

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
APOTEX INC., APOTEX CORP.,
EMCURE PHARMACEUTICALS LTD.,
HERITAGE PHARMA LABS INC.,
HERITAGE PHARMACEUTICALS INC.,
GLENMARK PHARMACEUTICALS, INC., USA,
GLENMARK HOLDING SA,
GLENMARK PHARMACEUTICALS, LTD., MYLAN
LABORATORIES LIMITED, TEVA PHARMACEUTICALS USA, INC.,
FRESENIUS KABI USA, LLC, and WOCKHARDT BIO AG,

Petitioners

v.

ELI LILLY AND COMPANY,

Patent Owner.

Case IPR2016-00318¹
U.S. Patent 7,772,209

**PETITIONER SANDOZ INC.'S RESPONSE TO PATENT OWNER'S
MOTION FOR OBSERVATIONS ON THE DEPOSITION OF
EXPERT PATRICK J. STOVER, PH.D.**

¹ Cases IPR2016-01429, IPR2016-01393, and IPR2016-01340 have been joined
with the instant proceeding.

I. PATENT OWNER’S MOTION FOR OBSERVATIONS INCLUDES IMPROPER ARGUMENTS AND SHOULD BE EXPUNGED

Petitioner respectfully requests that the Board dismiss Patent Owner’s Motion for Observations on the Deposition of Petitioner Sandoz’s Expert Dr. Patrick Stover (“Motion” or “Mot.”) and expunge its supporting exhibits because the purported observations in the Motion are a masked attempt to submit additional argumentative sur-reply pages in contravention of the Board’s guidance and prior decisions. Instead of a short statement of relevance, Patent Owner’s observations include argument, some of which spans several sentences. *E.g.*, Paper 61, Mot. at 2 and 3. Moreover, many of Patent Owner’s arguments are new; they do not match the positions taken on the portions of the prior briefing Patent Owner cites. Sandoz discusses particularly egregious examples in further detail in its responses below.

As the Office Patent Trial Practice Guide makes clear, “[a]n observation should be a concise statement of the relevance of identified testimony to an identified argument or portion of an exhibit [It] is not an opportunity to raise new issues, re-argue issues, or pursue objections.” 77 Fed. Reg. 48,755, 48,767-68 (Aug. 14, 2012). The Board has further noted that “each item included as an observation on cross-examination should be precise, preferably no more than one short sentence in the explanation of relevance. Observations on cross-examination are not meant to serve the purpose of an argumentative surreply.” *Atrium Med. Corp. v. Davol Inc.*, IPR2013-00189, Paper 48 at 2 (February 28, 2014).

“The Board may refuse entry of excessively long or argumentative observations (or responses),” such as the observations contained in Patent Owner’s Motion. *See* 77 Fed. Reg. 48,755, 48,767-68 (Aug. 14, 2012). In fact, the Board has previously considered proposed observations similar to the Patent Owner’s submissions and dismissed them as containing improper argument. In *Medtronic, Inc. v. Nuvasive, Inc.*, the Board reviewed proposed observations that “cite[d] several pages of [the witness’s] testimony, as opposed to one portion” and “proceed[ed] to present an argument that the testimony is relevant” IPR2013-00506, Paper 37 at 3-4 (October 15, 2014). The Board found the statements improper, dismissed the Motion, and expunged the relevant exhibits. *Id.*; *see also LG Elecs., Inc. v. ATI Techs. ULC*, IPR2015-00325, Paper 52 at 2-5 (January 25, 2016). While Petitioner maintains that the Board should dismiss the Motion without considering Patent Owner’s proposed observations due to their inclusion of argument, Petitioner has responded to the proposed observations below.

II. SANDOZ’S RESPONSES TO PATENT OWNER’S OBSERVATIONS

Response to Observation 1

Patent Owner’s observations introduce new arguments that are improper because they misconstrue the relevance of Dr. Stover’s testimony, which is inconsistent with Lilly’s own reliance upon the opinions of Dr. Zeisel and Lilly’s definition of a POSA. Dr. Stover is not a POSA (i.e., an oncologist), and does not

purport to be one. His testimony is responsive to Dr. Zeisel who, like Dr. Stover, is not an oncologist. Dr. Stover made clear that his opinions come from the perspective of a nutritional scientist about knowledge available to a POSA in June 1999, which is consistent with Lilly's definition that "[t]he POSA also would have an understanding of how nutritional issues relate to the use of chemotherapy agents" Paper 36 at 14. Dr. Stover testified:

A. I can tell you what information was available to that person at that time, but I can't tell you what any one individual would or would not have known. I can tell you what the state of knowledge was in terms of both biochemistry and nutrition at that time.

Q. Right.

A. And, but in particular you can speak to the state of knowledge in biochemistry and nutrition but not to the state of oncology; is that fair?

A. I can tell you -- I don't think that's completely fair, no. I think that I can tell you what information would be available to an oncologist at that time.

* * *

Q. Okay. And, but my question is: Have you -- have you made any effort in your mind to separate out, you know, what you know and what people with your type of expertise would have known from the standpoint of an expert in one-carbon metabolism and biochemistry from what the person of ordinary skill in the art for purposes of this case would have known?

A. I don't see those as distinct, because I can tell you that many of the leading antifolate oncologists attend the same meetings I do. We speak in the

same sessions. The focus of the talks is different, but there is a free sharing of information among those groups.

Ex. 2137, 25:2-26:22.

Dr. Stover further explained the relevance of nutritional science to oncologists and how nutritional scientists and oncologists work together both in a research and clinical setting. He explained that “nutrition is an important part of cancer treatment” (Ex. 2137 at 23:24-24:14), that he is involved in “scientific meetings, which are held annually, [where] we have a blend of people in nutrition, people who are biochemists and clinicians” who “intermingl[e]” knowledge (*id.* 22:7-14), and that in a hospital setting, “a full clinical team that would include an oncologist” would also “include someone understanding nutrition, if not the oncologist him or herself” (*id.* at 108:7-109:25).

Dr. Stover also testified that he is qualified to opine on the topics related to folate metabolism that are the subject of Dr. Zeisel’s testimony in this proceeding:

Q. And your declaration here today was done in response to Dr. Zeisel; correct?

A. That's correct.

Q. Is he an oncologist?

A. Dr. Zeisel is not an oncologist.

* * *

Q. Do you know Dr. Zeisel?

A. I know Dr. Zeisel well.

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