

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 IPR2014-00903  
Patent 8,129,431

**DECLARATION OF STEPHEN G. DAVIES, D.Phil.**

PAGE 1 OF 58

SENJU EXHIBIT 2105  
INNOPHARMA v SENJU  
IPR2015-00903

IPR2015-01099

## Table of Contents

I.	BACKGROUND AND QUALIFICATIONS.....	2
II.	INFORMATION CONSIDERED.....	4
III.	LEGAL PRINCIPLES.....	5
IV.	THE '431 PATENT.....	5
V.	SUMMARY OF OPINIONS.....	11
VI.	STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFOR.....	14
A.	The Level of Skill in the Art.....	14
B.	Bromfenac is Structurally and Chemically Dissimilar to Diclofenac, Ketorolac and Pranlukast.....	14
1.	Comparison of Bromfenac and Diclofenac.....	14
2.	Comparison of Bromfenac and Ketorolac.....	22
3.	Comparison of Bromfenac and Pranlukast.....	27
C.	Dr. Laskar Has Not Established That a Precipitate Will Form between an NSAID such as Bromfenac and BAC.....	33
D.	Non-ionic Surfactants are Structurally and Chemically Diverse and Not Interchangeable.....	36
1.	Comparison of Polysorbate 80 and Tyloxapol.....	36
2.	Comparison of Octoxynol 9, Octoxynol 40 and Tyloxapol.....	39
E.	Cyclodextrins May Impact the Stability of the Claimed Bromfenac Formulations.....	46
VII.	NON-OBVIOUSNESS OF THE CLAIMS OF THE '431 PATENT.....	47
VIII.	CONCLUSION.....	50

I, Stephen G. Davies, under penalty of perjury, declare as follows:

1. I have been retained by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Senju Pharmaceutical, Co., Ltd. in connection with this action as an expert in organic chemistry and medicinal chemistry.

**I. BACKGROUND AND QUALIFICATIONS**

2. I am the Waynflete Professor of Chemistry at the University of Oxford, Oxford, England. I have been employed teaching chemistry at Oxford since 1980. From 2006 to 2011, I was Chairman of the Department of Chemistry. In this position, I had full responsibility for all teaching, research, financial and managerial matters in one of the largest chemistry departments in the world. I have also supervised more than 100 graduate students and 100 post-doctoral fellows in the area of organic, organometallic and medicinal chemistry.

3. In 1973, I earned a B.A. in Chemistry from the University of Oxford. In 1975, I earned a D. Phil. in Chemistry from the University of Oxford. In 1980, I received a D. Sc. in Chemistry from the University of Paris.

4. Over the course of my career, I have been a committee member of many professional organizations, a list of which can be found in my curriculum vitae, attached as Exhibit 2049.

5. I have authored over 550 publications and have given scores of research lectures. My research interests include synthetic organic and medicinal

chemistry, and in particular, the preparation of enantiomerically pure organic compounds, including the asymmetric and stereoselective synthesis of enantiomerically pure organic compounds for potential therapeutic use. A list of my publications may be found attached as Exhibit 2050.

6. I have also held several editorial appointments. I am the Founding Editor and Editor of Organic Series of "Oxford Chemistry Primers" and "Oxford Chemistry Masters," an Executive Editorial Board Member of "Tetrahedron," the Founding Editor and Editor-in-chief of "Tetrahedron: Asymmetry," and the Editor of the "On Chemistry" Books.

7. Over the course of my career, I have received several awards, including the Hickinbottom Fellowship (1984), Pfizer Award for Chemistry (1985), 1984 Corday Morgan Medal, Royal Society of Chemistry (1986), Royal Society of Chemistry Award for Organometallic Chemistry (1987), Pfizer Award for Chemistry (1988), Royal Society of Chemistry Bader Award (1989), Tilden Lecture Award, Royal Society of Chemistry (1996), Royal Society of Chemistry Award in Stereochemistry (1997), Prize Lectureship of the Society of Synthetic Organic Chemistry, Japan (1998), Distinguished Technopreneur Award, Singapore (2008), and Royal Society of Chemistry Perkin Prize for Organic Chemistry (2011).



8. I am also the founder of numerous companies including ones focused on the preparation of compounds for potential pharmaceutical use. Along with several others, I founded Oxford Asymmetry, Ltd. in 1992, which became a division of Oxford Asymmetry International plc, with a mission to provide pharmaceutical companies with enantiomerically pure compounds of interest on any desired scale, from small amounts for biological evaluation and research, to commercial quantities. Currently, I am the Founder and Non-executive Chairman of SciInk Ltd. I am also the Non-executive Director of Isis Innovation Ltd. I am also the Founder and Non-executive Director of OxStem Ltd. I am also the Founder and Non-executive Director of Summit Therapeutics plc, which develops pharmaceutical compounds and has two such compounds currently undergoing Phase II clinical trials.

9. On the basis of my education and the experience described above, I believe I am qualified to give the opinion set out herein.

## **II. INFORMATION CONSIDERED**

10. The opinions expressed in this declaration are based on my review of U.S. Patent No. 8,129,431 (“the ’431 patent”), the “Petition for *Inter Partes* Review of U.S. Patent No. 8,129,431” (“Petition”) and Exhibits to the Petition, including the declaration of Dr. Paul A. Laskar (EX1003). I have also reviewed the transcript of Dr. Laskar’s cross examination (EX2114). I have further

# 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.