Paper No. _____
Dated: May 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

IPR2015-01097 (US Patent No. 8,751,131)
IPR2015-01100 (US Patent No. 8,927,606)
IPR2015-01105 (US Patent No. 8,871,813)[1]

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

[1] The word-for-word identical paper is filed in each proceeding identified in the heading. IPR2016-00089 has been joined with IPR2015-01097; IPR2016-00091 has been joined with IPR2015-01100; and IPR2016-00090 has been joined with IPR2015-01105. Unless otherwise noted, citations to exhibits and papers herein apply with equal force to those filed in each proceeding identified in the heading.

Patent Owner Senju Pharmaceutical Co., Ltd. et al. ("Senju"), submits this Patent Owner's Motion for Observation Regarding Cross-Examination of Dr. M. Jayne Lawrence and Mr. Ivan T. Hofmann, pursuant to the Scheduling Order, Paper No. 10 (filed October 27, 2015), and the Joint Stipulation Adjusting Due Dates 1, 2 & 4, Paper No. 16 (filed January 6, 2016).

Observation #1 - In Ex. 2342, at 10:21-11:11, Dr. Lawrence acknowledged that it was her prior testimony that she had never been qualified by any court or by the U.S. Patent and Trademark Office as an expert in chemistry. At 11:12-20, Dr. Lawrence testified that she is not an expert in medicinal chemistry, organic chemistry, or antioxidant chemistry. *See also* EX2342, 9:11-14:10, 16:3-23:10 (additional testimony on Dr. Lawrence's background and qualifications). This testimony is relevant to the statements and conclusions in Dr. Lawrence's reply declaration, Ex. 1094, ¶¶ 31, 33, 36-37, 48-49, 51-52, 73, n.5, regarding and relying on chemistry, and in Petitioners' Reply[2] at pp. 1, 6-9. This testimony is relevant to the weight and understanding to be given to Dr. Lawrence's statements and conclusions in her declaration because it establishes her lack of qualification to testify on the subject matter for which she has offered opinions.

Observation #2 - In Ex. 2342, at 179:20-180:1, when asked whether the

[2] Petitioners' Reply ("Reply") is Paper No. 35 in IPR2015-01097, IPR2015-01100, and IPR2015-01105. All were filed April 22, 2016.

claimed formulations of the ’290, ’131, ’813, and ’606 patents contain metals or metal cations, Dr. Lawrence testified: “They contain sodium cation.” *See also* EX2342, 179:11-19 (on how metals and metal cations differ). This testimony is relevant to the statements in Dr. Lawrence’s reply declaration, Ex. 1094, ¶ 31, n.5, regarding the alleged teachings in the Merck Index (EX1096) and Remington: The Science and Practice of Pharmacy (1995) (EX1051) that tyloxapol is “oxidized by metals,” and the corresponding arguments in the Reply at p. 7. This testimony is relevant because it establishes that the alleged teachings of the Merck Index and Remington are inapplicable to the ’290, ’131, ’813, and ’606 patents (the “patents-at-issue”) because the claimed formulations contain metal cations, not metals.

Observation #3 - In Ex. 2342, at 180:21-181:8, Dr. Lawrence testified as follows: “Q. . . . The claimed formulations of the ’290, ’131, ’813, and ’606 patents are not formulated for nasal administration; correct? A. That’s my understanding, yes. Q. The claimed formulations of the ’290, ’131, ’813, and ’606 patents are not formulated for pharyngeal administration; correct? A. Yes, I believe that’s -- yes, that’s correct.” *See also* EX2342, 180:2-5 (the patents-at-issue are formulated for ophthalmic 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. Lawrence’s reply declaration, Ex. 1094, ¶ 31, n.5, and in the Reply at p. 7. 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 patents-at-issue because the claimed formulations are formulated for ophthalmic administration, not nasal or pharyngeal administration.

Observation #4 - In Ex. 2342, at 32:17-33:5, Dr. Lawrence agreed that Ogawa (EX1010) "identified the formulations of examples 6, 7, and 8 as not forming red insoluble matters and described them as stable, excellent for a long period of time" and testified that the formulations of Ogawa examples 6, 7, and 8 did "not [have any problems with instability or degradation] under the conditions tested." *See also* EX2342, 62:22-64:3. At 33:6-34:2, Dr. Lawrence further testified: "Q. In your view, the Ogawa '225 patent solved bromfenac's stability problem by showing that, under the conditions of examples 6, 7, and 8, the formulations were stable; correct? . . . THE WITNESS: The patent states under the one condition that the formulations were tested for. That is 60 degrees, say, at four weeks. It calls the formulations excellently stable." This testimony is relevant to the statements in Dr. Lawrence's reply declaration, Ex. 1094, ¶¶ 22, 26-27, 31, 37-42, and in the Reply at pp. 1-9. This testimony is relevant to the weight and understanding to be given to Dr. Lawrence's declaration statements regarding the alleged motivation of a person of ordinary skill in the art ("POSA") "to substitute tyloxapol for polysorbate 80" in Ogawa's example 6.

Observation #5 - In Ex. 2342, at 221:2-14, Dr. Lawrence testified that Doi (EX2030) "does not" teach the use of tyloxapol in any formulation. At 222:1-4, when asked if the alkylphenols of the Doi patent all contain an OH group directly attached to the phenyl ring, Dr. Lawrence testified "[t]hat is correct." And when asked whether she agreed with the prior testimony of Dr. Laskar[3] that "[t]he OH group [in tyloxapol] is not directly attached [to the phenyl ring]," Dr. Lawrence testified that "I think the average structure looks like that" and that she had not done any testing to confirm that any individual tyloxapol molecules would have a free hydroxyl on the ring. EX2342, 224:18-225:9. This testimony is relevant to the statements in Dr. Lawrence's reply declaration, Ex. 1094, ¶¶ 32-33, and in the Reply at pp. 6-7. This testimony is relevant to the weight and understanding to be given Dr. Lawrence's opinion that Doi teaches a "class of compounds to which tyloxapol belongs," because Doi does not teach the use of tyloxapol and the alkylphenols disclosed by Doi are structurally different from tyloxapol.

Observation #6 - In Ex. 2342, at 181:11-186:17, Dr. Lawrence agreed that the '956 application (EX1097) and WO '610 (EX1098) concern "a method and composition for treatment" "of snoring, sleep apnea, or sudden infant death syndrome and for improvement of nasal breathing" "by nasal and/or pharyngeal

[3] Dr. Laskar is the expert for the Petitioner in separate, but related, IPR proceedings involving the same family of patents.

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