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., 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
INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING, LLC, INNOPHARMA, INC., INNOPHARMA, LLC, MYLAN PHARMACEUTICALS, INC., and MYLAN INC., Defendants.	Civil Action No.: 1:14-cv-06893-JBS-KMW Civil Action No.: 1:15-cv-03240-JBS-KMW

DECLARATION OF JAYNE LAWRENCE, PH.D IN SUPPORT OF DEFENDANTS' CLAIM CONSTRUCTION BRIEF

I, Jayne Lawrence, Ph.D., declare and state as follows:

I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been asked to provide my opinion on the meaning of several claim terms in U.S. Patents 8,129,431 ("the '431 patent") (Ex. 12), 8,669,290 ("the '290 patent") (Ex. 13), 8,754,131 ("the '131 patent") (Ex. 14), 8,871,813 ("the '813 patent") (Ex. 15) and 8,927,606 ("the '606 patent") (Ex. 16) (collectively, "the patents in suit").

3. I am being compensated for my time in connection with this litigation at my standard consulting rate, which is GBP300 per hour. My compensation is not contingent on the

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conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

4. I have not testified in any case in the previous four years.

II. QUALIFICATIONS

5. 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.

6. I received a BSc 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 PhD studies was the design, synthesis and physic-chemical characterization of novel non-ionic surfactants[1] for use in aqueous pharmaceutical formulations. I performed my PhD studies under the supervision of Professors P.H. Elworthy and D. Attwood.

7. 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 Glaxo

[1] A surfactant is an amphiphilic molecule which contains a region that is hydrophobic (water-hating) and a region that is hydrophilic (water-loving). A non-ionic surfactant is a surfactant that does not dissociate into charged ions in solution. As a consequence of their dual nature, surfactants collect at surfaces, lowering surface tension as well as self-assembling/aggregates in solution. These unique properties make surfactants very attractive excipients in pharmaceutical formulations.

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Group Research (now GSK) concerned with the potential use of surfactants in the new propellant formulations.

8. I am currently Head of the Pharmaceutical Biophysics Group of The Institute of Pharmaceutical Science, King's College London and I have held this position since 2002. The Pharmaceutical Biophysics Group of The Institute of Pharmaceutical Science, King's College London currently consists of 6 academics and associated post-doctoral fellows and PhD students. The work of the group is concerned with securing an understanding at the molecular level of the physicochemical and biological properties of drug and gene delivery systems, through the combined application of advanced analytical techniques.

9. Since 2007, I have also held the role of Chief Scientist at the Royal Pharmaceutical Society on a part-time secondment from King's College London. At the present time, I equally divide my time between these two roles. My role at the Royal Pharmaceutical Society involves me representing it at the highest levels to outside organisations and key stakeholders (including government and public bodies), acting as its spokesperson on pharmaceutical sciences in the media and ensuring high quality pharmaceutical science input to policy development and implementation.

10. My past and current research has been in relation to pharmaceutical formulation and drug/gene delivery. I have been a principal or co-investigator on many formulation and drug/gene delivery studies, recent examples of which include the development of novel microemulsions for parenteral delivery, including for ocular administration; synthesis and characterisation of novel, non-ionic and zwitterionic surfactants with enhanced drug solubilisation capacity; the development of novel polymeric surfactants for pulmonary delivery;

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nanoparticles for the targeted delivery of therapeutic agents to the brain; and development of new injectable composites for gene delivery.

11. I have co-authored over 120 full scientific publications, with numerous conference papers and other scientific outputs such as articles for the scientific magazines. I have given over 150 invited (national and international) presentations. I have also been involved in the organisation of many pharmaceutical science meetings and conferences including the annual Academy of Pharmaceutical Sciences conference.

12. As listed in my curriculum vitae, I have also received numerous awards pertaining to my research and teaching. For example, in 2013 I became a Faculty Fellow of the Royal Pharmaceutical Society ("FFRPS"), while in 2012 I was awarded an Eminent Fellowship of the Royal Pharmaceutical Society ("EFAPS"), one of only 20 such Fellowships.

13. I currently hold senior positions in a number of national and international scientific committees, including the Academy of Pharmaceutical Sciences of Great Britain where I am currently vice-chair and the Formulation and Pharmaceutical Technology Special Interest Group of the International Pharmaceutical Federation where I am vice-chair but will become chair next year.

14. In addition to gaining expertise through educational training, professional experiences, and research experiences described above, I have kept abreast of the field of drug/gene delivery and formulation, particularly of aqueous liquid preparations by reading scientific literature, attending or presenting at scientific conferences, and attending or presenting at academic symposia. I have also been invited to participate in the peer review process for various scientific journals, and have reviewed many manuscripts submitted by other scientists relating to drug delivery, including ocular delivery. Some of the scientific journals for which I have reviewed

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scientific manuscripts include: International Journal of Pharmaceutics, Journal of Pharmaceutical Science, Langmuir, and Biochim. Biophys. Acta. Furthermore, I have collaborated with, or have communicated with, many researchers in the field of formulation and drug/gene delivery. Accordingly, I am an expert in the field of formulation and drug/gene delivery.

15. In formulating my opinions, I have relied upon my training, knowledge, and experience in the relevant art.

16. A copy of my current curriculum vitae is provided as Appendix A, and it provides a comprehensive description of my academic and employment history.

III. MATERIALS REVIEWED

17. In forming my opinions, I have reviewed, among other things, the materials cited in this report, the ’431 patent, the ’290 patent, the ’131 patent, the ’813 patent, the ’606 patent and papers filed in the Patent Office in connection with prosecution of each of these patents, which I understand to constitute the prosecution histories of the patents. A full list of materials I have considered can be found in Appendix B.

IV. LEGAL STANDARDS

18. I understand that for claim construction purposes, the Court will look to the meaning a person having ordinary skill in the art at the time of the invention would have ascribed to disputed claim terms, in view of the specification and prosecution history.

19. With respect to the level of ordinary skill in the art at the relevant times applicable to the subject patents, I understand that factors such as the education level of those working in the field, the sophistication of the technology, the types of problems encountered in the art, the prior art solutions to those problems, and the speed at which innovations are made may help establish

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