

**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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IPR2015-01097 (US Patent No. 8,751,131)  
IPR2015-01099 (US Patent No. 8,669,290)  
IPR2015-01100 (US Patent No. 8,927,606)  
IPR2015-01105 (US Patent No. 8,871,813)<sup>1</sup>

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

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<sup>1</sup> 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. 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 37 C.F.R. §§ 42.64(c) and 42.61(a), and the Federal Rules of Evidence, Patent Owner Senju moves to exclude three categories of evidence filed by Petitioners. First, Senju moves to exclude the Reply Declaration of M. Jayne Lawrence, Ph.D. (EX1094), specifically at least paragraphs 31, 33, 36-37, 48-49, 51-52, and 73, and footnote 5, allegedly supporting EX1174 and 1176, and the related testimony of Dr. Lawrence (EX2342), because Dr. Lawrence completely lacks expertise in organic or medicinal chemistry and, thus, she is not qualified by knowledge, skill experience, training or education necessary to form an opinion under FRE 702. Second, Senju moves to exclude paragraphs 31-33, 37-38, as well as footnote 5 of EX1094, and allegedly supporting EX1096-1098, 1100-1102, 1107-1109, and 1172-1173, 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 the new arguments contained to them. Finally, Senju moves to exclude the Reply Declaration of Ivan T. Hofmann (EX1122) in its entirety because of Mr. Hofmann's improper behavior during cross examination, and specifically at least paragraphs 25-27, 42, 59-60, 62, 69-70, 72-80, 86-87, 99, 102, and 110, and the related testimony of Mr. Hofmann (EX2343), because he also provides opinions on technical and medical matters for which he is not qualified by knowledge, skill, experience, training or education necessary to form an opinion under FRE 702.

**I. Dr. Lawrence'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. Lawrence's Qualifications During Cross Examination**

Senju timely objected to EX1094, specifically paragraphs 31, 33, 36-37, 48-49, 51-52, and 73, and footnote 5, under FRE 702 and 37 C.F.R. § 42.65 in objections filed and served April 29, 2016.<sup>2</sup> Further, during Dr. Lawrence's two cross-examinations (EX2316, 31:3-43:8; 141:15-142:2; EX2342, 9:11-14:10; 16:3-23:10; 263:21-264:10), Senju extensively challenged and objected to Dr. Lawrence's lack of qualifications necessary to form an opinion under FRE 702.

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

In her Reply Declaration, Dr. Lawrence offers opinions on 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. As she even readily admits, Dr. Lawrence completely lacks expertise in organic and medicinal chemistry—the central technology of this proceeding. Accordingly, Dr. Lawrence's opinions should be excluded.

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

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<sup>2</sup> (Paper 40 in IPR2015-1097, IPR2015-01100, and IPR2015-01105, and Paper 39 in IPR2015-1099.)

Dr. Lawrence held herself out to be an expert in “the field of formulation and drug delivery, specifically pharmaceutical formulation for oral and parenteral use . . .” (EX1094, ¶ 4.) She is not a medical doctor and has never practiced medicine or prescribed medication to a patient (EX2316, 31:6-11; EX2342, 13:11-15). Further, Dr. Lawrence is no longer an active pharmacist, having not dispensed a drug in the last 20 years (EX2316, 34:17-20; EX2342, 13:19-21), and she has never dispensed any bromfenac product. (EX2316, 34:21-35:2; EX2342, 13:22-14:2.) She has never formulated any marketed drug product or any product for treating an inflammatory disease of the eye and never conducted any research on any bromfenac product. (EX2316, 35:3-5; 35:11-18; EX2342, 16:3-17; 14:3-5.)

Dr. Lawrence’s formal education is in pharmacy, not chemistry. (EX2342, 12:22-13:5; EX1005, ¶ 5.) She has never held a faculty position in any chemistry department. (EX1005, ¶ 7.) She is not a member of the American Chemical Society and has never published anything in the Journal of the American Chemical Society. (EX2316, 39:5-22; EX2342, 11:21-12:21.) Dr. Lawrence has only ever filed two patent applications, and neither is relevant to the ’290, ’131, ’831, or ’606 patents. (EX2316, 42:7-43:8; EX2342, 22:11-23:10.) After an extensive review of her credentials during her cross examinations, Dr. Lawrence readily admitted that she is not an expert in medicinal chemistry, organic chemistry, or antioxidant chemistry and that she had never been qualified by any court or the U.S.P.T.O. as

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