

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

**Petition for *Inter Partes* Review of U.S. Patent No. 8,754,131 Under
35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123**

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. OVERVIEW	1
III. STANDING (37 C.F.R. § 42.104(a); PROCEDURAL STATEMENTS)	2
IV. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	2
A. Each Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))	2
B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2)).....	3
1. Judicial Matters	3
2. Administrative Matters	3
C. Designation of Lead and Back-Up Counsel and Service (37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4), 42.10(a), and 42.10(b)):	5
V. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFORE (37 C.F.R. § 42.22(a))	6
VI. THE '131 PATENT.....	6
A. CLAIM CONSTRUCTION	7
VII. PERSON OF SKILL IN THE ART (“POSA”) & STATE OF THE ART	7
VIII. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b)).....	10
A. The Scope and Content of the Prior Art.....	11
1. Aqueous Ophthalmic Preparation of Bromfenac.....	11
2. Tyloxapol and Related Surfactants in NSAID Aqueous Ophthalmic Preparations.....	12

B.	Ground 1: Claims 1-30 Are Unpatentable Under 35 U.S.C. § 103(a) Over Ogawa In Light Of Sallmann.....	13
1.	Ogawa (EX1004) and Sallmann (EX1009).....	13
2.	Independent Claims 1, 7, and 13.....	16
3.	Dependent Claims.....	26
C.	Ground 2: Claims 1-30 Are Unpatentable Under 35 U.S.C. § 103(a) over Ogawa in light of Sallmann and Fu.....	41
1.	Overview of Fu (EX1011).....	41
2.	Independent Claims 1, 7, and 13.....	43
3.	Dependent Claims.....	45
D.	Ground 3: Claims 1-30 Are Unpatentable Under 35 U.S.C. § 103(a) over Ogawa in light of Sallmann and Yasueda.....	48
1.	Overview of Yasueda (EX1012).....	48
2.	Independent Claims 1, 7, and 13.....	50
3.	Dependent Claims.....	53
E.	Objective Indicia of Nonobviousness.....	55
1.	No Unexpected Results Over the Closest Prior Art.....	55
2.	Other Objective Indicia.....	58
IX.	CONCLUSION.....	60

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Amneal Pharms., LLC v. Supernus Pharms., Inc.</i> , IPR2013-00368.....	55
<i>Chapman v. Casner</i> , 315 Fed. App'x 294 (Fed. Cir. 2009)	29, 35
<i>Friskit, Inc. v. Real Networks, Inc.</i> , 306 F. App'x 610 (Fed. Cir. 2009)	58
<i>Galderma Labs., L.P., v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013).....	29, 31
<i>In re Aller</i> , 220 F.2d 456	23-24, 31, 40
<i>In re Baxter Travenol Labs.</i> , 952 F.2d 388 (Fed. Cir. 1991)	24, 37, 39
<i>In re De Blauwe</i> , 736 F.2d 699 (Fed. Cir. 1984)	56
<i>In re Malagari</i> , 499 F.2d 1297 (C.C.P.A. 1974)	35
<i>In re Merchant</i> , 575 F.2d 865 (C.C.P.A. 1978)	56
<i>In re Peterson</i> , 315 F.3d 1325 (Fed. Cir. 2003)	22-24, 31, 35, 57
<i>InnoPharma Licensing, Inc. v. Senju Pharm. Co., Ltd.</i> , IPR2015-00902	passim
<i>In re Woodruff</i> , 919 F.2d 1575 (Fed. Cir. 1990)	23, 35
<i>Iron Grip Barbell Co., Inc., v. USA Sports, Inc.</i> , 392 F.3d 1317 (Fed. Cir. 2004).....	29

<i>KSR International Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	2, 7, 21, 32
<i>Lupin Ltd. v. Senju Pharm. Co., Ltd.</i> , IPR2015-01097.....	passim
<i>Metrics, Inc. v. Senju Pharm. Co., Ltd.</i> , IPR2014-01043.....	24, 25, 37, 39
<i>Newell Cos., Inc. v. Kenney Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988)	55
<i>Ormco Corp. v. Align Tech., Inc.</i> , 463 F.3d 1299 (Fed. Cir. 2006)	59
<i>Purdue Pharma Prods. L.P. v. Par Pharm., Inc.</i> , 377 Fed App'x 978 (Fed. Cir. 2010)	59
<i>Sakraida v. AG Pro, Inc.</i> , 425 U.S. 273 (1976).....	21
<i>Santarus v. Par Pharm</i> , 694 F.3d 1344 (Fed. Cir. 2012)	24, 37, 39
<i>Sinclair & Carroll Co., v. Interchemical Corp.</i> , 325 U.S. 327 (1945).....	19
<i>Stratoflex, Inc. v. Aeroquip Corp.</i> , 713 F.2d 1530 (Fed. Cir. 1983)	59, 60
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356 (Fed Cir. 2008)	13
<i>Titanium Metals Corp. of Amer. v. Banner</i> , 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).....	30-31, 46
<i>Tokai Corp. v. Eason Enters., Inc.</i> , 632 F.3d 1358 (Fed. Cir. 2011)	60
<i>Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC</i> , 683 F.3d 1356 (Fed Cir. 2012).....	21, 53
STATUTES	
35 U.S.C. § 102(b)	13, 15, 41, 48

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.