Paper No. 72
Filed: February 28, 2017

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 REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)

[1] Cases IPR2016-01191, IPR2016-01337 and IPR2016-01343 have been joined with the instant proceeding.

I. THE BOARD SHOULD EXCLUDE EXHIBIT 2120

Lilly argues that the Board should not exclude Dr. Chabner's testimony (Ex. 2120) because the District Court credited his testimony in a *different proceeding*. (Paper 66 at 1-2.) But the Board has held that "the deference a district court receives for expert credibility determinations is accorded by the Federal Circuit reviewing an appeal from the district court, not by the Board in an *inter partes* trial proceeding." (*Noven Pharm., Inc. v. Novartis AG*, IPR2014-00550, Paper 77 at 4 n.8 (denying rehearing of invalidity decision following District Court and Federal Circuit findings of validity.)

Lilly tries to force these proceedings into the mold that won at the District Court, ignoring crucial differences between these proceedings and the District Court case, especially with respect to Dr. Chabner's testimony. For example, two of the primary references here—EP 005 (Ex. 1010) and Rusthoven (Ex. 1011)—were not mentioned in the District Court decision or related Federal Circuit decision. *See* Ex. 1027; *Eli Lilly v. Teva*, 845 F.3d 1357 (Fed. Cir. 2017). All of the opposing experts are also different than in the District Court. (*Compare* Ex. 1027 with Exs. 1077, 1078, 1080.) Thus, Dr. Chabner's testimony before the District Court is irrelevant here. *Noven*, Paper 77 at 4 ("The Federal Circuit's [] decision does not control here because [Petitioner] has presented additional prior art and declaratory evidence that was not before the Court").

The declaratory evidence in *these proceedings* shows that Dr. Chabner "testified based on his own perspective and that he possesses 'extraordinary,' not ordinary, skill in the art, [such that] his conclusions are improper." *Neutrino Dev. Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529, 550 (S.D. Tex. 2006) (excluding expert testimony as unreliable based on use of personal, and not a POSA's standard to determine obviousness). Lilly tries to justify Dr. Chabner's use of the wrong standard by arguing that an invention that would be obvious to one of *ordinary* skill in the art should also be obvious to one of *extraordinary* skill in the art. (Paper 66 at 3.) Lilly misses the point. The fatal flaw in Dr. Chabner's testimony is not his skill beyond that of a POSA, but is the fact that he brought his own *personal biases* to the table when rendering his opinions.

For example, Dr. Chabner testified that his personal "views were formed about folate pretreatment based on [his] extensive work on methotrexate in the '70s and '80s"—decades before any of the relevant prior art references were published. (Ex. 1075 at 208:15-20.) Because of this bias, Dr. Chabner further testified that he required proof that the "regimen that was patented" "worked in the clinical setting" in order to "change my mind" because "my frame of mind was that it wasn't going to work, and this didn't [] present any evidence to change that, and what was really needed was clinical evidence to change that mind – my mindset about it." (Ex. 1075 at 214:2-25.)

Dr. Chabner did *not* testify as to a POSA's reasonable expectation of success, because this "does not necessitate an absolute certainty for success" from clinical evidence. *Par Pharm., Inc.v. TWi Pharms., Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). Instead, a POSA would have a reasonable expectation of success here where the prior art discloses "initiated human clinical trials for a therapeutic product or process." *In re Montgomery*, 677 F.3d 1375, 1382-83 (Fed. Cir. 2012). Because Dr. Chabner "failed to analyze the patents from the correct perspective, his opinions are inadmissible as unreliable." *Weber-Stephen Prods. LLC v. Sears Holding Corp.*, 2015 U.S. Dist. LEXIS 170989, *17 (N.D. Ill. Dec. 22, 2015); *Am. Med. Sys. v. Laser Peripherals*, LLC, 712 F. Supp. 2d 885, 901 (D. Minn. 2010) (Expert opinions are "inadmissible [if] they are based on incorrect legal standards.") (citing *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996)).

II. THE BOARD SHOULD EXCLUDE EXHIBIT 2116

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 these IPRs; and his testimony is offered to prove the truth of the matter asserted.

Instead, Lilly suggests Dr. Niyikiza's cross-examination at the District Court allows it to rely on his former testimony. This is not so. Fed. R. Evid. 804(b)(1)(B) 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 66 at 9.) Moreover, the former testimony exception is limited to prior testimony offered against the ***same*** party who had a chance to cross-examine the witness, an opportunity Neptune 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 v. WesternGeco*, prior testimony was admissible "because Petitioner had the opportunity to cross-examine [the witness] in this proceeding[.]" IPR2014-01477, Paper 71 at 75-76. *Arceo* and *Inadi* did not involve hearsay testimony used to avoid cross-examination. *See Arceo v. City of Junction City*, 182 F. Supp. 2d 1062, 1080-81 (D. Kan. 2002); *United States v. Inadi*, 475 U.S. 387, 394 (1986).

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. Lilly argues that the issues were not "the same" in the prior proceeding in *Organik*, 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 attempted 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.

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