

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. 8,871,813 to Sawa *et al.*
Issue Date: October 28, 2014
Title: Aqueous Liquid Preparation Containing
2-Amino-3-(4-
bromobenzoyl) Phenylacetic Acid

Inter Partes Review No.: IPR2016-00090

**Petition for *Inter Partes* Review of U.S. Patent No. 8,871,813 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 '813 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.....	11

B.	Ground 1: Claims 1-27 Are Unpatentable Under 35 U.S.C. § 103(a) over Ogawa in light of Sallmann.....	12
1.	Ogawa (EX1004) and Sallmann (EX1009).....	13
2.	Independent Claims 1, 7, and 13.....	15
a.	Claim 1.....	15
(i)	It would have been obvious to substitute tyloxapol from Sallmann’s Example 2 for polysorbate 80 in Ogawa’s Example 6.....	19
(ii)	Sallmann teaches that the amount of tyloxapol is sufficient to stabilize the bromfenac, or in the alternative it would have been obvious to do so according to the teachings of Sallmann and Ogawa.....	23
b.	Claim 7.....	26
c.	Claim 13.....	27
3.	Dependent Claims.....	27
a.	Claims 2, 8, and 14—Sodium Sulfite.....	28
b.	Claims 3 and 15—Sodium Salt of Bromfenac.....	29
c.	Claims 4, 6, 10, 12, 16, 18, 21, 23, —Bromfenac Sodium and Tyloxapol Concentrations and Additional Additives.....	29
(i)	Bromfenac Sodium Concentration.....	29
(ii)	Tyloxapol Concentration.....	31
(iii)	Additional Additives.....	33
d.	Claims 5, 11, 17, and 22—pH Ranges.....	35
e.	Claims 9, 19, and 20—Storage Stability.....	36
f.	Claims 24-26—No Preservative.....	38
g.	Claim 27—Additional Additives.....	39
C.	Ground 2: Claims 1-27 Are Unpatentable Under 35 U.S.C. § 103(a) over Ogawa in light of Sallmann and Fu.....	40
1.	Overview of Fu (EX1011).....	40
2.	Independent Claims 1, 7, and 13.....	43
3.	Dependent Claims.....	44

a.	Claims 4, 6, 10, 12, 16, 18, and 21—Tyloxapol Concentration.....	45
D.	Ground 3: Claims 1-27 Are Unpatentable Under 35 U.S.C. § 103(a) over Ogawa in light of Sallmann and Yasueda	47
1.	Overview of Yasueda (EX1012).....	47
2.	Independent Claims 1, 7, and 13.....	50
3.	Dependent Claims	52
a.	Claims 4, 6, 10, 12, 16, 18, and 21—Tyloxapol Concentration.....	53
E.	Objective Indicia of Nonobviousness	54
1.	No Unexpected Results Over the Closest Prior Art.....	55
a.	Tyloxapol’s Stabilizing Effects	56
b.	Scope of Stabilizing Effects	57
2.	Other Objective Indicia.....	57
IX.	CONCLUSION.....	60

TABLE OF AUTHORITIES

	Page(s)
Federal 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)	30, 36
<i>Ecolab, Inc. v. FMC Corp.</i> 569 F.3d 1335 (Fed. Cir. 2009)	18
<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)	30, 32
<i>In re Aller</i> 220 F.2d 454, 458 (C.C.P.A. 1955).....	25, 32
<i>In re Baxter Travenol Labs.</i> 952 F.2d 388 (Fed. Cir. 1991)	25, 38
<i>In re De Blauwe</i> 736 F.2d 699 (Fed. Cir. 1984)	55
<i>In re Malagari</i> 499 F.2d 1297 (C.C.P.A. 1974).....	36
<i>In re Merchant</i> 575 F.2d 865 (C.C.P.A. 1978).....	55
<i>In re Johnston</i> 435 F.3d 1381 (Fed. Cir. 2006)	39
<i>In re Peterson</i> 315 F.3d, 1325, 1329-30 (Fed. Cir. 2003)	24, 25, 32, 36, 57
<i>In re Woodruff</i> 919 F.2d 1575 (Fed. Cir. 1990)	24, 36

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.