

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.

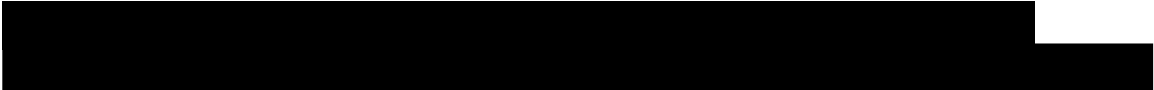
Case IPR2015-00903  
Patent 8,129,431

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

## TABLE OF CONTENTS

I.	INTRODUCTION .....	5
II.	BACKGROUND AND QUALIFICATIONS .....	5
III.	INFORMATION CONSIDERED .....	8
IV.	LEGAL PRINCIPLES .....	9
V.	THE '431 PATENT .....	9
A.	Specification and Claims .....	9
B.	Person of Ordinary Skill in the Art .....	15
VI.	SUMMARY OF OPINIONS .....	16
VII.	THE STATE OF THE ART AS OF JANUARY 21, 2003 .....	22
A.	A Person of Ordinary Skill in the Art Would Not Have Pursued Bromfenac Formulations Over Other NSAID Formulations .....	26
1.	No reason to pursue bromfenac formulations .....	26
2.	Design needs or market demands would not have supported the solution that InnoPharma proposes .....	29
B.	A Person of Ordinary Skill in the Art Would Not Have Considered Different Non-Ionic Surfactants Interchangeable .....	36
1.	No teaching of interchangeability of polysorbate 80 and tyloxapol in aqueous solutions of NSAIDs .....	37
2.	No teaching of polysorbate 80 or tyloxapol as a stabilizer of aqueous ophthalmic preparations of NSAIDs .....	42
C.	A Person of Ordinary Skill in the Art Would Not Have Considered Different NSAIDs Interchangeable .....	46
VIII.	THE TEACHINGS OF OGAWA, SALLMANN, AND FU WOULD NOT HAVE BEEN COMBINED WITH ANY REASONABLE EXPECTATION OF ARRIVING AT THE CLAIMED SUBJECT MATTER OF THE '431 PATENT .....	49

A.	A Person of Ordinary Skill in the Art Would Have Had No Reason to Focus on Ogawa and its Bromfenac Formulations .....	49
B.	At the Time of Invention, A Person of Ordinary Skill in the Art Would Not Have Combined Ogawa’s Teachings With Those of Sallmann.....	53
1.	Ogawa and the problem it identifies with bromfenac.....	53
2.	A person of ordinary skill in the art would not have looked to Sallmann or combined its teachings with those of Ogawa .....	57
3.	Dr. Laskar’s alleged motivation and expectation of success in fact would not have made the combination of Ogawa and Sallmann obvious to make.....	65
4.	A person of ordinary skill in the art would not have modified Sallmann with the teachings of Ogawa.....	70
C.	Dr. Laskar’s Reliance on Fu is Similarly Scientifically Unsupportable and Does Not Remedy the Deficiencies in his Reliance on Ogawa and Sallmann.....	73
1.	Dr. Laskar’s reliance on Fu for tyloxapol is unsupported .....	75
2.	Fu does not suggest an amount of tyloxapol that could be used to stabilize bromfenac.....	79
IX.	OBJECTIVE EVIDENCE OF NON-OBVIOUSNESS OF THE ’431 PATENT CLAIMS .....	83
A.	A Unique, Non-Prior Art, Aspect of the ’431 Patent Claims: The Use of Tyloxapol with Bromfenac.....	83
B.	The Unexpectedly Superior Chemical Stabilizing Benefits of Tyloxapol Compared to Polysorbate 80.....	85
1.	The ’431 patent compares against the closest prior art for purposes of showing unexpected results.....	86
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 .....	88
3.	Tyloxapol’s unexpectedly superior chemical stabilizing effect.....	90
C.	Tyloxapol is Unexpectedly Better than Polysorbate 80 at Maintaining Preservative Efficacy .....	99
D.	Tyloxapol’s Unexpectedly Superior Stabilizing Effect Led to Actual Benefits for Patients.....	101
E.	Copying of Prolensa® by Generic Drug Companies .....	104
X.	CONCLUSION.....	105
XI.	CLAIM CHART DEMONSTRATING THAT PROLENSA® FALLS WITHIN THE SCOPE OF CERTAIN CLAIMS OF THE ’431 PATENT .....	111
XII.		

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 two *inter partes* review (“IPR”) proceedings (IPR2015-00903 and IPR2015-00902) 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.

# 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.