

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.,)	
BAUSCH & LOMB INCORPORATED, and)	
BAUSCH & LOMB PHARMA HOLDINGS)	
CORP.,)	
Plaintiffs,)	
v.)	
)	C.A. No.: 1:14-cv-00667-JBS-KMW
LUPIN, LTD. and LUPIN)	C.A. No.: 1:14:cv-04149-JBS-KMW
PHARMACEUTICALS, INC.,)	C.A. No.: 1:14-cv-05144-JBS-KMW
Defendants.)	C.A. No.: 1:15-cv-00335-JBS-KMW
)	C.A. No.: 1:14-cv-06893-JBS-KMW
INNOPHARMA LICENSING, INC.,)	C.A. No.: 1:15-cv-03240-JBS-KMW
INNOPHARMA LICENSING, LLC,)	
INNOPHARMA, INC., INNOPHARMA,)	
LLC,)	
Defendants.)	

**OPENING EXPERT REPORT OF
M. JAYNE LAWRENCE, PH.D.**

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	COMPENSATION AND PRIOR TESTIMONY	4
III.	MATERIALS CONSIDERED	4
IV.	THE PERSON OF ORDINARY SKILL IN THE ART	4
V.	THE ASSERTED PATENT CLAIMS	5
A.	The Asserted Claims of the '431 Patent	5
B.	The Asserted claims of the '290 Patent	6
C.	The Asserted Claims of the '131 Patent	8
D.	The Asserted Claims of the '813 Patent	10
E.	The Asserted Claims of the '606 Patent	12
VI.	CLAIM CONSTRUCTION.....	14
VII.	BACKGROUND ON OPHTHALMIC FORMULATIONS CONTAINING NON- STEROIDAL ANTI-INFLAMMATORY DRUGS	15
A.	Non-Steroidal Anti-Inflammatory Drugs Were Widely Used for Ophthalmic Indications Prior to 2003.....	16
B.	Benzalkonium Chloride was One of the Most Commonly Used Preservative in Ophthalmic Formulations as of 2003	19
C.	Surfactants Were Known to Prevent the Formation of Insoluble Complexes Between NSAIDs and Benzalkonium Chloride	20
VIII.	DETAILED DESCRIPTION OF THE PRIOR ART	22
A.	U.S. Patent No. 4,910,225.....	22
B.	EP 0 306 984 A1	23
C.	Schott	26
D.	U.S. Patent No. 5,603,929.....	26
E.	U.S. Patent No. 5,891,913.....	27
IX.	LEGAL STANDARDS	28
A.	Legal Standards for Obviousness.....	28
B.	Legal Standard for Anticipation.....	30
C.	Legal Standard for Obviousness-Type Double Patenting.....	30
D.	Legal Standard for Written Description.....	31
E.	Legal Standard for Indefiniteness	31
F.	Legal Standard for Improper Dependency.....	32
X.	ANALYSIS OF THE ASSERTED CLAIMS	32
A.	U.S. Patent No. 8,129,431.....	32

CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

1.	The Asserted Claims of the '431 Patent are Obvious in Light of the '225 Patent and either EP '984 or the '913 Patent.....	32
2.	The Asserted Claims of the '431 Patent are Obvious In Light of the '913 Patent and The '225 Patent.....	44
B.	U.S. Patent No. 8,669,290.....	51
1.	The Asserted Claims of the '290 Patent are Obvious in Light of the '225 Patent and Either EP '984 or the '913 Patent.....	51
2.	The Asserted Claims of the '290 Patent are Obvious in Light of the '913 Patent and The '225 Patent.....	72
3.	Asserted Claims 1-3, 8-10, 14-16, 20-22, and 26-30 of the '290 Patent are Anticipated by the '929 Patent.....	84
4.	The Asserted Claims of the '290 Patent are Obvious in Light of the '929 Patent.....	86
C.	U.S. Patent No. 8,754,131.....	89
1.	The Asserted Claims of the '131 Patent are Obvious in Light of the '225 Patent and Either EP '984 or '913 Patent.....	89
2.	The Asserted Claims of the '131 Patent are Obvious in Light of the '913 Patent and The '225 Patent.....	109
3.	Asserted Claims 1-3, 7-9, 13-15, 19-21, 25-30 of the '131 Patent are Anticipated by the '929 Patent.....	122
4.	The Asserted Claims of the '131 Patent are Obvious in Light of the '929 Patent.....	124
D.	U.S. Patent No. 8,871,813.....	128
1.	The Asserted Claims of the '813 Patent are Obvious in Light of the '225 Patent and Either EP '984 or the '913 Patent.....	128
2.	The Asserted Claims of the '813 Patent are Obvious in Light of the '913 Patent and The '225 Patent.....	141
3.	The Asserted Claims of the '813 Patent are Obvious in Light of the '929 Patent.....	151
E.	U.S. Patent No. 8,927,606.....	154
1.	The Asserted Claims of the '606 Patent are Obvious in Light of the '225 Patent and Either EP '984 or the '913 Patent.....	154
2.	The Asserted Claims of the '606 Patent are Obvious in Light of the '913 Patent and The '225 Patent.....	174
3.	Asserted Claims 1-4, 11-14, 17, 19-22, 26, 28-30 of the '606 Patent are Anticipated by the '929 Patent.....	189
4.	The Asserted Claims of the '606 Patent are Obvious In Light of the '929 Patent.....	190
F.	The Asserted Claims of the '431 Patent Are Not Patentably Distinct From the '290 Patent, the '131 Patent, or the '544 Patent.....	194
1.	The Asserted Claims of the '431 Patent are Not Patentably Distinct From the '290 Patent.....	194

CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER

2.	The Asserted Claims of the '431 Patent are Not Patentably Distinct from Claims of the '131 Patent	198
3.	The Asserted Claims of the '431 Patent are Not Patentably Distinct From Claims of the '544 Patent	202
G.	The Asserted Claims of the '290 Patent Are Not Patentably Distinct From Claims of the '131 Patent.....	208
H.	Objective Indicia of Nonobviousness	210
1.	No Unexpected Results	211
2.	Other Objective Indicia	216
I.	Documents Produced by Plaintiffs Are Consistent With My Opinions Regarding Obviousness	218
J.	All of the Asserted Claims of the '290, '131, '813, and '606 Patents Are Indefinite .	220
K.	Asserted Claims 18-20 of the '431 Patent Do Not Meet the Written Description Requirement	227
L.	Asserted Claims 6 and 18 of the '131 Patent Do Not Incorporate All of The Limitations of the Claims from Which They Depend	227
M.	Asserted Claim 9 of the '606 Patent Does Not Incorporate All of The Limitations of the Claim from Which It Depends	228
XI.	MISCELLANEOUS	229

I, Jayne Lawrence, Ph.D., have been asked to render opinions regarding U.S. Patent 8,129,431 (“the ’431 patent”), U.S. Patent 8,669,290 (“the ’290 patent”), U.S. Patent 8,754,131 (“the ’131 patent”), U.S. Patent 8,871,813 (“the ’813 patent”) and U.S. Patent 8,927,606 (“the ’606 patent”) (collectively, “the patents-in-suit”). I hereby submit the following Expert Report on behalf of Defendants Lupin Limited, Lupin Pharmaceuticals, Inc., InnoPharma Licensing, Inc., InnoPharma Licensing, LLC, InnoPharma, Inc., and InnoPharma, LLC.

I. QUALIFICATIONS

1. I am an expert in the field of formulation and drug delivery, specifically pharmaceutical formulation for oral and parenteral use (i.e., non-oral, including intravenous, intramuscular, nasal, respiratory and ophthalmic), including aqueous liquid preparations. I have been an expert in this field since prior to 2003.

2. I received a B.Sc. with first class (top) honors from Liverpool Polytechnic in 1981, and a Ph.D. in Pharmacy from Manchester University in 1985. The subject of my Ph.D. studies was the design, synthesis and physico-chemical characterization of novel non-ionic surfactants for use in aqueous pharmaceutical formulations. I performed my Ph.D. studies under the supervision of Professors P.H. Elworthy and D. Attwood.

3. From 1984 to the present time I have held full-time, tenured academic positions of increasing seniority in Pharmacy (Lecturer 1984-1997, Senior Lecturer 1997-1999), Drug Delivery (Reader 2000-2003) and, most recently Biophysical Pharmaceutics (Professor 2003-to date) at King’s College London. I note that my professorship at King’s College London is the United Kingdom equivalent of a full, tenured Professorship in a university in the United States. In 1993 I spent a 6 month sabbatical working in Respiratory Product Development in

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.