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 B2

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 8), 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 February 17, 2017, Petitioners timely filed objections to Exhibits 2019 and 2041. Paper 28 at 6, 11. 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. 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.

Patent Owner did not respond, with supplemental evidence or otherwise, to Petitioners' objections to these exhibits.

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 26), 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 26 at 12.) Dr. Enns made a similar assertion in Ex. 2006 at ¶ 43 (cited at Paper 26 at 12).
- "[N]othing 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 have been to increase the dosage of nitrogen scavenging medication as opposed to focusing on adjusting the patient's diet, health, or amino acid supplements. Dr. Vaux entirely omits any discussion of the variable and multifaceted components of treating UCD patients." (Paper 26 at 34 (citations omitted).) For this proposition, Patent Owner also cited Dr. Enns's declaration, including ¶¶ 35-37, 41 and 87, which in turn rely on Exhibit 2019.

- "[T]he prior art gave no indication regarding what should be adjusted or changed in a patient with a normal plasma ammonia level. Dr. Enns further explains that diet was the cornerstone of UCD treatment, especially because diet was one of the reasons for plasma ammonia levels rising during the day. . . . The prior art reflects Dr. Enns's opinion and teaches stopping protein intake when a patient's plasma ammonia level goes above the upper limit of normal; not increasing any medication dosage." (Paper 26 at 35 (citations omitted).) For these propositions, Patent Owner also cited Dr. Enns's declaration, including ¶¶ 37 and 87, which in turn rely on Exhibit 2019.
- "Persons skilled in the art viewed a normal plasma ammonia level as acceptable because treating a UCD patient involved a difficult balance between diet, amino acid supplements, nitrogen scavenging drugs, and the patients' health. The skilled artisan treating a patient with a urea cycle disorder was constantly concerned about maintaining normal growth and avoiding hyperammonemic episodes." (Paper 26 at 40 (citations omitted).) For these propositions, Patent Owner also cited Dr. Enns's declaration, including ¶¶ 34, 35 and 113, which in turn rely on Exhibit 2019.
- "In another example, Haberle includes a table of the suggested actions to take in symptomatic patients based on their ammonia level. The Table does

not list any action to take when a patient is within a normal range of plasma ammonia. When the ammonia level is 'above upper limit of normal,' Haberle recommends stopping protein intake, IV glucose, and continued monitoring of plasma ammonia. Only at the next level, when ammonia level is even higher than the upper limit of normal, does the table recommend increasing the dosage of nitrogen scavenging drugs." (Paper 26 at 42-43 (citations omitted).) For these propositions, Patent Owner also cited Dr. Enns's declaration, ¶ 118, which in turn relies on Exhibit 2019.

- "For this reason, clinicians looked at the total picture of a UCD patient when considering treatment including diet, health, and supplements, and did not unnecessarily increase a patient's dosage." (Paper 26 at 45.) For this proposition, Patent Owner also cited Dr. Enns's declaration, ¶ 87, which in turn relies on Exhibit 2019.

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

- "It is estimated that one out of only 35,000 live births have this disorder, resulting in only 113 new patients in the U.S. per year." (Paper 26 at 8; Enns Declaration (Ex. 2006) at ¶ 33.)
- "Because of the rarity of this disorder [UCDs] (only approximately 113 new patients per year) and high mortality rate, a general pediatrician would not

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