

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD., and LUPIN PHARMACEUTICALS INC.,

Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,

Patent Owner.

IPR2015-01097 (Patent 8,754,131)
IPR2015-01099 (Patent 8,669,290)
IPR2015-01100 (Patent 8,927,606)
IPR2015-01105 (Patent 8,871,813)

**PETITIONERS' OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE¹**

¹ A word-for-word identical paper has been 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. Each of these joined proceedings includes Petitioners InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "InnoPharma") in addition to the parties identified above.

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Pursuant to the Scheduling Order (Paper 10 at 4), Petitioners file their Opposition to Patent Owner's Motion to Exclude under 37 C.F.R. § 42.64(c).

I. Dr. Lawrence Is Well-Qualified to Offer the Opinions in Her Reply Declaration

Patent Owner spends six full pages arguing that Dr. Lawrence is not an "expert" in chemistry, but all six of those pages are directed to an entirely irrelevant point. The issues in this action are related to formulations and Dr. Lawrence is by any measure a highly accomplished formulation expert. Part and parcel to the field of formulation is of course an understanding of basic chemistry relating to formulations; chemistry and formulation science are not mutually exclusive. Dr. Lawrence has more than enough experience and knowledge within her formulation expertise to address any chemistry issues in this action.

Dr. Lawrence has a PhD in Pharmacy, and has been an expert in the field of formulation and drug delivery since prior to 2003. EX1005, ¶3; EX1094, ¶¶4-5. She is Head of the Pharmaceutical Biophysics Group of the Institute of Pharmaceutical Science at Kings College, and has been the Chief Scientist at the Royal Pharmaceutical Society since 2007. EX1005, ¶¶7-8. At Kings College she taught multiple courses including physical chemistry of micelles, physical chemistry of emulsions and biopharmaceutics and bio-pharmacy. EX1054 at 7. She has performed research and published in the field of physical and colloid chemistry. *Id.* at 8.

Dr. Lawrence is also qualified under Patent Owner's own definition of a POSA. Patent Owner's "chemistry" expert, Dr. Davies, opines that a POSA would have at least a Bachelor's degree in a field of science which includes "pharmaceutical sciences or a related discipline with about three to five years of work experience in this area, or a comparable level of education and training." EX2105, ¶ 41. Dr. Lawrence also exceeds Dr. Williams's definition of a POSA, *See* EX2082 at 45 (characterizing Dr. Lawrence's definition of a POSA as "exaggerat[ing] the level of a" POSA).

Patent Owner made no attempt to determine Dr. Lawrence's understanding of the basic chemistry at issue here, in an apparent strategy to move to exclude on qualifications alone. *See* EX2342, 10:16 to 13:5. But in the related district court trial regarding the same patents and subject matter, Patent Owner substantively challenged Dr. Lawrence's chemistry abilities. EX2326, 196:23-197:3. In response, Dr. Lawrence testified to her knowledge of chemistry, including basic chemistry and acid chemistry involved in formulation of NSAID compounds in solution. *Id.* at 197:4-20. Patent Owner was satisfied with Dr. Lawrence's qualifications, and the district court recognized Dr. Lawrence as an expert "embracing the field of chemistry of NSAIDs." *Id.* at 197:23-198:1, 198:7-14.

Patent Owner also overly simplifies Dr. Lawrence's testimony that tyloxapol is an "alkylphenol" in an attempt to undermine her credentials. As Dr. Lawrence

explains in her Declaration and in her testimony, the issue is more nuanced, because tyloxapol's *p*-(1,1,3,3-tetramethylbutyl) phenol component is an alkylphenol. EX1094, ¶ 33; EX2342, 225:1-5. Patent Owner's Motion thus acts as a *de facto* sur-reply on the antioxidant activity of tyloxapol. This is improper. Regardless, per Dr. Lawrence, tyloxapol "retains functional groups to the original alcohol monomer, and these may confer its antioxidant capacity", *i.e.*, that the antioxidant capacity of tyloxapol stems from "functional groups [retained] of the original alcohol monomer," an oxygen atom conjugated to a phenyl ring. EX1094, ¶33; EX1102 at 1221-22. The system of an oxygen atom conjugated to a phenyl ring would be capable of accepting electrons from a radical species, and thus would impart antioxidant activity. EX1094, ¶33; EX1102, 1221-22.

This testimony does not contradict Dr. Laskar. Dr. Lawrence's testimony "assum[ed that] Dr. Laskar [was] referring to the average structure of what's known as a polymeric molecule. There will be molecules in there that have no ethoxylate group on them," in which case Dr. Laskar's testimony and Dr. Lawrence's testimony are consistent. EX2342, 224:3-7.

Patent Owner also fails to undermine Dr. Lawrence's credentials by characterizing certain references as "irrelevant." Motion at 5. Dr. Lawrence cited those references because they teach that tyloxapol has antioxidant activity, rendering them relevant to the oxidative degradation of bromfenac. EX1097, ¶

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