

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.

INNOPHARMA LICENSING, INC.,
INNOPHARMA LICENSING, LLC,
INNOPHARMA, INC. and INNOPHARMA,
LLC,

Defendants.

Civil Action No. 1:14-cv-00667 (JBS)(KMW)
Civil Action No. 1:14-cv-04149 (JBS)(KMW)
Civil Action No. 1:14-cv-05144 (JBS)(KMW)
Civil Action No. 1:15-cv-00335 (JBS)(KMW)
Civil Action No. 1:14-cv-06893 (JBS)(KMW)
Civil Action No. 1:15-cv-03240 (JBS)(KMW)

(Consolidated Actions)

**CONTAINS CONFIDENTIAL MATERIAL
PURSUANT TO STIPULATED
DISCOVERY CONFIDENTIALITY ORDER**

SUPPLEMENTAL EXPERT REPORT OF ADAM C. MYERS, Ph.D.

I. INTRODUCTION

1. I, Adam C. Myers Ph.D., submit this expert report at the request of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Senju Pharmaceutical, Co., Ltd. ("Senju"), Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "B+L") 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 summarized in my expert reports dated December 24, 2015, and established by my *curriculum vitae*, which was attached as Appendix A to my December 24, 2015, expert reports.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

2. In forming my opinions, I had available the documents cited herein, the documents cited in my December 24, 2015, expert reports as well as the publications listed on my *curriculum vitae*. I also based my opinions on my professional and academic experience in

the area of drug formulation and analytics. I reserve the right to testify about these materials and experience. To the extent I am provided additional documents or information, including any expert reports produced by InnoPharma, I may offer further opinions. In addition to these materials, I may consider additional documents and information in forming any rebuttal opinions. Additionally, I may prepare demonstratives to illustrate any opinions I may present.

III. STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFOR

3. Samples of B+L's Prolensa[®] product [REDACTED] [REDACTED] were sourced from each manufacturer. Each manufacturer shipped the samples to Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, who then shipped the samples to SSCI for testing. A portion of these samples were further shipped to BioScience Laboratories, Inc. These samples were evaluated for chemical stability at SSCI and for preservative efficacy at BioScience Laboratories, Inc. during the months of November 2015 through January 2016. I was personally present during the chemical stability testing of these samples.

4. SSCI has provided summary reports of both the chemical stability testing and preservative efficacy testing, which are attached as Appendix A. These reports describe the analytical methodology to quantitate bromfenac free acid in the stressed and unstressed conditions. The chemical stability results are reported in the document for all of the samples tested.

5. SSCI is a cGMP facility providing contract product development services to the pharmaceutical industry. SSCI's service offerings include analytical testing (e.g., chemical stability), product development, and manufacturing. The chemical stability testing of B+L's Prolensa[®] product samples was performed in SSCI's cGMP quality control laboratory.

6. Samples of B+L's Prolensa® product [REDACTED] [REDACTED] were received, stored, handled, and maintained according to SSCI's cGMP sample handling procedures. The samples were stored under ambient laboratory conditions in their original containers.

7. A portion of the samples was used for unstressed analysis, and the remaining samples were stressed in an oven for four weeks at 60° C. The HPLC analyses to measure chemical stability were performed using an Agilent 1100 series chromatograph and the chromatographic column was a Shiseido Capcell Pak C18.

8. The SSCI reports correctly details the analytical testing that was performed and accurately reports the chemical stability test results, as well as the preservative efficacy test results.


IV. COMPENSATION

9. I am a salaried employee of AMRI SSCI, LLC and its affiliates and I receive no additional compensation for this matter. No part of my compensation is contingent upon the outcome of this matter or any issue in it.

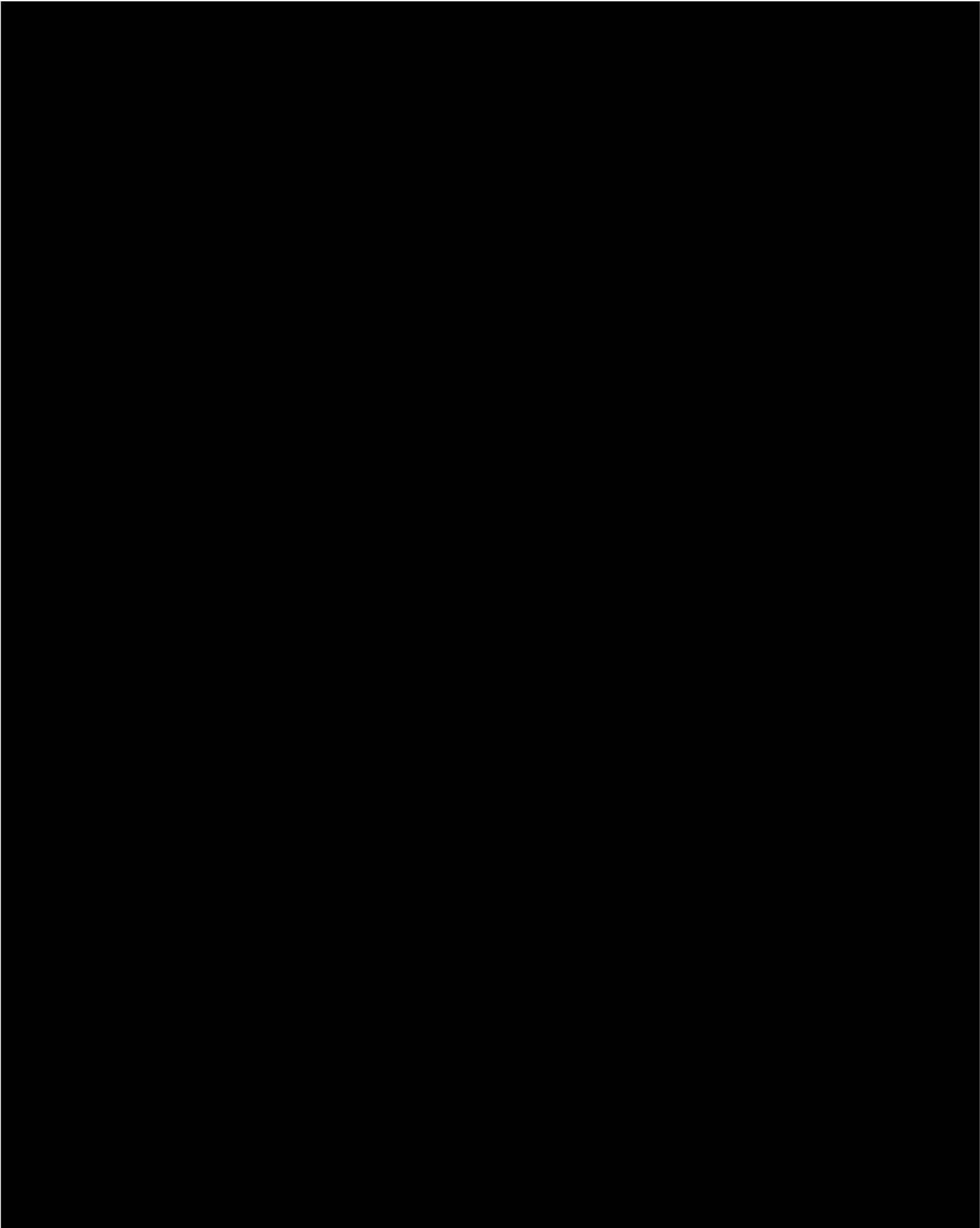
V. PRIOR EXPERT TESTIMONY

10. During the past four years, I have not testified as an expert in any cases.

11 Jan 2016
Date


Adam C. Myers, Ph.D.

Appendix A



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