

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.
Patent Owner.

U.S. Patent No. 8,927,606 to Sawa *et al*
Issue Date: January 6, 2015

Title: Aqueous Liquid Preparation Containing 2-Amino-3-(4-
Bromobenzoyl)Phenylacetic Acid

Inter Partes Review No: IPR2016-00091

DECLARATION OF PAUL A. LASKAR, PH.D.

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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 Petitioner for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$250 per hour. My compensation is in no way dependent on the outcome of this IPR.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 8,927,606 (“the ’606 patent”) (EX1001), which was issued on January 6, 2015, from U.S. Application No. 14/483,903 (“the ’903 application”), naming Shirou Sawa and Shuhei Fujita as the inventors. The ’903 application is a division of application No. 14/261,720 (“the ’720 application”), now U.S. Patent No. 8,871,813, which is a division of application No. 14/165,976 (“the ’976 application”), now U.S. Patent No. 8,754,131, which is a division of application No. 13/687,242 application (“the ’242 application”), now U.S. Patent No. 8,669,290, which is a division of application No. 13/353,653 (“the ’653 application”), now U.S. Pat. No. 8,497,304, which is a division of application No. 10/525,006 (“the ’006 application”), now U.S. Patent No. 8,129,431, which was 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 '606 patent is January 21, 2003, the filing date of the Japanese priority application. I further understand that, according to the USPTO records, the '606 patent is currently assigned to Senju Pharmaceutical Co., Ltd. ("Senju," "the patentee," or "the patent owner").

4. Claim 1 of the '606 patent is reproduced below:

1. A method for treating an inflammatory disease of an eye, the method comprising administering to said eye a stable aqueous liquid preparation that comprises: (a) a first component; and (b) a second component; wherein the first component is 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate; the first component is the sole pharmaceutical active ingredient contained in the preparation; the second component is tyloxapol and is present in said liquid preparation in an amount sufficient to stabilize said first component; wherein said stable liquid preparation is formulated for ophthalmic administration; and wherein said liquid preparation is administered to said eye at a dose and a frequency effective to treat said inflammatory disease.

(EX1001, 11:17-31).

5. Claims 2-10 and 28 either depend directly or indirectly from Claim 1. Claims 2 and 3 recite the disease to be treated. Claim 4 recites that the bromfenac is a sodium salt. Claims 5-9 recite the addition of a quaternary ammonium salt,

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