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 IPR2017-01160
Patent 9,326,966

PETITIONERS' MOTION TO EXCLUDE EVIDENCE

I. Statement of Precise Relief Requested

Pursuant to 37 C.F.R. § 42.64(c), the Board's Scheduling Order (Paper 11), and the Federal Rules of Evidence, Petitioners Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Petitioners") hereby move to exclude Patent Owner's Exhibits 2019 and 2041, and the portions of the Declaration of Dr. Enns (Ex. 2006) that rely on Exhibit 2019.

II. Identification of Original Objections

On October 13, 2017, Petitioners timely filed objections to Exhibits 2019 and 2041. (Paper 12 at 4, 7-8.) Petitioners asserted that Exhibits 2019 and 2041 were, *inter alia*, dated after September 30, 2011, and thus irrelevant and prejudicial under Federal Rules of Evidence ("FRE") 402 and 403, respectively, to the extent they were relied upon for any teaching prior to September 30, 2011. (*Id.*) Petitioners also objected to the Declaration of Dr. Enns (Ex. 2006) to the extent it includes or relies on such irrelevant information or information the probative value of which is substantially outweighed by the danger of unfair prejudice, wasting time, or needlessly presenting cumulative evidence. (*Id.* at 3.)

III. Identification of Where Patent Owner Relied Upon Evidence

A. Exhibit 2019

Exhibit 2019 is a purported copy of a 2012 article by Häberle *et al.*, entitled *Suggested Guidelines for the Diagnosis and Management of Urea Cycle Disorders*, published in ORPHANET JOURNAL OF RARE DISEASES.

In its Patent Owner's Response (Paper 19), Patent Owner cited Exhibit 2019 in support of the following assertions regarding the purported common practices of a person of ordinary skill in the art at the time of the alleged invention:

- "Clinicians only considered plasma ammonia levels well above the upper limit of normal as cause to take further action." (Paper 19 at 10.) Dr. Enns made a similar assertion in Ex. 2006 at ¶ 45 (cited at Paper 19 at 10).
- "When plasma ammonia levels are above the upper level of normal, which is the highest level of plasma ammonia in the range of normal values, a clinician may take action by initiating further evaluation or a change in treatment." (Enns Declaration (Ex. 2006) at ¶ 44.)
- "Moreover, nothing supports the assumption that a physician would have been concerned or taken any action when a patient had a normal plasma ammonia level; or that the action would be to increase the dosage of nitrogen scavenging medication as opposed to focusing on adjustments to the patient's diet, health, or amino acid supplements. Dr. Vaux entirely

omits any discussion of these standard components of treating a urea cycle disorder patient." (Enns Declaration (Ex. 2006) at ¶ 91 (citations omitted).)

- "[A] normal level was viewed as acceptable by a POSA because treating a patient with UCD involved such a difficult balance between diet, amino acid supplements, nitrogen scavenging drugs, and the patient's health." (Paper 19 at 26; Enns Declaration (Ex. 2006) at ¶ 104.)
- "One of ordinary skill treating a patient with urea cycle disorder was constantly concerned about maintaining normal growth and avoiding hyperammonemic episodes." (Enns Declaration (Ex. 2006) at ¶ 104.)
- "In addition, Häberle includes a table of the suggested actions for a POSA to take in rendering treatment to symptomatic patients based on their ammonia level. Notably the Table does not suggest any action when a patient exhibits normal plasma ammonia. When the ammonia level rises to 'above upper limit of normal,' Häberle recommends stopping protein intake, administering IV glucose, and continued monitoring of plasma ammonia, but significantly does not recommend increasing the dosage of nitrogen scavenging drugs. It is only once the ammonia level rises to the next stage, well above the ULN (>100 μmol/L), that Häberle recommends increasing the dosage of nitrogen scavenging drugs." (Paper 19 at 27-28 (citations and emphasis omitted).) For this proposition, Patent Owner also

cited Dr. Enn's declaration, including ¶ 109, which in turn relies on Exhibit 2019.

- "Furthermore, the prior art taught clinicians to conduct a holistic evaluation of the patient's diet, health, and supplements to avoid unnecessary increases in a patient's dosage." (Paper 19 at 29). For this proposition, Patent Owner also cited Dr. Enn's declaration, including ¶¶ 90-91, which in turn rely on Exhibit 2019.
- "While Häberle acknowledges that LPI may cause hyperammonemia in certain cases, it nonetheless expressly excludes LPI from its treatment guidelines for UCDs because of the condition's only 'tangential relationship with UCD.'" (Paper 19 at 45.) Dr. Enns made a similar assertion in Ex. 2006 at ¶¶ 118-19.

Patent Owner and Dr. Enns also cited Exhibit 2019 for the following general propositions regarding urea cycle disorders:

- "It is estimated that only one out of 35,000 live births have this disorder, resulting in only 113 new patients in the U.S. per year." (Paper 19 at 7; Enns Declaration (Ex. 2006) at ¶ 35.)
- "Because of the rarity of these disorders (only approximately 113 new patients per year) and high mortality rate, a general pediatrician would not

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