

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

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner

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

**PATENT OWNER'S MOTION TO EXCLUDE
UNDER 37 C.F.R. § 42.64(C)**

¹IPR2015-01871 has been joined with this proceeding.

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Pursuant to 37 C.F.R. §§ 42.64(c) and 42.61(a), and the Federal Rules of Evidence, Patent Owner Senju first moves to exclude the Reply Declaration of Paul Laskar, Ph.D. (EX1104), specifically at least paragraphs 8, 10-13, and 17-19, and the testimony of Dr. Laskar (EX2114 and EX2272), because Dr. Laskar completely lacks expertise in organic or medicinal chemistry and, thus, Dr. Laskar is not qualified by knowledge, skill, experience, training or education necessary to form an opinion under FRE 702. Second, Senju moves to exclude paragraphs 4-34 of Ex. 1104, and allegedly supporting EX1089, 1092, 1093, 1105, 1106, 1091, 1094 and 1148, because these exhibits lack relevance under FRE 402, as they exceed the proper scope of Petitioner's Reply under 37 C.F.R. § 42.23(b), and because they are prejudicial under FRE 403 to Senju, as Senju is unable to respond to them. Third, Senju moves to exclude EX1075, EX1098 and EX1076 for lack of relevance under FRE 402, because these exhibits were used in connection with a new argument in Petitioner's Reply (Paper 51), which exceeds the proper scope of a Reply under 37 C.F.R. § 42.23(b) and their use is prejudicial to Senju under FRE 403. Senju further moves to exclude Dr. Laskar's testimony at his first cross examination on redirect, Ex. 2114, 258:14-263:1, because that testimony was unreliable, having been elicited after consultation with Petitioner's counsel during a break, and in light of Dr. Laskar's repeated refusal to provide responsive, accurate answers on cross-examination during his cross examination.

I. Dr. Laskar's Opinions and Testimony Regarding any Issue of Organic or Medicinal Chemistry Should Be Excluded Under FRE 702

A. Senju Timely Objected to and Challenged Dr. Laskar's Qualifications During Cross Examination

Senju timely objected to Ex. 1104, specifically paragraphs 8, 10-13, and 17-19, under FRE 702 and 37 C.F.R. § 42.65 in objections filed and served March 25, 2016. (Paper 54.) Further, during Dr. Laskar's cross-examination on his Declaration (Ex. 2114, 25:21-32:17; 257:14-18) and on his Reply Declaration (EX2272, 14:10-25:7), Senju extensively challenged and objected to Dr. Laskar's lack of qualifications necessary to form an opinion under FRE 702.

B. Dr. Laskar Is Not Qualified to Offer Opinions on Organic or Medicinal Chemistry, or Challenge Those Opinions of Senju's Qualified Expert

In his declarations in support of the petition and the reply, Dr. Laskar offers opinions on, among other things, organic and medicinal chemistry issues to argue that the instituted claims are allegedly obvious and to challenge the declarative evidence on secondary considerations submitted by Patent Owner. Dr. Laskar, however, completely lacks expertise in organic and medicinal chemistry—the central technology of this proceeding. Accordingly, and as discussed below, Dr. Laskar's opinions should be excluded.

Dr. Laskar was cross-examined twice during this proceeding, and each time, Patent Owner explored his complete lack of relevant expertise. At the outset, Dr.

Laskar held himself out to be an expert in “the field of formulations and drug delivery, specifically pharmaceutical formulations for ophthalmic administration including topical aqueous liquid preparations.” (EX2114, 24:3-14.) But Dr. Laskar has never practiced medicine (EX2114, 28:4-23) and is no longer “an active registered pharmacist” (EX2272, 14:22-15:2). In fact, Dr. Laskar has not dispensed a drug since the mid-1970s, has never dispensed any bromfenac product, and does not recall ever dispensing an ophthalmic product containing tyloxapol. (EX2272, 14:13-15:22.) Since 1982, he has formulated drug products, but he has never formulated products with bromfenac and has never formulated any NSAID product containing tyloxapol. (EX2272, 22:1-13.) Nor has Dr. Lasker conducted any research on bromfenac products. (EX2114, 28:25-29:5.)

Dr. Laskar’s formal education is in general science, pharmacy, and pharmaceutical sciences, not in chemistry. (EX2272, 22:17-23-15.) He has never held a faculty position in any chemistry department and never held **any** faculty position at all beyond associate professor. (EX2272, 20:10-16.) Dr. Laskar has only ever submitted two patent applications, and neither is relevant to the ’290 or ’431 patents. (EX2114, 26:3-27:1; EX2272, 16:1-18:7.) He has only authored eight peer reviewed publications in his entire career, the last one in 1993 related to sunscreen products, and the most recent one before that in 1977. (EX2272, 18:13-19:15.) None of his publications relates to antioxidants, a topic on which he opines

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