

Paper No. \_\_\_\_  
Filed: April 29, 2016

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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LUPIN LTD. and LUPIN PHARMACEUTICALS INC.  
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.  
Patent Owner.

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Case IPR2015-01099 (Patent 8,669,290 B2)

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**PATENT OWNER'S OBJECTIONS  
UNDER 37 C.F.R. § 42.64(B)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner objects to Exhibits 1094 and 1122, served with Petitioners' Reply (Paper Nos. 32 & 34 (Confidential Version)). Patent Owner objects to Exhibit 1094 (Reply Declaration of M. Jayne Lawrence, Ph.D.) because portions of the Exhibit lack relevance (FRE 402), as they exceed the proper scope of Petitioners' Reply. 37 C.F.R. § 42.23(b) states “[a] reply may only respond to arguments raised in the corresponding . . . patent owner response.” As explained in the Trial Practice Guide, “new evidence necessary to make out a prima facie case for [] unpatentability” and “new evidence that could have been presented in a prior filing” are improper. 77 Fed. Reg. 48767. “[A] reply that raises a new issue or belatedly presents evidence will not be considered and may be returned.” *Id.* For instance, paragraphs 29, 31-33, 37-38, 40, and 80, as well as footnote 5, of Exhibit 1094 are all directed to new testimony from Dr. Lawrence that tyloxapol is allegedly an antioxidant (¶¶ 31-33, 37-38, and footnote 5); the specific NSAIDs diclofenac and ketorolac are allegedly subject to oxidative degradation (¶ 31); tyloxapol is allegedly less toxic to the ocular membranes (¶ 29); and that too much non-ionic surfactant, specifically polysorbate 80, allegedly reduces the effectiveness of benzalkonium chloride (¶ 80). That Petitioner knew bromfenac degraded by oxidation and that this new testimony regarding the alleged use of an antioxidant could have been previously presented is

confirmed and recognized in Dr. Lawrence's initial declaration (EX1005), where at ¶ 66(e) it states that stabilizers, such as antioxidants, are added to ophthalmic formulations to decrease the decomposition of the active ingredient and that Ogawa Example 6 uses the stabilizer sodium sulfite (EX1005, ¶186, last sentence), a well-known antioxidant.

Patent Owner further objects to Exhibit 1094 because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence and arguments therein (FRE 403). As explained above, at least paragraphs 29, 31-33, 37-38, 40, 80, and footnote 5, of Exhibit 1094, containing Dr. Lawrence's new testimony, exceed the proper scope of Petitioners' Reply and are thus irrelevant, untimely, prejudicial, and objectionable under FRE 402 and FRE 403.

Patent Owner further objects to Exhibit 1094 under FRE 702 and 37 C.F.R. § 42.65 because the opinions offered by Dr. Lawrence in her reply declaration, specifically at least paragraphs 31, 33, 36-37, 48-49, 51-52, and 73, and footnote 5, evidence a complete lack of expertise in organic or medicinal chemistry and thus Dr. Lawrence is not qualified by knowledge, skill, experience, training or education necessary to form an opinion. Patent Owner further objects to Exhibit 1174 and 1176, upon which Dr. Lawrence relies on for her unqualified opinions in

paragraphs 36 and 48, as irrelevant, untimely, prejudicial and objectionable under FRE 402 and FRE 403.

Patent Owner objects to Exhibit 1122 (Reply Declaration of Ivan Hofmann) under FRE 702 and 37 C.F.R. § 42.65 because the opinions offered by Ivan Hofmann in his reply declaration, specifically at least paragraphs 25-27, 42, 59-60, 62, 69-70, 72-80, 86-87, 99, 102, and 110, discuss subject matter beyond economics for which Mr. Hofmann is not qualified by knowledge, skill, experience, training or education necessary to form an opinion.

Patent Owner also objects to Exhibits 1096, 1097, 1098, 1100, 1101, 1102, 1172, and 1173, which Dr. Lawrence discusses in detail in Exhibit 1094 in paragraphs 31, 33 and 37, and footnote 5, in support of her new testimony that tyloxapol is allegedly an antioxidant. Patent Owner further objects to Exhibit 1169, which Dr. Lawrence discusses in paragraph 29 of Exhibit 1094, in support of her new testimony that tyloxapol is allegedly less toxic to ocular membranes. Patent Owner further objects to Exhibits 1170 and 1171, which Dr. Lawrence discusses in Exhibit 1094 in paragraph 31, in support of her new testimony that the specific NSAIDs diclofenac and ketorolac are allegedly subject to oxidative degradation. Exhibits 1096, 1097, 1098, 1100, 1101, 1102, 1169, 1170, 1171, 1172, and 1173 all lack relevance (FRE 402), as they exceed the proper scope of

Petitioners' Reply. *See* 37 C.F.R. § 42.23(b); 77 Fed. Reg. 48767. Patent Owner further objects to these Exhibits because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence therein (FRE 403).

Patent Owner objects to Exhibits 1107, 1108, and 1109, which Petitioners use to allegedly support a new argument in Petitioners' Reply (Paper Nos. 32 & 34) that a person of ordinary skill in the art would expect switching polysorbate 80 with tyloxapol to improve preservative efficacy because polysorbate 80 allegedly was known to neutralize BAC. Patent Owner also objects to Exhibits 1179 and 1180, which Dr. Lawrence discusses in Exhibit 1094 in paragraph 80, in support of her new testimony that it was allegedly understood in the art that using too much non-ionic surfactant could reduce the effectiveness of BAC, which would have allegedly informed the person of ordinary skill in the art that lower levels of surfactant would be effective and expected. Exhibits 1107, 1108, 1109, 1179, and 1180 lack relevance (FRE 402), as they exceed the proper scope of Petitioners' Reply. *See* 37 C.F.R. § 42.23(b); 77 Fed. Reg. 48767. Patent Owner further objects to these Exhibits because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence therein (FRE 403).

Date: April 29, 2016

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