

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2016-00829

Patent 9,095,559

**PATENT OWNER'S OPPOSITION TO PETITIONER'S
MOTION TO EXCLUDE**

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I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.64 and 42.23 and the Board’s Scheduling Order (Paper No. 8), Patent Owner Horizon Therapeutics, LLC (“Patent Owner” or “Horizon”) files this opposition to Lupin Ltd. and Lupin Pharmaceuticals Inc.’s (collectively “Petitioner” or “Lupin”) Motion to Exclude Evidence (Paper No. 35). In its motion, Petitioner improperly seeks to exclude relevant evidence from the record, including testimony of Horizon’s expert concerning the state of the prior art.¹ As explained below, Petitioner’s motion is meritless and would erroneously remove evidence from the record that rebuts its obviousness argument. Moreover, Petitioner’s arguments for exclusion of evidence go to the weight of the evidence rather than its admissibility, which is not appropriate in a motion to exclude.

Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co., CBM2012-00002, Paper 66 at

¹ Petitioner refers to Exhibit 2019 as a “purported” copy of a 2012 article by Häberle et al. Petitioner did not object, however, to this exhibit on the basis of authenticity (Paper No. 28 at 6) or move to exclude it on this basis (Paper No. 35). Similarly, Petitioner refers to Exhibit 2041 as a “purported” copy of the Prescribing Information for RAVICTI[®], but did not move to exclude this exhibit for lacking authenticity (Paper No. 35). Any implied objections to these exhibits for lack of authenticity should therefore be rejected.

61 (P.T.A.B. Jan. 23, 2014); *see also* 37 C.F.R. § 42.64(c). For these reasons, Petitioner's motion is legally defective and should be denied.

II. EXHIBIT 2019 IS RELEVANT AND ADMISSIBLE

Petitioner objects to Exhibit 2019 ("Häberle") as irrelevant and unduly prejudicial because it published after the priority date of the '559 patent and/or is cumulative of other evidence. But Häberle is squarely relevant under FRE 401 and 402 because it reflects prior art guidelines for urea cycle disorder ("UCD") treatment that conflict with Petitioner's theory that a person of skill in the art ("POSA") would have been motivated to perform the methods recited in the challenged claims. *See* FRE 401 (evidence being relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence").

Petitioner's assertion that Häberle is not relevant because it fails to establish the prior art practices of a POSA is inconsistent with the teachings of the reference itself. Häberle is titled "Suggested guidelines for the diagnosis and management of urea cycle disorders," and provides that "[d]evelopment of these guidelines spanned the time period, **October 2008 until August 2011,**" which is immediately prior to the September 30, 2011, priority date of the '559 patent. (Ex. 2019 at 2 (emphasis added).) Thus, although published on May 29, 2012, Häberle exemplifies the state of the art with respect to UCD treatment guidelines prior to the '559 patent priority date and, thus, is relevant and admissible. *See e.g., Gould*

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