

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY,
Petitioner

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Patent Owner

Case IPR2018-01710
Patent 8,586,045 B2

**TEVA PHARMACEUTICALS INTERNATIONAL
GMBH'S REPLY IN SUPPORT OF THE MOTION TO EXCLUDE**

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The Board should grant Teva's Motion to Exclude Evidence ("Motion") because Lilly's Opposition to the Motion ("Opposition") misrepresents the law and offers irrelevant arguments that fail to rebut Teva's showing that the challenged evidence is inadmissible, as explained below.

I. Exhibit 1287 lacks foundation and should be excluded

Teva's Motion identifies several reasons why Exhibit 1287 is inadmissible here and should be excluded under FRE 901. Motion, 2-7. The evidentiary flaws with EX1287's authentication remain unrebutted, and none of Lilly's reply arguments remedy those foundational defects.

First, Teva's reference to EX1287 as a "dissertation by Dr. Tan," does not indicate acceptance of that identity, as Lilly asserts. Opposition, 1. Teva has consistently objected to and maintained that Lilly has not authenticated EX1287 as Dr. Tan's thesis. Motion, 2; EX1303, 176:2-18; Paper 34, 2. And Lilly's mere assertion that Mr. Carney "fully authenticates the thesis," (Opposition, 1) fails to address the numerous failings exposed in Teva's Motion: (1) the lack of evidence of cataloguing and shelving practices at Cambridge University Library; (2) the inconsistency between Lilly's many purported dates of availability and cataloguing; (3) Lilly's provision of inadmissible hearsay evidence (Ms. Clarke's email); and (4) that Ms. Clarke's hearsay statement itself casts doubt on EX1287's authenticity.

Lilly casts Teva's arguments regarding EX1287 as one of public accessibility, "not properly raised in a motion to exclude." Opposition, 2. But Lilly itself linked EX1287's foundation to "public availability." EX1307, ¶19.

Authentication necessarily requires producing evidence sufficient to support a finding that the item (a thesis) is what the proponent claims it is—a document, which in Lilly's words, purports to be evidence from "actual researchers in the field before November 2005." FRE 901(a); Opposition, 3. Teva cited to cases relating to public availability because those cases identify the evidence that is necessary to establish the origin and public availability of EX1287 before 2005. The absence of such evidence undermines Lilly's efforts to authenticate EX1287 under FRE 901—Lilly's Reply provides nothing to remedy that lack of evidence.

Faced with a gap in its authentication evidence, Lilly argues that it used EX1287 for purposes that do not require prior art status. *Id.*, 2-3. Lilly's assertion is irrelevant—Lilly "must produce evidence" of EX1287's authenticity regardless of Lilly's intended use. FRE 901(a). Further, Lilly's selective and misleading quotation from *Chi. Mercantile Exch., Inc. v. 5th Mkt., Inc.*, CBM2014-00114, Paper 35 (PTAB Aug. 18, 2015) ("*CME*") is unconvincing. *Id.*, 2. Lilly neglected to disclose that the *CME* panel stated that "addressing the admissibility of evidence, e.g., authenticity or hearsay, underlying the factual determinations of whether [the exhibit] is a prior art printed publication *may be the subject of a*

motion to exclude.” *CME*, 52. The *CME* panel properly analyzed whether there was “credible or sufficient evidence as to where [the exhibit in question was] obtained” and when it “was made available publicly.” *Id.*, 53. Applying that analysis here—as performed in Teva’s Motion—shows that EX1287 lacks sufficient foundation.

Lilly’s attorney arguments about purported similarities between EX1287 and Tan 1994 (EX1021) and Tan 1995 (EX1022) also does not establish foundation because such are not “distinctive characteristics” that would establish identity. Opposition 1-2; FRE 901(b)(4); *TRW Automotive U.S. LLC v. Magna Electronics Inc.*, IPR2014-01348, Paper 25, 10 (PTAB Jan. 15, 2016) (holding “attorney argument” regarding alleged “distinctive characteristics” insufficient to establish foundation).

Finally, Lilly’s argument that EX1287 is a “self-authenticating ancient document” suffers from a critical flaw. Opposition, 2. Lilly offers a conclusory assertion sans support that a Cambridge thesis purportedly from 1994 would qualify as an ancient document. *Id.* But Lilly has not presented sufficient evidence to establish the baseline facts regarding EX1287’s identity or date of publication. Nor has Lilly established that such date of publication—whatever that date may be—qualifies as “ancient.” Therefore, Lilly has not adequately authenticated EX1287 or established it as a self-authenticating document.

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