Paper No. \_\_\_\_ Filed: May 26, 2015

## 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. Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and BAUSCH & LOMB PHARMA HOLDINGS CORP. Patent Owner.

> Case IPR2015-00903 Patent 8,129,431

PATENT OWNER'S PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107

A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET

## **TABLE OF CONTENTS**

I.	Introduction					
	A.	Back	ground of related litigations	2		
	B.	InnoF	Pharma's failed prima facie case of obviousness	4		
	C.	Senju	's compelling objective evidence of patentability	9		
II.	Stater	nent o	f relief requested	13		
III.	Claim	n construction				
IV.	Level	el of skill in the art				
V.	The petition should be denied for failing to establish a reasonable likelihood that any of the challenged claims is unpatentable					
	A.	The in	nventive ophthalmic preparations of the '431 patent	16		
	B.	The combination of Ogawa and Sallmann, in either direction, does not render any claim of the '431 patent obvious				
	C.	InnoPharma has established no reason, other than hindsight, to focus on Ogawa and bromfenac preparations				
	D.	Ogawa in view of Sallmann: a combination the person of ordinary skill in the art would not have made				
		1.	Ogawa and the problem it sought to solve	20		
		2.	Sallmann's singular purpose does not align with Ogawa's	23		
		3.	It would not have been obvious to modify Ogawa's Example 6 in view of Sallmann's Example 2	24		
		4.	InnoPharma's arguments of motivation and expectation of success ring hollow in view of the demonstratively strong evidence counseling against the proposed combination of Ogawa in view of Sallmann	28		

DOCKET

E.	Sallmann in view of Ogawa: a hindsight-laden combination that would not have been made prior to invention			
	1.	The proposed combination destroys the essential purpose of Sallmann, ignores the blaze marks in the art, and runs afoul of the '431 patent's claim language	33	
	2.	InnoPharma's arguments to modify Sallmann's Example 2 in view of Ogawa's Example 6 are legally insufficient, internally inconsistent, and belied by the very art it relies on	37	
F.		•	42	
	1.	A POSA would not have looked to Fu	42	
	2.	InnoPharma's attempted connection between Fu and tyloxapol is untenable	43	
	3.	InnoPharma has failed to demonstrate unpatentability of claims 6, 15-17, and 20-22, requiring a tyloxapol concentration of about 0.02 w/v %	47	
Senju's compelling objective evidence of patentability enhances an already strong case of no prima facie obviousness, which InnoPharma fails to adequately rebut				
A.	Innol	Pharma fails to offer evidence refuting unexpected results	50	
	1.	The '431 patent compares against the closest prior art for purposes of showing unexpected results	50	
	2.	Polysorbate 80's expected ability to stabilize	51	
	3.	Tyloxapol's unexpectedly superior stabilizing effect	53	
B.	Addi	tional compelling objective evidence of patentability	56	
Conc	Conclusion 5			
	F. Senju alread fails t A. B.	would 1. 2. F. Fu do comb 1. 2. 3. Senju's cond already strop fails to adec A. Innol 1. 2. 3. B. Addi	<ul> <li>would not have been made prior to invention</li> <li>1. The proposed combination destroys the essential purpose of Sallmann, ignores the blaze marks in the art, and runs afoul of the '431 patent's claim language</li> <li>2. InnoPharma's arguments to modify Sallmann's Example 2 in view of Ogawa's Example 6 are legally insufficient, internally inconsistent, and belied by the very art it relies on</li> <li>F. Fu does not remedy the deficiencies in InnoPharma's combination of Ogawa and Sallmann</li> <li>1. A POSA would not have looked to Fu</li> <li>2. InnoPharma's attempted connection between Fu and tyloxapol is untenable</li> <li>3. InnoPharma has failed to demonstrate unpatentability of claims 6, 15-17, and 20-22, requiring a tyloxapol concentration of about 0.02 w/v %</li> <li>Senju's compelling objective evidence of patentability enhances an already strong case of no prima facie obviousness, which InnoPharma fails to adequately rebut</li> <li>A. InnoPharma fails to offer evidence refuting unexpected results</li> <li>1. The '431 patent compares against the closest prior art for purposes of showing unexpected results</li> <li>2. Polysorbate 80's expected ability to stabilize</li> <li>3. Tyloxapol's unexpectedly superior stabilizing effect</li> </ul>	

DOCKET

IPR2015-00903 Patent Owner's Preliminary Response Patent No. 8,129,431

## **TABLE OF AUTHORITIES**

## Page(s)

## **Federal Cases**

36
passim
27
55
13, 58
57
49
15, 17, 20, 39

<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009)19, 28
<i>Leo Pharm. Prod., Ltd. v. Rea,</i> 726 F.3d 1346 (Fed. Cir. 2013)
Novartis Pharm. Corp. v. Watson Labs., Inc., No. 2014-1799, 2015 WL 2403308 (Fed. Cir. May 21. 2015) (unpublished)
<i>Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc.,</i> 520 F.3d 1358 (Fed. Cir. 2008)
<i>Pfizer Inc. v. Mylan Pharm. Inc.</i> , No. 10-528-GMS, 2014 WL 5388100 (D. Del. Oct. 22, 2014)passim
RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440 (Fed. Cir. 1984)13, 58
<i>In re Soni</i> , 54 F.3d 746 (Fed. Cir. 1995)5
Specialty Composites v. Cabot Corp., 845 F.2d 981 (Fed. Cir. 1988)57
Unigene Labs., Inc. v. Apotex, Inc., 655 F.3d 1352 (Fed. Cir. 2011)15, 18, 19
In re Wesslau, 353 F.2d 238 (C.C.P.A. 1965)
Federal Statutes
35 U.S.C. § 10315
35 U.S.C. § 11916
35 U.S.C. § 314(a)
35 U.S.C. § 315(b)

## DOCKET A L A R M



# 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.