

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. 8,754,131 to Sawa *et al*
Issue Date: June 17, 2014

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

Inter Partes Review No: IPR2016-00089

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. 8,754,131 (“the ’131 patent”) (EX1001), which was issued on June 17, 2014, from U.S. Application No. 14/165,976 (“the ’976 application”), naming Shirou Sawa and Shuhei Fujita as the inventors. The ’976 application 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”), 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 ’131 patent is January 21, 2003, the filing date of the Japanese priority application. I further understand that, according to the USPTO records, the

'131 patent is currently assigned to Senju Pharmaceutical Co., Ltd. (“Senju,” “the patentee,” or “the patent owner”).

4. Claim 1 of the '131 patent is reproduced below:

1. A stable aqueous liquid preparation comprising: (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 and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %; the second component is tyloxapol and is present in said liquid preparation in an amount sufficient to stabilize said first component; and wherein said stable liquid preparation is formulated for ophthalmic administration.

(EX1001, 12:2-15).

5. Claims 2-6, 25-26, and 30 either depend directly or indirectly from Claim 1. Claims 3-6 and 30 recite the addition of a quaternary ammonium salt, concentrations of tyloxapol and/or bromfenac or its sodium salt, the pH of the preparations, and additional additives. Claim 2 recites that the bromfenac is a sodium salt. Claims 25 and 26 recites a preservative efficacy standard.

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