### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,

and

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC. Petitioners,

v.

HORIZON THERAPEUTICS, INC., Patent Owner.

Case IPR2015-01117<sup>1</sup> Patent 8,642,012

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### PETITIONERS' MOTION TO EXCLUDE

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Pharmaceuticals, Inc., has been joined with this proceeding.



<sup>&</sup>lt;sup>1</sup> Case IPR2015-00283, instituted on a petition filed by Lupin Ltd. and Lupin

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### I. <u>INTRODUCTION</u>

Pursuant to 37 C.F.R. §§ 42.64(c) and 42.61(a) and the Federal Rules of Evidence, and the Scheduling Orders (Paper Nos. 14 and 19), Petitioners Par Pharmaceutical, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Petitioners"), respectfully request that the Board exclude Patent Owner Horizon Therapeutics, Inc.'s Exhibits 2027 and 2028, and that the Board exclude each instance where unsupported attorney argument is made by Patent Owner in its Response (Paper No. 25) regarding what a person of ordinary skill in the art would have thought (understood, considered, concluded, etc.). Petitioner Par timely objected to this evidence on April 4, 2016.<sup>2</sup>

### II. EXHIBIT 2027 (AMBROSE/SHERWIN '33)

Patent Owner cites Ambrose/Sherwin '33 (Exhibit 2027) as a publication that allegedly discredited Sherwin '19 (Exhibit 1016), which reported a conversion of PAA to UPAGN of about 50% to 67%. (Paper No. 25 at 5, 45; Paper No. 30 at 12.) Patent Owner's reliance on Ambrose/Sherwin '33 (Exhibit 2027) should be excluded for at least two separate reasons.

<sup>&</sup>lt;sup>2</sup> Petitioners Lupin Ltd. and Lupin Pharmaceuticals, Inc., were joined with this proceeding on June 8, 2016. Par's motion to file such objections out of time is currently pending. (Paper No. 34.)



First, Ambrose/Sherwin '33 (Exhibit 2027) should be excluded as lacking relevance under Fed. R. Evid. 401 and 402. Despite the fact that Ambrose/Sherwin '33 (Exhibit 2027) never even cites Sherwin '19 (Exhibit 1016), Patent Owner, based on mere speculative and conclusory attorney argument, contends that Ambrose/Sherwin '33 (Exhibit 2027) discredited Sherwin '19 (Exhibit 1016). The methodologies used and questions addressed in Sherwin '19 (Exhibit 1016) and Ambrose/Sherwin '33 (Exhibit 2027) are different, however. (Paper No. 30 at 14.) There is no evidence in the record that Ambrose/Sherwin '33 (Exhibit 2027) replicated the studies in Sherwin '19 (Exhibit 1016). Instead, Ambrose/Sherwin '33 (Exhibit 2027) reported results that conflict with Patent Owner's conclusions. (Paper No. 30 at 14.) Accordingly, Ambrose/Sherwin '33 (Exhibit 2027) is irrelevant under Fed. R. Evid. 401 and inadmissible under Fed. R. Evid. 402 as it does not have the tendency to make a fact more or less probable.

Second, even if Ambrose/Sherwin '33 (Exhibit 2027) is deemed relevant, it should be excluded from the record to prevent confusion of the issues. *See Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1183 (Fed. Cir. 2008). Therefore, it should be excluded under Fed. R. Evid. 403.



# III. EXHIBIT 2028 (E.D. TEX. JOINT CLAIM CONSTRUCTION CHART)

Patent Owner cites to the joint claim construction chart submitted in the pending district court litigation in support of its argument for the claim term "about 60%." (Paper No. 25 at 27.) Evidence is relevant if (1) "it has any tendency to make a fact more or less probable than it would be without the evidence; and" (2) "the fact is of consequence in determining the action." Fed. R. Evid. 401. The district court's construction has no relevance here because it was made using a different claim construction standard and would merely confuse the issue and cause undue prejudice. Accordingly, Exhibit 2028 is improper under Fed. R. Evid. 401, 402, and 403. Innolux Corp. v. Semiconductor Energy Laboratory Co., Ltd., No. IPR2013-00028, 2013 WL 5970146, at \*6 (P.T.A.B. Apr. 30, 2013) (rejecting Patent Owner's reliance on a district court's construction of a term because that construction "was performed under a different standard with different considerations and constraints).

## IV. IMPROPER ATTORNEY ARGUMENT

It is well settled that argument of counsel cannot take the place of evidence lacking in the record. *See, e.g., In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984); *Euro-Pro Operating LLC v. Acorne Enterprises, LLC*, No. IPR2014-00351, 2015 WL 4240982, at \*9



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