

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. 8,129,431 to Sawa *et al.*
Issue Date: March 6, 2012
Title: Aqueous Liquid Preparation Containing 2-Amino-3-(4-bromobenzoyl)phenylacetic Acid

Inter Partes Review No.: IPR2014-01041

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

Metrics EX1003

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***Inter Partes Review of USPN 8,129,431
Declaration of Dr. Uday B. Kompella (EX1003)***

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. 8,129,431 (“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”).

4. Claim 1 of the ’431 patent is reproduced below.

*Inter Partes Review of USPN 8,129,431
Declaration of Dr. Uday B. Kompella (EX1003)*

1. An aqueous liquid preparation *consisting essentially of* the following two components, 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 and the second component is *tyloxapol*, wherein said liquid preparation is formulated for ophthalmic administration, and wherein when a quaternary ammonium compound is included in said liquid preparation, the quaternary ammonium compound is benzalkonium chloride.

(EX1001, 11:66-12:9) (emphasis added).

5. Claims 2-17 depend, either directly or indirectly, from claim 1 and further recite certain salts of bromfenac, concentrations of tyloxapol and/or bromfenac or its sodium salt, the pH of the preparations, and additional additives. (EX1001, 12:10-13:14).

6. Claim 18 of the '431 patent is reproduced below.

18. An aqueous liquid preparation consisting essentially of:

(a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate

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