IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

METRICS, INC.
Petitioner
v.
SENJU PHARMACEUTICAL CO., LTD.
Patent Owner

U.S. Patent No. 8,669,290 to Sawa *et al.*
Issue Date: March 11, 2014
Title: Aqueous Liquid Preparation Containing 2-Amino-3-(4-bromobenzoyl)phenylacetic acid

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Inter Partes Review No: IPR2014-01043

SECOND CORRECTED DECLARATION OF UDAY B. KOMPELLA, PH.D.

Metrics EX1003

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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 Metrics, Inc. 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 $750 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. 8,669,290 ("the '290 patent"), Exhibit 1001, which issued on March 11, 2014, from U.S. Application No. 13/687,242 ("the '242 application"), naming Shirou Sawa and Shuhei Fujita as the inventors. The '242 application is a division of application No. 13/353,653, 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 '290 patent is January 21, 2003, the filing date of the Japanese priority application. I further understand that, according to the USPTO records, the '290 patent is currently assigned to Senju Pharmaceutical Co., Ltd. ("Senju," "the patentee," or "the patent owner").

4. Claim 1 of the ’290 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; 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, 12:1-13)

5. Claims 2-7 and 26 depend either directly or indirectly from Claim 1. Claims 2-7 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 26 recites a preservative efficacy standard.

6. Claim 8 is reproduced below

> 8. 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

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