

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES,

Defendants.

Civil Action Nos. 15-cv-03324 (SRC) (CLW)  
16-cv-04918 (SRC) (CLW)  
16-cv-09035 (SRC) (CLW)

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC.,

Defendants.

Civil Action Nos. 15-cv-03327 (SRC) (CLW)  
16-cv-04921 (SRC) (CLW)

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC.,

Plaintiffs,

v.

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,

Defendants.

Civil Action Nos. 15-cv-03326 (SRC) (CLW)  
16-cv-04920 (SRC) (CLW)



**(Return Date: September 4, 2018)**

**Oral Argument is Requested**

**MEMORANDUM OF MYLAN AND DRL IN SUPPORT OF  
THEIR MOTION FOR SUMMARY JUDGMENT OF INVALIDITY  
OF U.S. PATENT NOS. 9,220,698 AND 9,393,208**

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## **I. Introduction**

The patent statutes require that the specification of a patent must conclude with one or more claims “particularly pointing out and distinctly claiming” the invention. 35 U.S.C. § 112, ¶ 2. That requirement for clarity, or definiteness, in claim language ensures that the public receives fair notice regarding the extent of the patentee’s exclusive rights and that the patent office and the courts receive a clear measure of the invention for evaluating patentability in light of the supporting disclosure and the prior art. A claim that is indefinite—too unclear to fulfill those requirements—is invalid.

Here, the asserted claims of the ’698 and ’208 patents recite dosage forms that “target” a set of pharmacokinetic (“PK”) and pharmacodynamic (“PD”) parameters. Those claims are indefinite in scope, and therefore invalid, due to their “target” PK and PD terms. The Court has construed “target” to mean “set as a goal.” ECF No. 82 at 11.<sup>1</sup> From that construction, it is clear that the “target” PK and PD parameters in the claims merely convey a set of goals that need not necessarily be achieved. There can be no genuine dispute that these aspirational “target” parameters render the claims invalid.

The “targeted” PK and PD ranges are indefinite because they are presented as aspirational goals that need not be met in all instances, and the ’698 and ’208

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<sup>1</sup> Unless otherwise noted, all ECF citations in this brief refer to the Court’s docket for Case No. 15-cv-03324.

patents provide no guidance regarding how often, if ever, the recited ranges must be met or how close one must come to those ranges to infringe the asserted claims. In fact, the patents' shared specification demonstrates that administering the claimed drug formulations leads to wide variation between patients in the claimed properties, with outcomes that can and commonly do fall well outside of the claimed ranges. Nothing in the claims, the specification, or the prosecution history allows those skilled in the art to discern with any reasonable certainty where the boundaries of the asserted claims lie.

The definiteness requirement of 35 U.S.C. § 112, ¶ 2, exists to protect the public from precisely this type of uncertainty. Enforcing definiteness standards ensures that patent claims provide clear notice of the patentee's rights and how far those rights extend as a condition for the exclusivity those claims confer upon their owner. The claims of the '698 and '208 patents lack reasonably clear boundaries and cast doubt and uncertainty over an indeterminate swath of commercial and clinical activities.

There are no material facts in dispute. The asserted claims fall short of the definiteness required by § 112, ¶ 2, as a matter of law, and summary judgment of invalidity is appropriate. Fed. R. Civ. P. 56.

## II. Background

The asserted '698 and '208 patents claim methods of administering a drug formulation that combines naproxen, a non-steroidal anti-inflammatory drug (“NSAID”), and esomeprazole, a proton pump inhibitor (“PPI”) that reduces stomach acidity. Naproxen (*e.g.*, Aleve<sup>®</sup>) has long been used for treating pain and inflammation in chronic conditions such as arthritis. SUMF ¶ 6.<sup>2</sup> It is also well known, however, that long-term naproxen administration can cause stomach injury. SUMF ¶ 7. Esomeprazole (*e.g.*, Nexium<sup>®</sup>) and other PPIs were used before the asserted patents’ priority date to mitigate gastric complications from long-term use of naproxen and other NSAIDs. SUMF ¶ 8.

The '698 and '208 patents share a common specification—the '208 patent was filed as a continuation of the '698—and feature nearly identical claims. All claims of the '698 and '208 patents recite methods of administering a co-formulation of naproxen and esomeprazole. The recited formulation comprises 500 mg of naproxen and 20 mg of esomeprazole, identified in the patents’ shared specification as formulation “PN400/E20.” SUMF ¶ 9. Independent claim 1 of the '698 patent begins:

1. A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need

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<sup>2</sup> Citations to “SUMF ¶ \_\_” reference numbered paragraphs from the Statement of Material Facts Not in Dispute submitted by Mylan and DRL and filed concurrently herewith.

thereof an AM unit dose form and, 10 hours ( $\pm 20\%$ ) later, a PM unit dose form, wherein:

the AM and PM unit dose forms each comprises:

naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and

esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole;

said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater, ...

SUMF ¶ 10; Ex. 1 at 52:25-38 (claim 1).<sup>3, 4</sup>

In addition to the administration steps and formulation limitations recited above, Plaintiffs added certain intended pharmacokinetic (“PK”) and pharmacodynamic (“PD”) properties to the claims of the ’698 and ’208 patents. Upon administering a drug to a patient, various pharmacological effects can be observed in the body—for example, a drug may act quickly or slowly, it may reduce pain, or it may alter stomach pH. ECF No. 50-33 at ¶ 20; *see also* ECF No. 82 at 5. Scientists and clinicians measure such effects in terms of PK and PD values. SUMF ¶ 15. PK values measure the rate at which the body absorbs and processes the drug, and PD values measure the drug’s effect on the body. SUMF ¶ 16.

The claims of the ’698 and ’208 patents recite certain PK and PD results in a patient who is administered the PN400/E20 formulation as recited in the claims.

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<sup>3</sup> Claim 1 of the ’208 patent is nearly identical to claim 1 of the ’698 patent but is framed more broadly as a “method for delivering a pharmaceutical composition to a patient in need thereof.” SUMF ¶ 14; *See* Ex. 2 at 46:33-34.

<sup>4</sup> Citations to “Ex. \_\_\_” reference numbered exhibits attached to the Declaration of Bryan D. Beel, concurrently filed herewith.

SUMF ¶ 18. Specifically, the '698 and '208 patents describe PK parameters that include certain terms of art: " $C_{max}$ " " $T_{max}$ ," and "area under the curve" or "AUC." To a skilled artisan,  $C_{max}$  refers to the maximum concentration the drug achieves in the patient's plasma. SUMF ¶ 19.  $T_{max}$  identifies the time after administration at which the patient's  $C_{max}$  is achieved. SUMF ¶ 19. Finally, "area under the curve" or AUC measures the cumulative amount of a drug in the plasma over a certain period after administration, for example after ten hours ( $AUC_{0-10}$ ) or after twenty-four hours ( $AUC_{0-24}$ ). SUMF ¶ 19. The asserted claims recite certain PK parameters for naproxen, certain PK parameters for esomeprazole, and a PD effect of administering esomeprazole (*i.e.*, raising the stomach pH), as exemplified by the PK/PD values recited in claim 1 of the '698 patent:

... the AM and PM unit dose forms ***target***:

i) a pharmacokinetic (pk) profile for naproxen where:

- a) for the AM dose of naproxen, the mean  $C_{max}$  is 86.2  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{max}$  is 3.0 hours ( $\pm 20\%$ ); and
- b) for the PM dose of naproxen, the mean  $C_{max}$  is 76.8  $\mu\text{g/mL}$  ( $\pm 20\%$ ) and the median  $T_{max}$  is 10 hours ( $\pm 20\%$ ); and

ii) a pharmacokinetic (pk) profile for esomeprazole where:

- a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours ( $\pm 20\%$ ) after the AM dose is administered ( $AUC_{0-10,am}$ ) is 1216  $\text{hr} \cdot \text{ng/mL}$  ( $\pm 20\%$ ),
- b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours ( $\pm 20\%$ ) after the PM dose is administered ( $AUC_{0-14,pm}$ ) is 919  $\text{hr} \cdot \text{ng/mL}$  ( $\pm 20\%$ ), and



c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours ( $\pm 20\%$ ) after the AM dose is administered ( $AUC_{0-24}$ ) is 2000 hr\*ng/mL ( $\pm 20\%$ ); and

the AM and PM unit dose forms further *target* a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

SUMF ¶ 10; Ex. 1 at 52:39-67 (claim 1) (emphases added).

As emphasized above, the claims of the '698 and '208 patents specify that the recited naproxen-esomeprazole formulations merely “target” the stated PK and PD values, not that the administered doses achieve PK or PD results within the recited ranges. Because the Court has construed “target” to mean “set as a goal,” the PK and PD ranges set forth in the claims represent goals aspired to, but not necessarily met, for every patient. ECF No. 82 at 11. The Court “recognize[d] that this construction of ‘target’ could conceivably impact the validity of the claim,” *id.*, but expressly deferred deciding whether the “targeted” PK and PD values render the claims indefinite, *id.* at 10 (“This Court considers indefiniteness arguments on summary judgment or at trial, and not at claim construction.”).

### III. Legal Standards

“Summary judgment is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.” *EKR Therapeutics, Inc. v. Sun Pharm. Indus., Ltd.*, 633 F. Supp. 2d 187, 192 (D.N.J. 2009) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). A dispute about

a material fact is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The court must view the facts and reasonable inferences drawn therefrom “in the light most favorable to the party opposing the motion.” *EKR Therapeutics*, 633 F. Supp. at 192 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). But the non-moving party must “do more than simply show that there is some metaphysical doubt as to material facts” and must instead produce evidence upon which a reasonable fact finder could rely. *Id.* (quoting *Matsushita*, 475 U.S. at 586).

A patent is invalid for indefiniteness “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). In particular, “a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Id.* at 2129 (quotation & citations omitted). Definiteness, like claim construction, is a question of law sometimes involving subsidiary factual determinations. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382 (Fed. Cir. 2015). In assessing definiteness, “claims are to be read in light of the patent’s specification and prosecution history,” and courts apply the “viewpoint of a person skilled in the art at the time the patent was

filed.” *Nautilus*, 134 S. Ct. at 2128 (alterations and citation omitted). Summary judgment of indefiniteness is appropriate when the language of a claim lacks the precision necessary to “appris[e] the public what is still open to them.” *In re TR Labs Patent Litig.*, No. 09-3883-PGS, 2014 WL 3500596, at \*4 (D.N.J. July 14, 2014) (citations omitted).

#### **IV. The Aspirational “Target” PK/PD Limitations Render the Claims Invalid for Indefiniteness**

The asserted claims must be held invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2.<sup>5</sup> The claims of the ’698 and ’208 patents recite dose forms that “target”—but need not necessarily achieve—particular PK/PD properties, leaving those skilled in the art to guess at the boundaries and ultimate scope of the claims.<sup>6</sup>

To meet the definiteness requirement, claims must “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129. Enforcing the definiteness standard serves the “public notice function of patent claims.” *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249

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<sup>5</sup> Section 112, ¶ 2 was re-designated as § 112(b) when the AIA took effect on September 16, 2012. The ’698 and ’208 patents both claim priority from applications filed before that date, so Defendants refer to the pre-AIA version of § 112 for purposes of this motion.

<sup>6</sup> Defendants have asserted, and maintain, that the “target” PK/PD values recited in the claims are non-limiting, and the Court has yet to resolve that issue. ECF No. 82 at 11 n.3. In contrast, Plaintiffs contend that the “target” terms are limiting, substantive requirements of the asserted claims. ECF No. 49 at 20-22. Defendants disagree with Plaintiffs’ view of the claims, but if that view is accepted, the asserted claims are invalid for indefiniteness as explained in this brief.

(Fed. Cir. 2008). Accordingly, the Federal Circuit has explained that § 112, ¶ 2, requires patent claims to “provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014); *see also In re TR Labs*, 2014 WL 3500596, at \*4 (explaining that the definiteness standard “requires every ‘patent to be precise enough to afford clear notice of what is claimed’” (alterations omitted) (quoting *Nautilus*, 134 S. Ct. at 2129)).

The independent claims of both patents recite methods for administering co-formulated naproxen and esomeprazole where the dose forms “target” specified PK values and “further target” a PD benchmark for intragastric pH levels. SUMF ¶¶ 10, 12, 22; Ex. 1 at 52:39-67; Ex. 2 at 46:48–47:9. As used in the claims of the ’698 and ’208 patents, “target” means to “set as a goal.” ECF No. 82 at 11. The PK and PD profiles in the claims thus represent “statements of a goal aspired to, but not met, for every patient.” *Id.*

So construed, the claims are indefinite. There can be no genuine dispute that the aspirational “target” elements prevent those skilled in the art from determining the metes and bounds of the claims with reasonable certainty. Plaintiffs acknowledged as much during the *Markman* hearing:

THE COURT: Okay. Look, the bottom line is this: If “target” is construed as being aspirational, is this claim viable anymore?

[Plaintiffs’ Counsel]: *No, it’s not*. That’s their indefiniteness argument.

SUMF ¶ 23; Ex. 6 at 20:15-19 (emphasis added). The “target” PK and PD elements in the claims have now been definitively construed as aspirational, and Plaintiffs correctly recognized the effects of that construction under § 112, ¶ 2.

**A. The patents provide no boundaries regarding when a particular PK/PD value is “target[ed]”**

The claims of the ’698 and ’208 patents recite ranges of PK/PD values, including numerous PK values encompassing “±20%” and a mean steady-state interval of elevated intragastric pH “for about a 24 hour period ... that is at least about 60%.” SUMF ¶¶ 10, 12. That the dose forms merely “target,” and need not achieve, those values opens the claims to additional breadth of indeterminate scope beyond the stated ranges.

In other words, claims that target PK and PD values as a goal for the dosage forms lack the “objective boundaries” required under § 112, ¶ 2 because they provide no discernable standard for how far a particular formulation administered to any given patient or group of patients can stray from the stated goals and still infringe the claims. *See Interval Licensing*, 766 F.3d at 1371. By analogy, “targeting” a bullseye is not the same as hitting the bullseye. Indeed, one can hit a bullseye without targeting it, and two shots targeted at the same bullseye with the same

arrow can have different results under different conditions. Whether at a target range or in the clinic, persons of ordinary skill can only wonder whether any particular arrow or dose form “targets” a stated goal, regardless of their objective performance.

The record provides no basis to identify, with reasonable certainty, how much a formulation that “targets” the stated PK and PD values can deviate from those goals. In short, it is not clear what must be done to infringe the asserted claims, and if the infringing acts involve particular PK and PD results, it is not clear what those results must be. Because the ’698 and ’208 patents provide no answer to those questions, the claims are indefinite.

Nothing in the patents’ shared specification sheds any light on the objective scope of the claims—the term “target” appears only in passages that mirror the claim language itself, without further elaboration. SUMF ¶ 24. Similarly, the prosecution histories do not address what it means for a dose form to “target” a particular PK or PD value. SUMF ¶ 25.

Defendants’ expert Dr. Forrest explained that the examples disclosed in the ’698 and ’208 patents confirm that administering the disclosed dose forms resulted in varied PK values that often fell outside the ranges specified in the claims, SUMF ¶ 26, but the patents provide no reasonably certain limits on the breadth of permissible variation. In Example 1 of the patents’ specification, the claimed PN400/E20

formulation was administered to a group of patients according to the claimed methods, and the resulting PK/PD data were measured. SUMF ¶ 27. The patents' specification reported various mean or median PK and PD values observed in the study participants, and several of those values were incorporated into the claims. SUMF ¶ 28. As demonstrated by the specification, however, the claimed methods often failed to achieve the aspirational PK and PD results specified in the claims.

On their face, the claims of the '698 and '208 patents recite methods for administering the specified naproxen/esomeprazole dose forms to an individual patient. SUMF ¶ 29. The Court therefore concluded the PK and PD values in the claims apply to a single patient, "not to results from multiple individuals." ECF No. 82 at 6-7. Yet the results reported in the patents' specification show that many individual patients exhibited PK values well outside the ranges specified in the claims upon receiving the claimed dosing regimen. This is not an instance of a patentee merely pursuing claims narrower than the scope of the disclosure. Rather, the disclosed experimental results show that the disclosed and claimed methods fall short of achieving the "target" PK ranges recited in the claims in many individual patients, but offer no standard for determining how close is close enough.

For example, the minimum AUC found for the AM esomeprazole dose in the PN400/E20 study group was 188 hr\*ng/mL and the maximum AUC observed for the same dose was 2931 hr\*ng/mL—both well outside the claimed range of

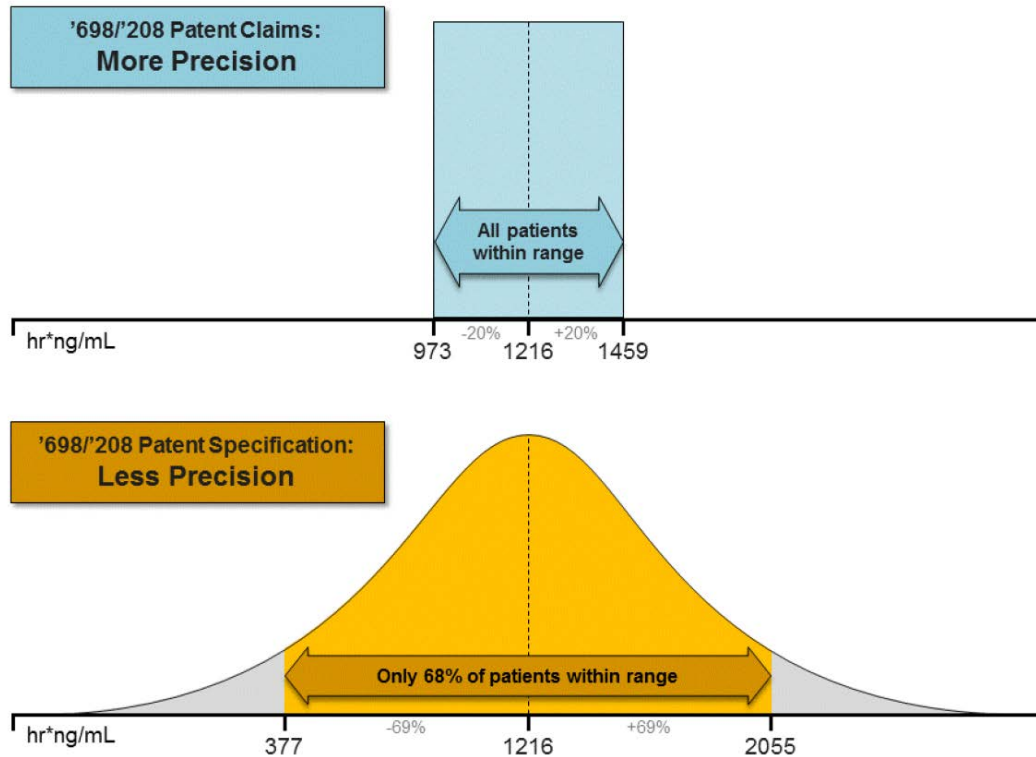
1216 hr\*ng/mL  $\pm$ 20% (*i.e.*, 973–1459 hr\*ng/mL). SUMF ¶ 30.

Moreover, the statistical data disclosed in the specification shows that the claimed PK and PD properties varied widely among study participants. For example, the reported coefficient of variation<sup>7</sup> for the patients' observed AUC values for the AM esomeprazole dose was  $\pm$ 69%, which means that only about 68% of the patient data fell within a range of 377-2055 hr\*ng/mL. SUMF ¶ 32. The discrepancy between the AUC range for the AM esomeprazole dose recited in the claims and the actual patient data reported in the specification is illustrated below:

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<sup>7</sup> Table 6 of the '698 and '208 patents' specifications expresses variation in terms of % CV, or coefficient of variation. SUMF ¶ 31. A coefficient of variation is defined as the standard of deviation of a sample, divided by the sample mean. SUMF ¶ 31. Large coefficients of variation reflect large interpatient variation. SUMF ¶ 31.





SUMF ¶ 32; Ex. 4 at ¶ 52. Other PK values recited in the claims showed even greater discrepancy from actual results during the disclosed study—for example, the reported coefficient of variation for the esomeprazole PM dose was  $\pm 84\%$ . SUMF ¶ 33.

Thus, the PK values disclosed in the specification demonstrate that administering the recited dose forms as claimed only sometimes achieved the targeted PK values. As described in the '698 and '208 patents, administering the naproxen-esomeprazole co-formulations as claimed can and does yield individual PK values well outside the  $\pm 20\%$  ranges recited in the claims, and the differences vary from patient to patient. SUMF ¶ 34. The '698 and '208 patents, however, provide no

reasonably certain boundaries on the breadth of permissible variation under the claims before one can conclude that the PK/PD results are not “targeted.”

The uncertainty of the scope of these claims is amplified when one considers Plaintiffs’ infringement allegations in this action. Plaintiffs’ theories of infringement boil down to bioequivalence; Plaintiffs contend that Defendants infringe because their proposed ANDA product is bioequivalent to Plaintiffs’ reference listed drug (Vimovo<sup>®</sup>), SUMF ¶ 20, which has a formulation that matches the PN400/E20 formulation in the ’698 and ’208 patents. Thus, according to Plaintiffs, Defendants’ bioequivalent ANDA products would present the same PK and PD profile as Plaintiffs’ formulations. But as discussed above, the PK characteristics of that formulation vary so widely relative to the claims that the results of administering the PN400/E20 formulation frequently fall outside of the recited ranges. And even if a skilled artisan could extrapolate PK and PD characteristics from the bioequivalence of Defendants’ formulations, Plaintiffs have offered no evidence that anyone has “target[ed]” the claimed PK and PD values. SUMF ¶ 21.

Thus, given the demonstrated gulf between real-world variation in PK values and the ranges in the claims, and the pervasive ambiguity about what and how much beyond the stated ranges the term “target” will indulge, the patents afford no reasonable certainty on where the ultimate boundaries of the claims lie and whether the proposed ANDA products or any others would infringe the patents-in-suit.

**B. The patents fail to specify with reasonable certainty who “target[s]” the claimed PK and PD values**

The claims create further ambiguity because they fail to specify with reasonable certainty who or what must “target” the PK and PD values in the recited methods. To continue the analogy to targeting an arrow: Is it the archer? The fletcher? Or the arrow itself?

The literal claim language appears to specify that *the dose form itself* “targets” the various PK and PD properties. *E.g.*, Ex. 1 at 52:39 (reciting that “the AM and PM unit dose forms target” specified PK values). While confounding on its face—it is difficult to understand how an inanimate drug composition could set any goal, whether PK/PD values or otherwise—that possibility reflects the actual language chosen by the patentee. Alternatively, one could plausibly envision that under the claimed methods, the prescribing physician must “target” the recited effects through administering the specified regimen. But that is problematic given that the formulation and dosing regimen are fixed and the prescribing physician cannot affect the PK and PD values arising in an individual patient beyond choosing whether to administer the drug. Still another possibility might identify the relevant entity as the drug maker, preparing a dose form in hopes of targeting a particular PK/PD profile. But, as in this case, a drug maker might develop an accused product without setting any of the recited PK/PD ranges as a goal, or without knowledge of those ranges at all.

Those various alternative possibilities would require different acts from different actors under the claims, and nothing in the claims, the specification, or the file history provides guidance as to which is correct. A claim is indefinite where, as here, “its language might mean several different things and no informed and confident choice is available among the contending definitions.” *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (internal quotation marks omitted) (quoting *Nautilus*, 134 S. Ct. at 2130 n.8); *see Dow Chem. Co. v. Nova Chems. Corp.*, 803 F.3d 620, 634-35 (Fed. Cir. 2015) (holding that the existence of multiple approaches leading to different results with no intrinsic guidance as to which should be used rendered claims indefinite).

The record provides no basis to identify, with reasonable certainty, who or what “targets” the stated PK and PD values or how much the results of such targeting can deviate from those goals and still fall under the claims. It is not sufficient that the Court was able to construe “target” as used in the claims. The fact that a court “can ascribe *some* meaning to a patent’s claims” does not satisfy § 112, ¶ 2. *Nautilus*, 134 S. Ct. at 2130. “Even if a claim term’s definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.” *Halliburton*, 514 F.3d at 1251. The aspirational “target” terms do not delimit the claims’ scope with reasonable certainty and indeed impose no limit at all—those terms instead inde-

terminately expand the boundaries of the claims by qualifying the various ranges as goals rather than requirements.

As noted, the “target” terms appear in independent claim 1 of the ’698 patent and independent claim 1 of the ’208 patent, rendering those claims indefinite for the reasons set forth above. Dependent claims 2-7 of each patent depend directly or indirectly from their respective independent claims and are therefore invalid for the same reasons under § 112, ¶ 2. SUMF ¶¶ 11, 13; *see Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1102 (Fed. Cir. 2014) (“Since these terms are found in the only independent claim of the ’313 patent, we conclude that all claims in the ’313 patent are invalid.”).

## **V. Conclusion**

For the foregoing reasons, the Mylan (Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd., and Mylan Inc.) and DRL (Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd.) defendants request entry of summary judgment that claims 1-7 of the ’698 patent and claims 1-7 of the ’208 patent are invalid for indefiniteness under § 112, ¶ 2.

Respectfully submitted,

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