

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. 8,129,431 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.: IPR2015-00903

DECLARATION OF PAUL A. LASKAR, PH.D.

TABLE OF CONTENTS

I. Introduction.....1

II. List of Documents Considered7

III. My background and qualifications12

IV. Person of ordinary skill in the art (POSA)16

V. The '431 patent.....16

VI. State of the art as of January, 2003.....18

 A. Non-steroidal anti-inflammatory compounds were known and approved for ophthalmic use18

 B. BAC was the preservative of choice in ophthalmic formulations22

 C. It was known that non-ionic surfactants stabilized aqueous preparations containing an NSAID and BAC24

 D. Tyloxapol is a non-ionic surfactant that was known and widely used in ophthalmic formulations by January 200325

 E. There is nothing inventive in the '431 patent in view of the prior art30

VII. Obviousness of Claims 1-22 of the '431 patent31

 A. The basis of my analysis with respect to obviousness31

 B. Obviousness Ground 1 - Ogawa and Sallmann.....33

 1. Independent Claims 1 and 18.....35

 2. Claims 2, 5, 11 and 1947

 3. Claims 3 and 4.....51

 4. Claims 6 and 15.....55

 5. Claims 7, 8, 13, 14, 16 and 1758

 6. Claims 9 and 10.....62

7.	Claim 12.....	65
8.	Claims 21, and 22.....	67
9.	Claim 20.....	68
VIII.	The claimed invention of the '431 patent does not possess unexpectedly superior properties.....	68
A.	Tyloxapol's stabilization of an aqueous ophthalmic bromfenac preparation is not unexpected in view of the prior art	69
B.	The stabilization of bromfenac preparations by tyloxapol is not observed across the entire range of the claimed preparations.....	72
1.	The supposed unexpected stability of aqueous bromfenac preparations is not observed across the entire range of claimed pH.....	73
2.	The supposedly unexpected increase in stability of aqueous bromfenac preparations is not observed across the entire range of claimed benzalkonium chloride homologues	75
C.	Tyloxapol's stabilization of the preservative effect of BAC is not unexpected in view of prior art	75
D.	No long-felt, unmet need existed for an ophthalmic NSAID preparation formulated with BAC.....	78
E.	The claimed bromfenac preparations were not met with skepticism.....	79
F.	The claimed bromfenac ophthalmic formulations have not received any praise	80
G.	Additional evidence of secondary considerations.....	80
IX.	Conclusion	81

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 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 IPR. *Metrics, Inc. v. Senju Pharmaceuticals Co., Ltd.*, IPR2014-01041. I understand that Petitioner seeks to become a party to

Declaration of Dr. Paul A. Laskar (EX1003)

proceedings in IPR2014-01041. Because IPR of the '431 patent has already been instituted, I have reviewed the materials submitted with the petition filed in that proceeding, including the petition itself (Second Corrected Petition, IPR2014-01041, Paper 9), the Second Corrected Declaration of Dr. Uday B. Kompella (IPR2014-01041, EX1003), the Board's Decision Instituting *Inter Partes* Review (IPR2014-01041, Paper 19), and the prior art and materials cited in each. I note that I agree with the analysis and opinions set forth by the petitioner's expert, Dr. Kompella, in the declaration that was submitted in the Metrics IPR proceeding and share many of those same opinions below. Because my independent analysis of the claims and prior art led to the same conclusions as the expert in the Metrics IPR, I have incorporated many of his opinions and characterizations below as my own. I understand that in its Decision Instituting *Inter Partes* Review the Board concluded that Petitioner Metrics, Inc. demonstrated a reasonable likelihood of prevailing on its assertion that claims 1-22 of the '431 patent are unpatentable. Specifically, the Board instituted review on two grounds: (1) claims 1-5, 7-14, and 18-19 are unpatentable over the Owaga and Sallmann references; and (2) claims 6, 15-17, and 20-22 are unpatentable over the Ogawa, Sallmann and Fu references. (IPR2014-01041, Paper 19, pg. 20). Therefore, because Petitioner is seeking to join the instituted review of the '431 patent, the opinions expressed herein are

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.