Paper No. 65
Filed: February 21, 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 IPR2016-00240[1]
Patent 7,772,209

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE DEPOSITION OF PETITIONER NEPTUNE GENERIC'S EXPERT JOEL B. MASON, M.D.

[1] Cases IPR2016-01191, IPR2016-01337 and IPR2016-01343 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 Joel B. Mason, 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. Instead of a short statement of relevance, Patent Owner's observations include argument, some of which spans several sentences or is strung together with a series of semicolons. (*E.g.*, Paper 59, observations 1, 2, 3, 4, 5.) Neptune discusses particularly egregious examples in further detail 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, 48,767-8 (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 attempts to set up a contradiction that does not exist and misleadingly cites to allegedly supporting papers filed in this proceeding, including Petitioner's Reply (Paper No. 47), which does not support Patent Owner's observation at all. Accordingly, Patent Owner's observation is nothing more than an improper attempt to submit an argumentative surreply. First, although Dr. Mason testified that when administering Vitamin B12 to a Vitamin B12 replete

patient "you're probably not going to further lower homocysteine levels," Patent Owner ignores testimony wherein Dr. Mason also indicated that none of the tests are perfect. Ex. 2134 at 146:7-20. Additionally, Dr. Mason did not testify, as Patent Owner attempts to argue, that it would not have been obvious to administer Vitamin B12 as a pretreatment to pemetrexed. In fact, Dr. Mason unequivocally testified, consistent with his expert report, that certain patient populations are more likely to present with Vitamin B12 deficiencies and "the POSA would have been treating a lot, many, most of his patients about to embark on pemetrexed with Vitamin B12." Ex. 2134 at 182:11-14; Ex. 2134 at 126:22-129:11 (testifying that "a POSA would likely have been particularly attune to certain patient groups that might be at a higher risk of B12 depletion" and, therefore, treated them with B12 before those patients received pemetrexed); Ex. 2134 at 129:12-130:17; *see also* Ex. 2134 at 140:18-141:7 (testifying that "[s]ince B12 has little or no side effects" it *would not* be "inappropriate to co-administer B12 with folic acid."); Ex. 2134 at 122:7-15 (testifying that "a person of ordinary skill in the art would have pretreated those who were found to have a low vitamin B12 status . . ."); Ex. 1078 at ¶¶ 58 et. seq.; Ex. 1078 ¶¶86-87, 91. This is in direct contradiction to Patent Owner's misleading statements and attorney argument indicating a POSA would allegedly be motivated to administer Vitamin B12 "only to patients who are not Vitamin B12 deficient"– an argument that Patent Owner misleadingly sets forth in its

observation and which does not appear in Petitioner's Reply. *See* Paper No. 47 at 27 (stating that the "methyl trap" would only be a concern for B12 deficient patients, who would be identified and repleted prior to pemetrexed therapy, and further stating that a POSA would not retrain from using Vitamin B12 in non-B12-deficient patients.). Furthermore, Dr. Mason testified, contrary to Patent Owner's attorney argument appearing in the observation but consistent with his expert report and Petitioner's Reply, that the "methyl trap" – wherein administering B12 to a B12 deficient patient can potentially cause usable folate to be released – would only be a concern for a B12 deficient patient-which patients would be repleted prior to pemetrexed therapy. Ex. 2134 at 21:10-21; Ex. 1078 at ¶¶53-56.

Response to Observation # 2

Patent Owner mischaracterizes and misstates Dr. Mason's testimony; Patent Owner's observation that Dr. Mason's testimony somehow supports Patent Owner's argument that the administration of Vitamin B12 may release an unpredictable amount of reduced folate making it available for cancer cells is nothing more than wishful thinking. First, consistent with his expert report, Dr. Mason testified that Patent Owner's argument was "theoretical" at best. Ex. 2134 at 32:12-14 ("on a *theoretical basis*, if vitamin B12 was administered to a B12 replete patient, it might make more tetrahydrofolate available.") (emphasis added); Ex. 1078 at ¶49. And, consistent with his expert report, Dr. Mason testified that

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