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 OPENING EXPERT REPORT OF ROBERT O. WILLIAMS, III, PH.D. ON INNOPHARMA'S INFRINGEMENT AND OBJECTIVE INDICIA OF NON-OBVIOUSNESS

I. QUALIFICATIONS

1. I, Robert O. Williams, III, Ph.D., submit this report at the request of Plaintiffs Senju Pharmaceutical, Co., Ltd., Bausch & Lomb Incorporated, and Bausch & Lomb Pharma Holdings Corp. 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 28, 2015, and established by my *curriculum vitae*, which was attached as Appendix A to my December 28, 2015, expert reports.

2. I am submitting this supplemental expert report in view of the supplemental expert reports by Dr. Adam C. Myers and Dr. Daryl S. Paulson dated January 11, 2016, regarding the stability of [redacted] Plaintiffs' Prolensa® product.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

3. In forming my opinions, I had available the documents cited herein, the documents cited in my December 28, 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 pharmaceutical formulation. 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

4. I have reviewed the supplemental expert reports by Dr. Myers and Dr. Paulson, and I conclude that the opinions expressed in my opening expert reports dated December 28, 2015, are consistent with these supplemental expert reports. To the extent I had referenced Dr. Myers or Dr. Paulson's expert reports in my opening expert reports, I reserve my right to rely on Dr. Myers and Dr. Paulson's supplemental expert reports as well as their expert reports dated December 24, 2015.

A. Plaintiffs' Prolensa® Product

5. Samples of Plaintiffs' Prolensa® product were tested for chemical stability and preservative efficacy using the test conditions specified in certain claims of the patents-in-suit. A portion of samples was used for unstressed (as received) analysis, and the remaining samples were stressed in an oven for four weeks at 60° C. Samples from both the unstressed and stressed conditions were evaluated for potency, *i.e.* chemical stability, and preservative efficacy. (*See, e.g.*, Myers Supplemental Report; Paulson Supplemental Report.)

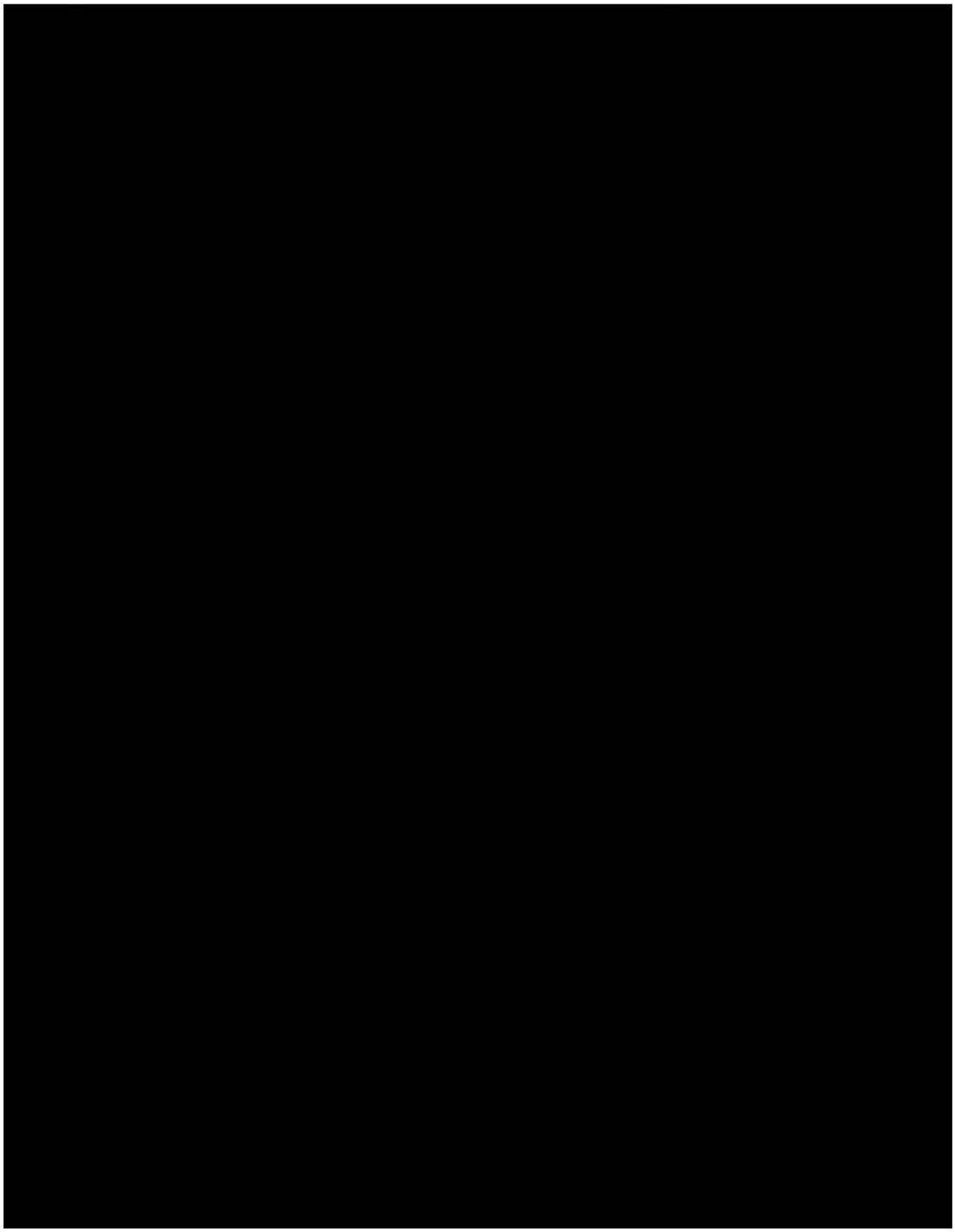
6. According to Dr. Myers' supplemental expert report, the average percent recovery of bromfenac free acid for samples that were stressed was 99.8%. (*See, e.g.*, Myers Supplemental Report.) These chemical stability results further support my opinion, consistent with the opinion provided in my opening expert reports, that Plaintiffs' Prolensa® product is a stable aqueous liquid preparation that has sufficient resistance to degradation to be formulated and maintained for ophthalmic use, as described in the claims of the '290, '131, '813 and '606 patents. These chemical stability results also support my opinion, consistent with the opinion provided in my opening expert reports, that Plaintiffs' Prolensa® product contains tyloxapol in an amount sufficient to stabilize bromfenac, as described in the claims of the '290, '131, '813 and '606 patents.

7. According to Dr. Paulson's supplemental expert report, the following test results were obtained for preservative efficacy of the unstressed and stressed samples (*see, e.g.*, Paulson Supplemental Report):

		Cell Count (CFU/mL)					
		Inoculum Count	Days After Inoculation				
Organism	Condition		1	7	14	21	28
S. aureus	Unstressed	1.97667×10^6	$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$	---	$<1.00 \times 10^1$
	Stressed		$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$	---	$<1.00 \times 10^1$
P. aeruginosa	Unstressed	1.7070×10^6	$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$	---	$<1.00 \times 10^1$
	Stressed		$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$	---	$<1.00 \times 10^1$
C. albicans	Unstressed	3.3953×10^5	---	---	$< 1.00 \times 10^1$	$< 1.00 \times 10^1$	$<1.00 \times 10^1$
	Stressed		---	---	$< 1.00 \times 10^2$	$< 1.00 \times 10^2$	$<1.00 \times 10^2$
A. niger	Unstressed	8.8837×10^5	---	---	$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$
	Stressed		---	---	$<1.00 \times 10^1$	$<1.00 \times 10^1$	$<1.00 \times 10^1$

8. It is my opinion, consistent with the opinion provided in my opening expert reports, based on the preservative efficacy test results above, that Plaintiffs' Prolensa® product, under both unstressed and stressed conditions, satisfies the EP-criteria B of the European

Pharmacopoeia, as described in claims 26-30 of the '290 patent and claims 28-30 of the '606 patent. Furthermore, because the Court construed "US Pharmacopoeia" in claims 25-29 of the '131 patent as "EP-criteria B of the European Pharmacopoeia," it is further my opinion that Plaintiffs' Prolensa® product, under both unstressed and stressed conditions, satisfies the EP-criteria B of the European Pharmacopoeia, as described in claims 25-29 of the '131 patent. The above preservative efficacy results, moreover, further support my opinion, consistent with the opinion provided in my opening expert reports, that Plaintiffs' Prolensa® product is a stable aqueous liquid preparation that has sufficient preservative efficacy to be formulated and maintained for ophthalmic use, as described in the claims of the '290, '131, '813 and '606 patents. Moreover, the claim charts in Appendices G-K identify the claims of the patents-in-suit that cover Plaintiffs' Prolensa® product and support that coverage with reference to each claim element.



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