IN THE 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.	§	
LUPIN, LTD. and LUPIN PHARMACEUTICALS, INC.,	§	1:14-cv-00667-JBS-KMW, 1:14-cv-04149-JBS-KMW, 1:14-cv-05144-JBS-KMW, 1:15-cv-00335-JBS-KMW,
Defendants.	§	
INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING, LLC, INNOPHARMA, INC., and INNOPHARMA, LLC,	§	1:14-cv-06893-JBS-KMW, and 1:15-cv-03240-JBS-KMW
	§	(Consolidated Actions)
Defendants.	§	**CONTAINS CONFIDENTIAL MATERIAL PURSUANT TO STIPULATED DISCOVERY CONFIDENTIALITY ORDER**

REPLY EXPERT REPORT OF JOHN C. JAROSZ ON OBJECTIVE INDICIA OF NON-OBVIOUSNESS

February 12, 2016

REPLY EXPERT REPORT OF

JOHN C. JAROSZ

ON OBJECTIVE INDICIA OF NON-OBVIOUSNESS

TABLE OF CONTENTS

I. INTRODUCTION

A. Assignment

1. I, John C. Jarosz, submit this reply expert report on behalf of Bausch & Lomb Incorporated, Bausch & Lomb Pharma Holdings Corp. (collectively, "Bausch & Lomb") and Senju Pharmaceutical Co. Ltd. ("Senju") (collectively, with Bausch & Lomb, "Patent Owners") in connection with the above captioned cases. I have been retained to provide expert analysis and testimony, if necessary, regarding the commercial success of the inventions described in U.S. Patent Nos. 8,129,431 ("the '431 patent"); 8,669,290 ("the '290 patent"); 8,754,131 ("the '131 patent"); 8,871,813 ("the '813 patent"); and 8,927,606 ("the '606 patent") (collectively, the "Patents-in-Suit"). It is my understanding that the asserted claims of the Patents-in-Suit are embodied in Bausch & Lomb's Prolensa® product.

2. On December 30, 2015, I submitted my opening expert report on objective indicia of non-obviousness in these cases.[1] Since then, I have received the responsive report of Ivan T. Hofmann.[2] I have been asked to provide my opinions regarding the analysis and conclusions set forth in the Hofmann Report. This report summarizes those opinions.

3. As with my initial report, I may modify or supplement my opinions, if necessary and allowed, based on the review and analysis of information provided to me subsequent to the filing of this report.

B. Qualifications

4. A complete description of my background and qualifications is provided in the Jarosz

---

[1] Opening Expert Report of John C. Jarosz on Objective Indicia of Non-Obviousness, December 30, 2015 ("Jarosz Report"). I submitted two versions of the Jarosz Report, one applicable to the Lupin Defendants and one applicable to the InnoPharma defendants. Page and Tab references in this report refer to the Lupin version of the Jarosz Report.

[2] Responsive Expert Report of Ivan T. Hofmann, CPA/CFF, CLP, February 1, 2016 ("Hofmann Report").

Report. An updated copy of my curriculum vitae is provided as Reply Tab 1.

C. Evidence Considered

5. Since submitting the Jarosz Report, I have reviewed additional information from a variety of sources, including the Hofmann Report, the responsive report of Dr. Robert C. Cykiert,[3] the reply report of Dr. William B. Trattler,[4] materials produced by Patent Owners in this litigation, and information from publicly-available sources, such as academic journals and analyst reports. A complete list of additional materials that I have received and reviewed since the date of the Jarosz Report is attached as Reply Tab 2.

D. Summary of Opinions

6. In his report, Mr. Hofmann concluded that

> Prolensa® is not a commercial success and the performance of Prolensa® is attributable to various extrinsic factors unrelated to the Patents-in-Suit. Specifically, the performance of Prolensa® is explained by the execution of a coordinated life-cycle management strategy for the bromfenac franchise which involved the following components: (1) the systematic migration to new bromfenac products and the discontinuation of legacy bromfenac products; (2) substantial marketing and promotional efforts; and (3) tactical pricing of Prolensa®. As a result, the performance of Prolensa® does not provide objective indicia of nonobviousness of the Patents-in-Suit.[5]

7. I disagree with Mr. Hofmann's conclusions for a number of reasons.

- Mr. Hofmann's conclusion that Prolensa® is not a commercial success is inconsistent with the evidence of Prolensa®'s marketplace performance over time. Prolensa® has achieved and maintained substantial acceptance, particularly in light of the array of competitive alternatives.

---

3 Responsive Expert Report of Robert C. Cykiert, M.D. on Objective Indicia of Non-Obviousness, February 1, 2016 ("Cykiert Report").

4 Reply Expert Report of William B. Trattler, MD, on Objective Indicia of Non-Obviousness, February 12, 2016 ("Trattler Reply Report").

5 Hofmann Report, at 15.

- Mr. Hofmann's conclusion that the success of Prolensa® is due to factors *other than* the Patents-in-Suit is inconsistent with evidence showing that the patents have been motivating (important) factors in Prolensa®'s success.
- Mr. Hofmann's characterization of any Prolensa® success as reflecting a "life-cycle management" strategy fails to acknowledge that the success of such a strategy requires that a new formulation must actually be deemed advantageous by the physician community before it will be prescribed. Here, physicians had a compelling reason to switch to Prolensa®, which is the improved side effect profile offered by Prolensa® relative to other available bromfenac formulations.
- Mr. Hofmann's analysis of Prolensa® marketing expenditures fails to recognize that marketing is one of many factors that influence physician prescribing behavior, and its impact is modest. Physicians are informed by marketing efforts, but weigh heavily the quality and effectiveness of a drug, as well as patient requests, when deciding what to prescribe. Marketing spending alone is not sufficient if the drug does not offer clinical benefits to patients, as Prolensa® does.
- Mr. Hofmann's conclusion that Prolensa® may be cheaper than generic bromfenac is inconsistent with the evidence and business realities. His analysis of Prolensa® net pricing relative to competing ophthalmic NSAIDs is incomplete.

II. FRAMEWORK

8. According to Mr. Hofmann, "any alleged commercial success must be *driven primarily by* and attributable to the purported merits of the claimed invention, and *not by other factors* unrelated to the allegedly novel features of the claimed invention. … there must be a causal correlation, or 'nexus,' between the unique merit of the claimed invention and

DOCKET ALARM

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.