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) [redacted] **(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.[1] 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

[1] 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.

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