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 IPR2016-00318[1]
U.S. Patent 7,772,209

PETITIONER SANDOZ INC.'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE DEPOSITION OF EXPERT DAVID B. ROSS, M.D.

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[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 David B. Ross, M.D. ("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 60, Mot. at 4, 6-7, 9. 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 observation misconstrues the relevance of Dr. Ross's testimony. Dr. Ross is not a POSA (i.e., an oncologist) and does not purport to be

one. Instead, Dr. Ross opined as an expert in FDA practice in the 1999 timeframe and explained his disagreement with Lilly's interpretation of FDA statements as purported evidence of skepticism. Ex. 1093, Ross Decl., ¶¶ 11-12.

Further, Lilly's observation omits Dr. Ross's testimony concerning his experience with oncology:

> A. . . . . [C]ertainly, from the clinical perspective and, you know, I don't want to get into this now, but from the FDA perspective, I have the knowledge base that I think I need to accomplish the things that I -- I want to accomplish.
>
> Q. And when you say -- the -- the end of that answer was a little vague. When you say you have the knowledge base that you think you need to accomplish the things you want to accomplish, you mean -- what are those things? In -- in your – you mean in your role as -- as -- at VHA or here as an expert?
>
> A. Well, VHA, but I think -- and I know we're not discussing this now, but in terms of regulatory role, I think the same thing is true. So, you know, there's -- just to expand, there's some things where the clinic -- I'm only talking clinically – that I'm not -- there's things where this would not -- where this would not apply.
>
> Let's take, in general, for example, stage one melanoma. Okay. That's, in general, you know, not something -- if -- clinically, if I saw a patient with a mole that I thought was suspicious -- and I've done this -- I would send it to a dermatologist probably or, you know, if -- if – you know, an oncologist if it was appropriate, but that doesn't mean that I don't know anything about it.

And so I'm not an oncologist, I don't hold myself out to be one, but what I'm saying is I do have some knowledge of it. It's -- that can apply, and I think the same is true in terms of my role as an expert witness, but not from a clinical perspective. I would not say, you know, here's the treatment for this, that, or the other thing.

Q. What do you see your role as here as an expert witness? What -- what do you consider yourself to be an expert in for purposes of this proceeding?

A. In FDA requirements for development of drugs and biologics, the practical implementation of those requirements with regard to clinical trials, and, from a practical sense, how these things play out in terms of getting a drug studied and seeing if it is safe and effective.

Q. So in a -- in a broad sense, you're -- you're here as an expert in the issues in this case that relate to the FDA and to clinical trial design; is that fair?

A. What I would say is I'm here with regard to a specific question I was asked to address involving interactions between Lilly and -- and the FDA during development of -- pemetrexed -- I'm sorry, pemetrexed.

Exhibit 2132, Ross Tr. at 35:7-37:12.

Additionally, Patent Owner ignores Dr. Ross's extensive FDA experience, which is relevant to his opinions:

Q. Could you describe your role at the FDA, please?

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