IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC,

Petitioner,

v.

NPS PHARMACEUTICALS, INC.

Patent Owner.

Cases IPR2015-00990 and IPR2015-01093
(Patent 7,056,886 B2)[1]

PATENT OWNER'S RESPONSE TO INTRODUCTION IN PETITIONER'S RESPONSE TO MOTION PRESENTING PATENT OWNER'S OBSERVATIONS REGARDING CROSS-EXAMINATION OF IVAN HOFMANN

[1] Pursuant to the Board's Scheduling Order in these IPRs, "the word-for-word identical paper is filed in each proceeding identified in the heading." *See, e.g.*, IPR2015-00990, Paper 29, footnote 1.

I. Introduction

This is in response to Petitioner's objections in the Introduction to its Response to Patent Owner's Observations Regarding Cross-Examination of Ivan Hofmann. *See, e.g.*, IPR2015-00990, Paper 57 ("Paper 57") at 1-4. Petitioner objects because the Observations allegedly are too long, are argumentative, raise new issues, and introduce new exhibits. Petitioner is incorrect because the observations: (1) provide citations encompassing the relevant testimony and context necessary for understanding its relevance and succinctly (*i.e.*, in two sentences or less) explain the relevancy to Petitioner's submissions; (2) scrupulously avoid any argument; (3) do not raise any new issues; and (4) provide exhibits against which all objections have been waived and which are used for rebuttal.

Furthermore, Petitioner's objections should not be considered and should be expunged because they go far beyond what was authorized by the Board. Objections are presented outside of the introduction (*see, e.g.*, Paper 57 at 6), which Petitioner acknowledges is the only place in its response that the Board authorized for such objections. *See* Paper 57 at 1.

II. The Observations Cite the Appropriate Testimony

Petitioner complains, without reason, that certain testimony citations are simply too long. Paper 57 at 3. There is no *per se* citation length rule. If the entire

citation is relevant to a stated issue, the entire citation is proper. Patent Owner should not be required to truncate important cross-examination testimony simply because Petitioner believes it is long, and Petitioner and the witness should not be able to manipulate Observations and be rewarded by unduly complicating questioning and giving non-responsive answers.

More importantly, the citation to 62:12-83:19 (Observation ("Ob.") 3) was necessary because the question of whether the '886 patent claims encompassed formulations of many different analogs had to be asked claim-by-claim in order to avoid confusing the witness, because, in some instances, the witness requested that (*see, e.g.,* Ex. 2070 at 69:13-21), and because the witness gave long, non-responsive answers. *See, e.g., id.* at 68:4-17. The citations to 159:9-169:14 (Ob. 7) (commercial success/nexus), 120:9-128:22 (Ob. 14) (long felt need), 192:15-200:19 (Ob. 17) (patient penetration), and 257:20-267:13 (Ob. 21) (sale of NPS and valuation) each concern testimony developed through a series of questions and answers on opinions given by Mr. Hofmann. This type of questioning is a useful cross-examination technique, and Patent Owner should not be precluded from it by a *per se* length exclusion rule.

It should be noted that Petitioner also made multiple citations and multi-page citations (*see, e.g.*,Paper 57, at II.2., II.4., II.5., II.7., II.9., II.12., II.14., II.19., II.20., II.21.; Paper 56, Resp. II.A.ii., II.A. iii., II.D.iii., II.H.i.), and did not use the

precise phrasing.

III. Each Observation Explains Its Relevancy in only One or Two Sentences and Avoids Argument

Each observation includes only one or two sentences that explain the relevancy of the cited cross-examination testimony, *i.e.*, a short paragraph. Each Observation includes citations to Petitioner's Reply or the Witness's Reply Declaration showing to what the Observation relates. Finally, each Observation suitably groups the testimony citations according to a common issue of relevance.

Petitioner persistently characterizes cross-examination citations that are inconsistent with or rebut Mr. Hofmann's opinions in his Reply Declaration as reargument or argumentative. *See*, *e.g.*, Paper 57 at 2 and Resp. to Obs. 3, 4, 5, 7, and 9. Petitioner essentially asserts that if Patent Owner raised an issue first (such as a blocking patent or commercial success) and then Mr. Hofmann replied in his declaration, Patent Owner should be precluded (based upon theories of reargument and being argumentative) from offering Hofmann's cross-examination testimony on that issue in an Observation because Mr. Hofmann did not raise the issue first. No tribunal could sanction such an illogical approach (which would prevent testing any of Mr. Hofmann's opinions) to cross-examination.

The present Observations merely indicate the issues to which they apply. Each issue was addressed by Mr. Hofmann in his Declaration. Therefore, these issues were properly cross-examined. Argument would include application of facts

to law with reasons why the citations demonstrate a lack of expertise and use of hindsight. The Observations deliberately avoid that.

Furthermore, Petitioner now argues relevancy to Mr. Hofmann's expertise and qualifications (Paper 57 at Resp. to Ob. 1), to Mr. Hofmann's previous explanation that coupons, rebates, and patient insulation were not properly taken into account by Patent Owner (*id*. at Resp. to Ob. 10), the price of Gattex as a non-indication of commercial success (*id*. at Resp. to Ob. 11), whether the patient population for other drugs is relevant to the commercial success and long-felt need analysis for Gattex (*id*. at Resp. to Obs. 17-18), and that "the price paid by Shire for NPS is not evidence of any commercial success of Gattex" (*id*. at Resp. to Ob. 21). Petitioner's double standard shows its objections are baseless.

IV. The Rebuttal Exhibits Were Properly Introduced during Cross-Examination; Petitioner Did Not Make a Timely Motion to Exclude

Petitioner argues that Patent Owner has improperly introduced Exs. 2161-2169, 2172, and 2173. Paper 57 at 3-4. However, each was properly introduced as a rebuttal exhibit during the Hofmann cross-examination. *See* Ex. 2170 at 2-3. 37 CFR 42.53(f)(8) states: "Any objection to the content, form, or manner of taking the deposition, including the qualifications of the officer, is waived unless made on the record during the deposition and preserved in a timely filed motion to exclude." Petitioner never made a motion to exclude, and the deadline (*i.e.*, May 18, 2016) has passed. Any objections to these exhibits have been waived. Further,

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