Paper No. ____
Filed: March 31, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA INC., INNOPHARMA LLC,
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,
LUPIN LTD., and LUPIN PHARMACEUTICALS, INC.,

Petitioners

v.

SENJU PHARMACEUTICAL CO., LTD.,

Patent Owner.

Case IPR2015-00903 (Patent 8,129,431 B2)[1]

PATENT OWNER'S MOTION FOR OBSERVATION REGARDING CROSS-EXAMINATION OF REPLY WITNESSES DR. PAUL A. LASKAR, Ph.D. AND IVAN T. HOFMANN, CPA/CFF, CLP

[1] IPR2015-01871 has been joined with this proceeding.

Patent Owner Senju Pharmaceutical Co., Ltd. et al. ("Senju"), submits this Motion for Observation Regarding Cross-Examination of Dr. Paul A. Laskar and Mr. Ivan T. Hofmann, pursuant to the Scheduling Order (Paper No. 17, filed Aug. 7, 2015), and Joint Stipulation to Extend Due Dates 1, 2, 4 & 5 (Paper No. 29, filed Dec. 10, 2015).

Observation #1

In Ex. 2272, at 20:17-22, Dr. Laskar testified that "I have not held myself as an expert in [medicinal or organic chemistry], only in pharmaceutical development and formulation development." *See also* EX2272, 14:22-25:7 (additional testimony on Dr. Laskar's background and qualifications). This testimony is relevant to the statements and conclusions in Dr. Laskar's reply declaration, Ex. 1104, ¶¶ 2-38, regarding and relying on the use of chemistry, and in Petitioner's Reply[2] at pp. 3, 5-6, 12-14. This testimony is relevant to the weight and understanding to be given to Dr. Laskar's statements and conclusions in his declaration because it establishes his lack of qualification to testify on the subject matter for which he has offered opinions in his reply declaration.

Observation #2

In Ex. 2272, at 68:20-69:7, Dr. Laskar testified that the formulations of the '431 and '290 patents as well as the formulations of Yasueda (EX1012) that

[2]Petitioner's Reply is Paper No. 49, filed March 18, 2016.

contain tyloxapol "do not contain any traditional antioxidant or compound that functions in an antioxidant capacity." This testimony is relevant to the statements and conclusions in Dr. Laskar's reply declaration, Ex. 1104, ¶¶ 4-34, and in Petitioner's Reply at pp. 12-14. The testimony is relevant to the weight and understanding to be given to Dr. Laskar's statements and conclusions because his testimony that tyloxapol is not a "traditional antioxidant or compound that functions in an antioxidant capacity" contradicts the statements throughout ¶¶ 4-34 of his declaration regarding tyloxapol allegedly being an antioxidant and having "antioxidant properties."

Observation #3

In Ex. 2272, at 29:14-20, when asked whether the claimed formulations of the '431 and '290 patents contain metals or metal cations, Dr. Laskar testified: "Specifically, the claims refer to salts, of which -- and I recall predominantly sodium salts. And so, therefore, the sodium is present as the sodium cation." *See also* EX2272, 29:14-20 (on how metals and metal cations differ). This testimony is relevant to the statements in Dr. Laskar's reply declaration, Ex. 1104, ¶¶ 21-22, regarding the alleged teachings in the Merck Index (EX1089) and Remington: The Science and Practice of Pharmacy (19th Ed.) (EX1106) that tyloxapol is "oxidized by metals," and corresponding arguments in Petitioner's Reply at pp. 13-14. This testimony is relevant because it establishes that the alleged teachings of the Merck

Index and Remington are inapplicable to the ’431 and ’290 patents because the claimed formulations contain metal cations, not metals.

Observation #4

In Ex. 2272, at 32:17-33:1, when asked whether the claimed formulations of the ’431 and ’290 patents are formulated for nasal administration, Dr. Laskar testified: “The claims themselves, as I recall, do not refer to routes of administration other than ophthalmic.” At 33:3-9, he testified that “[t]he formulations as -- in the claims [of the ’431 and ’290 patents] do not explicitly indicate their use for pharyngeal administration.” This testimony is relevant to the statements regarding the alleged behavior of tyloxapol in liquid preparations for nasal and/or pharyngeal applications in Dr. Laskar’s reply declaration, Ex. 1104, ¶¶ 23-27, and in Petitioner’s Reply at pp. 12-14. This testimony is relevant because it establishes that the alleged behavior of tyloxapol in liquid preparations for nasal and/or pharyngeal applications is irrelevant to the subject matter of the ’431 and ’290 patents because the claimed formulations are formulated for ophthalmic administration, not nasal or pharyngeal administration.

Observation #5

In Ex. 2272, at 37:18-38:3, Dr. Laskar testified that Fu (EX1011) “does not explicitly use the word ‘tyloxapol.’” At 38:4-46:10, Dr. Laskar acknowledged that in prior testimony he stated that: (1) “[Fu] does not mention tyloxapol by name”;

(2) "[Octoxynol 40 and tyloxapol] do have different structures"; (3) "[Octoxynol 9 and tyloxapol] do have different chemical structures"; and (4) based on Schott (EX1024), " I'm sure that -- that a polymer chemist would -- would say that [tyloxapol is] not a true oligomer [of Octoxynol 9]." This testimony is relevant to the statements in Dr. Laskar's reply declaration, Ex. 1104, ¶¶ 2-3, and in Petitioner's Reply at p. 6. This testimony is relevant to the weight and understanding to be given to the statements regarding tyloxapol allegedly "fall[ing] within the disclosure of Fu," because Dr. Laskar testified that tyloxapol is not expressly disclosed in Fu and that there are differences between tyloxapol and the surfactants that Fu actually discloses.

Observation #6

In Ex. 2272, at 52:14-17, Dr. Laskar testified that Octoxynol 9 and p-(1,1,3,3-tetramethylbutyl) phenol "differ structurally." At 98:8-11, Dr. Laskar testified that "p-(1,1,3,3-tetramethylbutyl) phenol is the original alcohol monomer from which tyloxapol is made." This testimony is relevant to the statements in Dr. Laskar's reply declaration, Ex. 1104, ¶¶ 2-3, n.4, and in Petitioner's Reply at p. 6, regarding Fu's alleged inclusion of tyloxapol. This testimony is relevant to the weight and understanding to be given to Dr. Laskar's opinion that tyloxapol allegedly is an oligomer of Octoxynol 9 (EX1104, n.4; *see also* EX1003, ¶¶ 36, 70, 105-106), because Dr. Laskar testified that the monomeric unit of tyloxapol differs

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