should not be imported, and so NTP does not offer an example of a textual reference in claim language with sufficient association with a proffered

claim construction to justify importing a claim limitation. As already stated, Plaintiffs did not give the Court an analysis of the NTP decision that might elucidate how this Court should apply NTP to the facts of this case.

DRL, on the other hand, relies on the Federal Circuit's decision in Alloc, Inc. v. ITC, 342 F.3d 1361, 1371 (Fed. Cir. 2003), and argued in its opposition brief that the facts of the instant case are analogous to those in Alloc. In short, in Alloc, the Federal Circuit held that certain claims should be construed to have a "play" limitation, based on the specification, despite the fact that the word "play" did not appear in the claims. Id. at 1368-73. The word "hook" does not appear in the Alloc decision, and so this Court examines the Federal Circuit's reasoning to see what relationship "play" had with the language of the relevant claims.

The Federal Circuit began its discussion as follows:

> Turning to the Commission's finding that the claims include a "play" limitation, none of the asserted patent claims recites the term play. Even so, the claims recite floor system features, which are emphasized in the claim language above, in which play is necessarily present. These features, and their associated claim terms, relate to "displacement" and "disassembly."

Id. at 1368. The Federal Circuit then examined the specification and explained the basis for the conclusions that "play between components of the locking joint permits displacement" and "play in the joint also permits 'disassembly.'" Id. at 1369. The Federal Circuit considered the prosecution history, including the prosecution history of a parent application, and stated: "the applicant represented to the USPTO examiner that play facilitated its novel system set forth in the revised claims." Id. at 1372. The Federal Circuit found that "play facilitates displacement and disassembly," and concluded: "the patent applicant tethered the displacement and disassembly features of the claims to the play feature." Id. at 1372-73. The Federal Circuit held that the claims at issue should be construed to require play. Id. at 1373.

Thus, in Alloc, the Federal Circuit examined the language of the claims and the intrinsic record and found that a product feature disclosed in the specification, but not in the claims, facilitated and permitted product features that were expressly claimed. This Court now inquires into whether the instant case presents analogous facts. DRL argues that the intrinsic evidence demonstrates that the invention, in general, requires that the uncoated esomeprazole be effective to raise the gastric pH to at least 3.5; this would be the product feature disclosed in the specification. Two of the four independent claims include the phrase, "release of at least a portion of said naproxen is inhibited unless the pH of said medium is 3.5 or higher," while the other two independent claims include the phrase, "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." The product property disclosed in the specification – the uncoated esomeprazole is effective to raise the gastric pH to at least 3.5 – facilitates or permits the product property disclosed in the claims: the naproxen is not released until the pH of the medium is 3.5 or higher. On the present record, it appears that the patentee tethered the naproxen release feature disclosed in the claims to the effectiveness of the esomeprazole to raise gastric pH disclosed in the intrinsic record. DRL has persuaded this Court that Alloc is analogous, and that there is "a textual reference in the actual language of the claim with which to associate [the] proffered claim construction." NTP, 418 F.3d at 1310.

The intrinsic evidence strongly supports the inference that the applicants for the '996 and '920 patents understood the invention, as a whole, to comprise immediate release esomeprazole which is effective to raise gastric pH to at least 3.5. Applying Alloc, this Court tentatively finds that the applicants tethered the naproxen release feature disclosed in the claims to the effectiveness of the esomeprazole to raise gastric pH disclosed in the intrinsic record, and

construes the claims at issue to include this limitation.

With this foundation, this Court considers the impact of the Federal Circuit's decision in Nuvo. In Nuvo, the Federal Circuit held: "we hold that the '907 and '285 patents are invalid for lack of an adequate written description given that the shared specification does not adequately describe the claimed effectiveness of uncoated PPI." Nuvo, 923 F.3d at 1384. At oral argument on this motion, the parties agreed that the '920, '996, '907, and '285 patents share a common specification. No one has argued that esomeprazole is not a PPI. This Court has tentatively construed the asserted claims to include a limitation requiring immediate release esomeprazole which is effective to raise gastric pH to at least 3.5. The Federal Circuit has held that the common specification does not adequately describe uncoated PPI which is effective to raise the gastric pH to at least 3.5.

On this basis, this Court finds that DRL has raised a substantial question of patent validity, which Plaintiffs have not shown lacks substantial merit. The Court makes this finding not based on the application of any preclusion doctrine; the parties have not raised a preclusion argument on this motion. Instead, the Court considers Nuvo as relevant to estimating the likelihood of success of the parties, in view of the burdens and presumptions that will inhere at trial. The reported decision shows that the parties before the Federal Circuit in Nuvo were the same parties now before this Court. 923 F.3d at 1368. The Federal Circuit concluded: "we hold that the '907 and '285 patents are invalid for lack of an adequate written description given that the shared specification does not adequately describe the claimed effectiveness of uncoated PPI." Id. at 1384. It is a common-sense proposition that, if Plaintiffs-Cross-Appellants Nuvo and Horizon were unable to persuade the Federal Circuit that the shared specification – shared with the '996 and '920 patents, the parties agreed – provides adequate written description

support for a claim limitation of effective uncoated PPI, they are unlikely to succeed in defeating the same validity challenge in this case.

Neither Plaintiffs' reply brief nor their arguments to this Court at the hearing suggest otherwise. The reply brief restates Plaintiffs' position that the words of all claims should have their ordinary meaning, and does not seriously challenge DRL's argument that the intrinsic evidence, under Alloc, supports construing the claims to require effective uncoated esomeprazole. Plaintiffs' approach to the Nuvo decision is to ignore it: it is not even cited in the reply brief. Plaintiffs assert that DRL cannot meet its burden of proof, but Plaintiffs bear the burden of proof on this motion. As the parties know, pursuant to 35 U.S.C. § 282(a), a patent shall be presumed valid, and, at trial, the challenger bears the burden of proof of invalidity. While the presumption of validity applies in the context of deciding a preliminary injunction motion, the burdens of proof differ somewhat from those at trial. As the Federal Circuit has explained:

> A patent holder seeking a preliminary injunction bears the ultimate burden of establishing a likelihood of success on the merits with respect to the patent's validity. If the alleged infringer raises a "substantial question" of invalidity, the preliminary injunction should not issue. The burden on the accused infringer to show a substantial question of invalidity at this stage is lower than what is required to prove invalidity at trial. "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com*, 239 F.3d at 1359 ("In resisting a preliminary injunction . . . one need not make out a case of actual invalidity. . . . The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself."). Once the accused infringer satisfies this requirement, the burden shifts to the patentee to show that the defense lacks substantial merit.

Altana Pharma AG v. Teva Pharm. USA, Inc., 566 F.3d 999, 1005-06 (Fed. Cir. 2009) (citations omitted). At this juncture, DRL does not bear the burden of proof of invalidity by clear and convincing evidence. It need only show the vulnerability of the patents at issue to a validity

challenge, and it has done so. The burden then shifted back to Plaintiffs to show that the defense lacks substantial merit, and Plaintiffs have not met this burden.

Plaintiffs have failed to demonstrate that their "infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability." Mylan, 857 F.3d at 866. Plaintiffs have therefore failed to show a likelihood of success on the merits. The motion for a preliminary injunction is denied.

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

Dated: December 18, 2019