

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA INC., INNOPHARMA LLC,
MYLAN PHARMACEUTICALS INC., MYLAN INC., LUPIN LTD., and LUPIN
PHARMACEUTICALS INC.,
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.
Patent Owner.

Case IPR2015-00903 (Patent 8,129,431)¹

Filed: April 6, 2016

**Petitioner's Response to Patent Owner' Motion for Observation
Regarding Cross-Examination of Reply Witnesses
Dr. Paul A. Laskar, Ph.D. and Ivan T. Hofmann, CPA/CFF, CLP**

¹ IPR2015-01871 has been joined with IPR2015-00903.

Pursuant to the Scheduling Order (Papers 17 and 29), Petitioner hereby files its response to Patent Owner's Motion for Observation (Paper 61).

I. INTRODUCTION

Patent Owner's Motion for Observation mischaracterizes the testimony of Dr. Laskar and Mr. Hofmann, and further includes several arguments to the merits, which is an improper use of the Motion for Observation as a vehicle to make arguments in sur-reply. Furthermore, those arguments to the merits, which ultimately fail to contradict any of Petitioner's positions in this proceeding, further show why Patent Owner's Motion to Exclude Dr. Laskar's Reply Declaration and associated exhibits (Paper 59 at 8-10) is without merit. Accordingly, the Board should expunge or give no weight to Patent Owner's purported observations.

II. RESPONSES TO OBSERVATIONS ON CROSS-EXAMINATION

Observation #1: Patent Owner cites a small part of Dr. Laskar's testimony to imply that Dr. Laskar lacks qualification to provide the testimony in his reply declaration (EX1104). [REDACTED]

[REDACTED] Dr. Laskar is plainly qualified even under Patent Owner's definition of a POSA. Indeed, Dr. Davies, Patent Owner's own expert, states a POSA would have at least a Bachelor's degree in a field of science which includes "pharmaceutical sciences or a related discipline with about three to five

years of work experience in this area, or a comparable level of education and training.” EX2105, ¶ 41. Dr. Laskar also is qualified under Dr. Williams’s definition of a POSA and the definition of a POSA in the Patent Owner’s Response. EX2082, ¶ 41; Patent Owner’s Response, Papers 34 at 6. Petitioner provide a more complete response as to Dr. Laskar’s proper qualifications for the offered opinions and testimony in his Reply Declaration in the concurrently filed Petitioner’s Opposition to Patent Owner’s Motion to Exclude.

Observation #2: Patent Owner mischaracterizes Dr. Laskar’s testimony to suggest his testimony is inconsistent with his statement regarding tyloxapol’s antioxidant properties. Patent Owner distorts the record by mischaracterizing Dr. Laskar’s answer to Patent Owner’s vague and ambiguous questioning. EX2272, 69:3-4 (Petitioner objecting to the question as vague and ambiguous). Dr. Laskar testimony is consistent with the teaching that tyloxapol has antioxidant properties.

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See EX1104, ¶¶ 30-31; EX1012, Tables 4 and 5. Dr. Laskar did not state that tyloxapol was not an antioxidant. This aspect of Dr. Laskar’s testimony is clear when read in context of his Reply Declaration (EX1104) and his cross-examination testimony on November 4, 2015 (EX2114),
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generalized teaching that tyloxapol has antioxidant properties. EX1089, 1751; EX1106, 1415; EX1080, 114:6-16; EX1104, ¶¶21-22. If tyloxapol were not an antioxidant, and instead an oxidizing agent (which it is not), then it would not be oxidized by oxidizing agents. Whether or not the sodium in bromfenac sodium is in cation form or not has no relevance to Dr. Laskar's analysis.

Observation #4: Patent Owner's questions seeking legal conclusions whether a prior art is relevant in view of the preamble of the claims is improper and misleading. EX2272, 32:20, 33:6. Furthermore, Patent Owner omits other parts Dr. Laskar's testimony, [REDACTED] EX2272, 127:13-17; EX1104, ¶¶ 25-26.

Indeed, Patent Owner's own expert's testimony contradicts Patent' Owner's improper legal conclusion, stating that inhalation and nasal formulations have the same characteristics as ophthalmic formulations. EX1079, 20:13-21 ("I -- I study - - these often involve solution formulations and suspension formulations especially the one for the inhalation and nasal. So the characteristics are the same, but my application at the current time is not necessarily for the eye but for the lungs and nasal. So the properties of the materials I, mean, to me -- to a person of skill in the art would be quite similar."). Moreover, the '431 patent and Ogawa similarly involve nasal formulations. EX1001, 4:10-13, 11:48-51; EX1004, 4:60-62,

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