

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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U.S. Patent No. 8,129,431 to Sawa *et al.*  
Issue Date: March 6, 2012  
Title: Aqueous Liquid Preparation Containing 2-Amino-3-(4-  
bromobenzoyl) Phenylacetic Acid

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*Inter Partes* Review No.: Unassigned

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**DECLARATION OF M. JAYNE LAWRENCE, PH.D**

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I, Jayne Lawrence, Ph.D., declare and state as follows:

## **I. Introduction**

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Lupin Ltd. and Lupin Pharmaceuticals Inc. (“Petitioner”) for the above captioned *inter partes* review (“Lupin IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is GBP300 per hour. My compensation is not contingent on the conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

3. I understand that the Lupin IPR involves U.S. Patent No. 8,129,431 (“the ‘431 patent”), (EX1001), which issued on March 6, 2012, from U.S. Application No. 10/525,006 (“the ‘006 application”), naming Shirou Sawa and Shuhei Fujita as the inventors. The ‘006 application is the U.S. National Stage of PCT Application No. PCT/JP2004/000350 (“the ‘350 application”), filed on January 16, 2004. The ‘350 application claims priority to Japanese Application No. 2003-12427, filed on January 21, 2003. It is my understanding that the earliest possible priority date of the ‘431 patent is January 21, 2003, the filing date of the Japanese priority application. I further understand that, according to the USPTO records, the ‘431 patent is currently assigned to Senju Pharmaceutical Co., Ltd. (“Senju,” “the patentee,” or “the patent owner”). I

understand that the '431 patent is currently subject to a previous IPR, *InnoPharma Licensing, Inc. v. Senju Pharmaceuticals Co., Ltd.*, IPR2015-00903 (the “InnoPharma IPR”), as well as a now-settled IPR, *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01041 (the “Metrics IPR”). I understand that Petitioner seeks to become a party to the InnoPharma IPR. I have reviewed the materials submitted with the petition filed in the InnoPharma IPR, including the petition itself (IPR2015-00903, Paper 2), the Declaration of Dr. Paul A. Laskar (IPR2015-00903, Exhibit 1003), the Board’s Decision Instituting *Inter Partes* Review (IPR2015-00903, Paper 15), and the prior art and materials cited in each. I have also reviewed the materials submitted in connection with the Metrics IPR, including the petition itself (Second Corrected Petition, IPR2014-01041, Paper 9), the Second Corrected Declaration of Dr. Uday B. Kompella (IPR2014-01041, Exhibit 1003), the Patent Owner’s Preliminary Response (IPR2014-01041, Paper 13), and Board’s Decision Instituting *Inter Partes* Review (IPR2014-01041, Paper 19). I note that I agree in all material respects with the analysis and opinions set forth by the petitioner InnoPharma’s expert, Dr. Laskar, in the declaration that was submitted in the InnoPharma IPR and share the same opinions below.<sup>1</sup> I also note that I agree in all material respects with the analysis and opinions

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<sup>1</sup> I do not independently address claim construction in this Declaration, because I understand that, in instituting IPR2015-00903, the Board has credited the testimony of Dr. Laskar “on the views of a hypothetical person of ordinary skill in the art at the time of the invention,” and has already determined that the claim terms are to be given their

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