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 IPR2015-01097

Patent 8,754,131 B2

DECLARATION OF ROBERT O. WILLIAMS, III, PH.D

Ря**σе 1 of 172**

RM

Δ

SENJU EXHIBIT 2082 LUPIN v SENJU

Find authenticated court documents without watermarks at docketalarm.com.

1

TABLE OF CONTENTS

I.	INTRODUCTION				
II.	BACKGROUND AND QUALIFICATIONS				
III.	INFORMATION CONSIDERED				
IV.	LEGAL PRINCIPLES				
V.	7. THE '131 PATENT				
	А.	Specification and Claims9			
	B.	Level of Skill in the Art			
	C.	Claim Construction			
		1. "Stable" and "Amount Sufficient to Stabilize"			
		2. "Satisfies the preservative efficacy standard of US Pharmacopoeia as follows: viable cell counts of bacteria (<i>S. aureus, P. aeruginosa</i>) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (<i>C. albicans, A. niger</i>) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation"			
VI.	SUMMARY OF OPINIONS24				
VII.	II. THE STATE OF THE ART AS OF JANUARY 21, 2003				
	A.	A Person of Ordinary Skill in the Art Would Not Have Pursued Bromfenac Formulations Over Other NSAID Formulations			
		1. No reason to pursue bromfenac formulations			
		2. Design needs or market demands would not have supported the solution that Lupin proposes			
	В.	A Person of Ordinary Skill in the Art Would Not Have Considered Different Non-Ionic Surfactants Interchangeable			

Daga 1 of 171

		1.	No teaching of interchangeability of polysorbate 80 and tyloxapol in aqueous solutions of NSAIDs50
		2.	No teaching of polysorbate 80 or tyloxapol as a stabilizer of aqueous ophthalmic preparations of NSAIDs
	C.		rson of Ordinary Skill in the Art Would Not Have sidered Different NSAIDs Interchangeable69
VIII.	HAV EXP	'E BEI ECTA	CHINGS OF OGAWA AND SALLMANN WOULD NOT EN COMBINED WITH ANY REASONABLE TION OF ARRIVING AT THE CLAIMED SUBJECT OF THE '131 PATENT
	A.		rson of Ordinary Skill in the Art Would Have Had No on to Focus on Ogawa and its Bromfenac Formulations71
	B.	Wou	e Time of Invention, A Person of Ordinary Skill in the Art ld Not Have Combined Ogawa's Teachings With Those of nann
		1.	Ogawa and the problem it identifies with bromfenac75
		2.	A person of ordinary skill in the art would not have looked to Sallmann or combined its teachings with those of Ogawa
		3.	Dr. Lawrence's alleged motivation and expectation of success in fact would not have made the combination of Ogawa and Sallmann obvious to make
		4.	A person of ordinary skill in the art would not have modified Sallmann with the teachings of Ogawa106
IX.			YE EVIDENCE OF NON-OBVIOUSNESS OF THE '131 CLAIMS
	А.		nique, Non-Prior Art, Aspect of the '131 Patent Claims: Use of Tyloxapol with Bromfenac112
	В.		Unexpectedly Superior Chemical Stabilizing Benefits of xapol Compared to Polysorbate 80114

DOCKET

		1. The '131 patent compares against the closest prior art for purposes of showing unexpected results115		
		2. A person of ordinary skill in the art would have had no expectation, based on polysorbate 80, of tyloxapol's effect on the chemical stability of bromfenac formulations		
		3. Tyloxapol's unexpectedly superior chemical stabilizing effect		
	C.	Tyloxapol is Unexpectedly Better than Polysorbate 80 at Maintaining Preservative Efficacy129		
	D.	Tyloxapol's Unexpectedly Superior Stabilizing Effect Led to Actual Benefits for Patients		
	Е.	Copying of Prolensa [®] by Generic Drug Companies134		
Х.	SEPA	ARATE PATENTABILITY OF INDIVIDUAL CLAIMS		
	А.	Claims 4, 6, 10, 11, 16, 22 and 23: About 0.01 w/v % to About 0.05 w/v % Tyloxapol; Claim 18: About 0.02 w/v % to About 0.05 w/v % Tyloxapol; Claim 12: About 0.02 w/v % Tyloxapol136		
	В.	Claims 7-12, 19-23 and 27: Greater Than About 90% of Bromfenac Remains After Storing at 60° C. for 4 Weeks		
	C.	Claims 25-29: EP-Criteria B Standard for Preservative Efficacy		
XI.	CON	ONCLUSION155		
XII.	CLAIM CHART DEMONSTRATING THAT PROLENSA [®] FALLS WITHIN THE SCOPE OF CERTAIN CLAIMS OF THE '131 PATENT			
XIII.	CHART DEMONSTRATING THAT LUPIN'S GENERIC BROMFENAC PRODUCT IS AN EXACT COPY OF PROLENSA [®] 171			

1 7 7

I, Robert O. Williams, III, Ph.D., under penalty of perjury, declare as follows:

I. INTRODUCTION

1. I have been retained by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Senju Pharmaceutical, Co., Ltd. in connection with six *inter partes* review ("IPR") proceedings (IPR2015-00903, IPR2015-00902, IPR2015-01097, IPR2015-01099, IPR2015-01100 and IPR2015-01105) before the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("Board") as an expert in the field of the design, evaluation, and formulation of drug products. My qualifications in these areas, as well as other areas, are established below and by my *curriculum vitae*, which is attached as EX2115.

II. BACKGROUND AND QUALIFICATIONS

2. I am currently the Johnson & Johnson Centennial Chair of Pharmaceutics at the University of Texas at Austin College of Pharmacy in Austin, Texas, where I have been teaching and conducting research for twenty years. Also, I am the Division Head of Pharmaceutics.

3. I received a B.S. degree in biology from Texas A&M University in 1979, a B.S. degree in pharmacy from the University of Texas at Austin in 1981, and a Ph.D. degree in pharmaceutics from the University of Texas at Austin in 1986. I am a licensed pharmacist.

5

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.