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

Case IPR2015-00902 (Patent 8,669,290 B2)

Filed: April 11, 2016

**PETITIONER'S REPLY TO PATENT OWNER'S OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE UNDER 37 C.F.R. § 42.64(c)**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

I. Patent Owner Cannot Justify the Lateness of Exhibits 2247-2263

Patent Owner cannot justify any delay in providing Exhibits 2247-2263. Patent Owner's only explanation is to insist that the untimely exhibits were Petitioner's fault for not objecting sooner, thus notifying Patent Owner of *its own deficiencies*. Presumably, Patent Owner was aware that the preservation efficacy testing was incomplete because Dr. Paulson's declaration admits that it would not be complete until "12/26/15," *i.e.*, after Patent Owner's filing. *See, e.g.*, EX2128 at 11. Given Patent Owner has had access to its product for years, it simply should not have waited so late to run its tests. Patent Owner's "explanation" that it only became aware of the incompleteness of *its* reports "because of the parallel district court litigations" (Opp'n, Paper 70 at 9) strains credulity because Patent Owner is stating that it is not aware of its own testing and the express content of its reports. Patent Owner does not dispute that Petitioner timely objected. Further, Petitioner's use of the served exhibits at the cross-examinations were subject to Petitioner's objections in the event Patent Owner later filed the exhibits, which it has. *See, e.g.,* EX1082 at 60:15-61:4; Opp'n, Paper 70 at 4 (relying on EX2247-2263 to support Dr. Paulson's testing). The Board should exclude these untimely exhibits.

II. Patent Owner Fails to Show that Dr. Paulson's Methods Were Reliable

Patent Owner's only response to the Rule 702 challenge is that Dr. Paulson didn't think the numerous deviations from the European Pharmacopeia procedures

1

were a problem. *See* Opp'n, Paper 70 at 4-5 (regarding the excessively high concentration of initial inoculum, Patent Owner insists that "Petitioner ignores Dr. Paulson's testimony, however, that he does not agree that this number is too high because 'it's not calculated that way,' as explained in EX2257."). All other deviations are brushed off in the same causal manner. *See* Opp'n, Paper 70 at 5-6 (Dr. Paulson insisted that deviations "never caused a problem" and they weren't "anything major"). These conclusory statements are not enough to establish that the deviations did not affect the reliability of the tests and justify exclusion. *Rembrandt Vision Techs. v. Johnson & Johnson Vision Care, Inc.*, 282 F.R.D. 655, 667 (M.D. Fla. 2012) *aff'd*, 725 F.3d 1377 (Fed. Cir. 2013).

Patent Owner brushes off *Rembrandt* by insisting the deviations in *Rembrandt* were "serious" but according to the *ipse dixit* of Dr. Paulson, his were not. (EX1082 at 138:12-139:19.) *Rembrandt* didn't focus on the seriousness of the deviations, but rather whether the methodology complied with generally accepted scientific standards that made it sufficiently reliable. *Id.* at 666. EP standards are governed by well-established criteria and Dr. Paulson's deviated from them. For example, Dr. Paulson's numerous deviations included using incorrect: (1) initial concentrations of inoculum; (2) concentrations of inoculum for the neutralization validation testing; (3) media for neutralization validation procedures; (4) temperature for the molten agar; (5) and the wrong incubation time.

2

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