Paper No. __ Filed: August 3, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD LUPIN, LTD. and LUPIN PHARMACEUTICALS INC., Petitioner

v.

SENJU PHARMACEUTICAL CO., LTD.
Patent Owner

Case IPR2015-01100 Patent 8,927,606 B2

NIED!C DDEI IMINIA DV DECDAN

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



TABLE OF CONTENTS

I.	Introduction				
	A.	Back	ground of related litigations	2	
	B.	Lupi	n's failed <i>prima facie</i> case of obviousness	4	
	C.	Senj	u's compelling objective evidence of patentability	10	
II.	State	ement o	of relief requested	13	
III.	Clair	m construction			
IV.	Leve	el of skill in the art		14	
V.	The petition should be denied for failing to establish a reasonable likelihood that any of the challenged claims is unpatentable				
	A.	The	claims of the '606 patent	14	
	B.	The combinations of Ogawa in view of Fu and Ogawa in view of Sallmann do not render any claim of the '606 patent obvious		15	
	C.	Lupin has established no reason, other than hindsight, to focus on Ogawa and bromfenac preparations			
	D.	Ogawa in view of Fu: a combination that a person of ordinary skill in the art would not have made		18	
		1.	Ogawa and the problem it sought to solve	18	
		2.	It would not have been obvious to modify Ogawa's Example 6 in view of Fu's Example 5	20	
		3.	Because neither Ogawa nor Fu disclose tyloxapol, their combination fails to satisfy all elements of the claims	24	
		4.	Lupin's arguments of motivation and expectation of success ring hollow in view of the demonstratively strong		



IPR2015-01100 Patent Owner's Preliminary Response Patent No. 8,927,606

			evidence counseling against the proposed combination of Ogawa in view of Fu	28
	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 '606 patent's claim language	35
		2.	Lupin's alternative modification of Ogawa Example 6 in view of Sallmann similarly fails	38
		3.	Lupin's arguments to modify Sallmann in view of Ogawa, in any direction, are legally insufficient, internally inconsistent, and belied by the very art Lupin relies on	40
VI.	alread	Senju's compelling objective evidence of patentability enhances an already strong case of no prima facie obviousness, which Lupin fails to adequately rebut		
	A.	Lupii	n fails to offer evidence refuting unexpected results	44
		1.	The '606 patent compares against the closest prior art for purposes of showing unexpected results	44
		2.	Polysorbate 80's expected ability to stabilize	45
		3.	Tyloxapol's unexpectedly superior stabilizing effect	47
	B.	Addi	tional compelling objective evidence of patentability	51
VII.	Separ	ate pa	tentability of individual claims	53
	A.	Lupii 5	n has failed to demonstrate unpatentability of claims 1 and	53
	B.	Lupinand 1	n has failed to demonstrate unpatentability of claims 11	54
	C.	Lupin has failed to demonstrate unpatentability of claim 29		56



	D.	Lupin has failed to demonstrate unpatentability of claim 18 and		
		claim 25	57	
VIII.	I. Conclusion		60	



TABLE OF AUTHORITIES

Page(s)
Federal Cases
Application of Merchant, 575 F.2d 865 (C.C.P.A 1978)
Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281 (Fed. Cir. 1985)
Cadence Pharm. Inc. v. Exela PharmSci Inc., 780 F.3d 1364 (Fed. Cir. 2015)
Catalina Lighting, Inc. v. Lamps Plus, Inc., 295 F.3d 1277 (Fed. Cir. 2002)
<i>CFMT, Inc. v. Yieldup Intern. Corp.</i> , 349 F.3d 1333 (Fed. Cir. 2003)
<i>In re Gordon</i> , 733 F.2d 900 (Fed. Cir. 1984)
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (2011)
Insite Vision Inc. v. Sandoz, Inc., 783 F.3d 853 (Fed. Cir. 2015)
Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino, 738 F.3d 1337 (Fed. Cir. 2013)
Janssen Pharm. NV v. Mylan Pharm., Inc., 456 F. Supp. 2d 644 (D.N.J. 2006), aff'd per curiam, 223 Fed. Appx. 999 (Fed. Cir. 2007)
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)
Leo Pharm. Prod., Ltd. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)



DOCKET

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.

