Paper No. 69
Filed: February 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
APOTEX INC., APOTEX CORP., TEVA PHARMACEUTICALS,
FRESENIUS KABI USA, LLC, and
WOCKHARDT BIO AG,

PETITIONERS,

V.

ELI LILLY & COMPANY,

PATENT OWNER.

Case IPR2016-00237[1]
Patent 7,772,209

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE DEPOSITION OF PETITIONER NEPTUNE GENERIC'S EXPERT DAVID W. FEIGAL, JR., M.D.

[1] Cases IPR2016-01190, IPR2016-01335 and IPR2016-01341 have been joined with the instant proceeding.

Petitioner respectfully requests that the Board dismiss Patent Owner's Motion for Observations on the Deposition of Petitioner Neptune Generic's Expert David W. Feigal, Jr., M.D. ("Motion") and expunge its supporting exhibits because the purported observations in the Motion are a masked attempt to submit an argumentative surreply in contravention of the Board's guidance and prior decisions.

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, 48,767-8 (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 Medical Corporation v. Davol Inc.*, IPR2013-00189, Paper 48 (February 28, 2014) at 2.

"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, 48,767-8 (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 (October 15, 2014) at 3-4. 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.

Response to Observation # 1

Patent Owner's claim that Dr. Feigal is not "rendering an opinion on that *subject* [of obviousness]" is misleading. Dr. Feigal clearly testified that although he was not opining about obviousness "in the patent sense," he was opining that "in the everyday meaning of that language there has been a role in vitamins in the evaluation of most of the antifolate drugs so in that sense of a developing a new one, it is an obvious aspect of developing this class of drugs." Ex. 2133 at 16:13-20. He further testified that the FDA documents at issue "reflect [] the fact the FDA recognized that with antifolate drugs that folate is sometimes part of the regimen in order to have drugs that are safer and more effective. So most of the

discussions where not about whether this made sense, but how exactly to study it and meet the statutory requirements for approval." Ex. 2133 at 18:3-14; *see also* Ex. 2133 at 21:23-22:20. Consistent with these statements and his report, Dr. Feigal testified that: (1) the FDA "insisting on having a statistical plan before agreeing to make a change to include vitamins in the clinical trials and having a statistical plan *does not bear on the issue of whether – whether vitamins were obvious or not*" (Ex. 2133 at 18:22-19:4; Ex. 1080 ¶39(a) (emphasis added)); (2) modifying clinical protocol in the midst of trial "is a very generic issue that has to do with what happens with trials that are split and trials that are modified in the course that may become difficult to interpret so i*t doesn't directly relate to the issue of obviousness*" (Ex. 2133 at 19:6-16 (emphasis added); Ex. 1080 ¶39(b)); (3) changing a treatment midstream becomes an issue "because the first half of the study and the second half, that's not a randomized comparison that – that such studies are difficult to interpret no matter what the topic of the study is so, again, that's why I felt in my opinion the FDA was raising these issues as issues that would undermine the quality of the evidence necessary for approval of the product and *didn't relate to the obviousness issue with respect to the vitamins*" (Ex. 2133 at 19:17-20:5 (emphasis added); Ex. 1080 ¶39(c)); and (4) that FDA policies on combination drug regulations have nothing to do with obviousness, instead they demonstrate "specifics what combination products need to do for approval . . . and

how the trials would – would, could or might not accomplish that," (Ex. 2103 at 20:6-13; Ex. 1080 ¶39(d)).

Response to Observation # 2

Patent Owner's observation that Dr. Feigal's testimony concerning the FDA's statements regarding efficacy purportedly supports Patent Owner's argument that "the FDA expressed skepticism about pretreatment with folic acid and vitamin B12," which testimony supports a finding of nonobviousness, is both misleading and false. Dr. Feigal clearly testified that the "FDA was *not expressing skepticism* as to the benefits of vitamin supplementation." Ex. 2133 at 93:14-18 (emphasis added). Dr. Feigal further testified that safety and effectiveness *must always* be evaluated in accordance with "statutory requirements that evidence of effectiveness comes from adequate and well-controlled trials . . . So every product that is approved has to, you know, has to meet that standard and FDA has the responsibility to decide how to apply that standard . . ." Ex. 2133 at 94:10-95:4. Additionally, Dr. Feigal testified that "the FDA's concerns about successful clinical trials would almost always – almost always involve that the trials are adequate to establish efficacy . . . *efficacy is almost always involved*." Ex. 2133 at 96:3-20 (emphasis added). Accordingly, Dr. Feigal's testimony does not and cannot support Patent Owner's argument of nonobviousness, where Dr. Feigal testified: (1) that the "FDA recognized that with antifolate drugs that folate is

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