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 REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE

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

I. DR. NIYIKIZA'S PRIOR TESTIMONY SHOULD BE EXCLUDED

A. Dr. Niyikiza's Prior Testimony Should Be Excluded As Hearsay

Lilly does not refute the facts establishing that Dr. Niyikiza's testimony (Ex. 2116) is hearsay: Dr. Niyikiza's prior testimony was not made while testifying in this IPR; and that testimony is offered to prove the truth of the matter asserted.

Instead, Lilly suggests Dr. Niyikiza's cross-examination in the Teva Litigation allows it to rely on his former testimony. This is not so. Fed. R. Evid. 804(b)(1) provides that former testimony is only exempted from the hearsay rule if "the declarant is unavailable as a witness." Lilly states that Dr. Niyikiza is not under Lilly's "control," but never asserts that he is ***unavailable***. Paper 72 at 1. Notably, Petitioners' Motion To Cross-Examine Dr. Niyikiza is still pending, which could have been avoided had Lilly cooperated in producing Dr. Niyikiza. Moreover, the former testimony exception is limited to prior testimony offered against a party who had a chance to cross-examine the witness, an opportunity Sandoz never had. *See* Fed. R. Evid. 804(b)(1)(B). Nothing suggests Teva's cross-examination can serve as a substitute – particularly since Teva did not examine the context of the particular hearsay testimony on which Lilly now relies.

Lilly's cases do not hold otherwise. In *Petroleum Geo-Services Inc. v. WesternGeco LLC*, prior testimony was admissible "because Petitioner had the opportunity to cross-examine [the witness] ***in this proceeding***[.]" IPR2014-01477,

Paper 71 at 75-76 (July 11, 2016) (emphasis added). *Arceo* and *Inadi* did not involve hearsay testimony used to circumvent cross-examination. *See Arceo v. City of Junction City*, 182 F. Supp. 2d 1062, 1080-81 (D. Kan. 2002) (noting no right to cross-examine existed at summary judgment stage and thus permitting transcript); *United States v. Inadi*, 475 U.S. 387, 394 (1986) (recognizing one of many rationales behind the hearsay treatment of prior testimony).

By contrast, the Board's holding that prior testimony was entitled to no weight in *Organik Kimya AS v. Rohm & Haas Co.* is directly on point. IPR2014-00185, Paper 42 at 2 (Dec. 18, 2014). Lilly vaguely argues that the issues were not "the same" in the prior proceeding in *Organik* (Paper 72 at 8), but this is belied by the fact that prior anticipation-related testimony was considered relevant to whether the motion to amend in the later proceeding overcame the anticipatory art. Like *Organik*, Lilly's end-run around the Board's rules requiring an affidavit – and cross-examination – should result in exclusion, or at minimum, the testimony being given no weight. *See* 37 C.F.R. §§ 42.53(a), 42.51(b)(1)(ii). Further, Lilly cannot hide behind the "prepared for the proceeding" clause of the affidavit rule here where Dr. Niyikiza's testimony was "affirmatively relied upon by a patent owner" and thus interjected into the current proceeding. *See Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, PGR2015-00011, Paper 29 at 2 (Apr. 1, 2016).

Lilly disingenuously argues that Sandoz put Dr. Niyikiza's testimony into

evidence because the petition cites Dr. Niyikiza's summary of FDA documents relied on by Lilly to show purported skepticism. Paper 72 at 1-2; Paper 2 at 45 (citing Ex. 1036 at 808-10, 874-76). Sandoz only cited this testimony because the documents themselves were not accessible at the time. Ex. 2019, 28:15-29:1. Now that Lilly has reluctantly produced the documents (*id.* at 23:23-24), there is no need to consider the testimony. Further, under Fed. R. Evid. 801(d)(2)(B), Dr. Niyikiza's testimony is not considered hearsay when Sandoz cites it against the opposing party (Lilly) because it is a party admission.

Finally, corroboration cannot salvage Dr. Niyikiza's hearsay. *See* Paper 72 at 2. Rather than corroborating Dr. Niyikiza's testimony, Dr. Ross disagreed that the FDA believed folic acid would reduce efficacy. Ex. 2132 at 116:10-117:5. Moreover, the hearsay exception for statements against interest is the only one that includes a corroboration provision. *See* Fed. R. Evid. 804(b)(3)(B). Dr. Niyikiza's self-serving hearsay certainly does not qualify and thus corroboration is irrelevant.

B. Dr. Niyikiza's Double Hearsay Should Be Excluded

Lilly defends Dr. Niyikiza's self-serving double hearsay about others' statements of skepticism by arguing these statements are not offered for their truth because "what matters to skepticism is that they were said." Paper 72 at 10. This is false. A third party's hearsay statement, e.g., "I am skeptical," can have no bearing on whether skepticism existed unless offered for the truth. Further, it is

telling that the district court's stated reasoning for allowing such hearsay was, "I'll overrule it. It's interesting. I would like to hear it." Ex. 2116 at 722-23.

II. PARAGRAPHS 24-28 AND 44-78 OF DR. ZEISEL'S DECLARATION (EXHIBIT 2118) SHOULD BE EXCLUDED

"Lilly agrees that Dr. Zeisel is not an oncologist, and by himself does not have all the skills of the POSA." Paper 72 at 12. Lilly even admits that Dr. Zeisel "may not be able to speak with confidence to everything the POSA would think . . . ." *Id.* at 14. Despite this, Dr. Zeisel purports to offer opinions from the perspective of a POSA. *See id.* These improper opinions should be excluded.

Federal Circuit precedent requires exclusion of experts like Dr. Zeisel who offer opinions beyond their area of expertise. Paper 64 at 12 (citing *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363-64 (Fed. Cir. 2008); *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360-61 (Fed. Cir. 2006)). These cases do not support Lilly's claim that having any relevant experience suffices to avoid exclusion. *See* Paper 72 at 13-14. For example, in *Flex-Rest*, the invention applied ergonomic principles. 455 F.3d at 1360-61. Nonetheless, the court excluded an ergonomics expert's opinions on anticipation and obviousness because the POSA was a keyboard designer. *Id.* Similarly, the Board should exclude Dr. Zeisel, a nutritionist, from opining as a POSA who is indisputably an oncologist.

Lilly's presentation of an admitted non-POSA to present testimony on a POSA's opinions runs counter to Lilly's own cases, which involved experts

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