IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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ELI LILLY AND COMPANY,
Petitioner

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Patent Owner

_____

Case IPR2018-01425
Patent 9,890,210 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 addresses and identifies several reasons why Exhibit 1287 is inadmissible in these proceedings and should be excluded under FRE 901. Motion, 2-7. Significantly, the evidentiary flaws associated with authentication of EX1287 remain unrebutted. *Id.* Lilly's Opposition does not address the lack of evidence regarding the cataloguing and shelving practices of the Cambridge University Library ("CUL"), the confusion and inconsistency regarding EX1287's purported dates of availability and cataloguing, Lilly's provision of inadmissible hearsay evidence as supplemental evidence (Ms. Clarke's email), or the fact that even her hearsay statement casts doubt on the authenticity of EX1287. None of Lilly's arguments in reply remedy the foundational defects for EX1287.

First, Lilly argues that because Teva refers to EX1287 as a "dissertation by Dr. Tan," "Teva does not dispute that Exhibit 1287 is Dr. Tan's doctoral thesis." Opposition, 1 (citing Teva's Motion to Strike, Paper 43, 2). Reference to the purported identity of an exhibit, however, does not indicate acceptance of that identity. *Id.* As is apparent from Teva's Motion, Teva has consistently objected to

and maintained that Lilly has not authenticated EX1287 as Dr. Tan's thesis.

Motion, 3; EX1303, 176:2-18; Paper 39, 2.

Next, 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" after Teva objected. 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, 2-3. 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. Opposition, 2. And as explained in Teva's Motion, the absence of such evidence undermines Lilly's efforts to authenticate EX1287 under FRE 901—Lilly's Reply provides nothing to supplement that lack of evidence.

Faced with a gap in its authentication evidence, Lilly argues that it used EX1287 for purposes that don't require prior art status. *Id.*, 2-3. Lilly's assertion is irrelevant—a document must be authenticated regardless of Lilly's intended use. Further, Lilly supports its flawed assertion by a selective and misleading quotation from a single non-precedential decision. *Id.*, 2 (citing *Chi. Mercantile Exch., Inc. v. 5th Mkt., Inc.*, CBM2014-00114, Paper 35 (PTAB Aug. 18, 2015) ("*CME*")). The

CME panel acknowledged that "a motion to exclude is not the proper vehicle to challenge the sufficiency of the evidence used to demonstrate that [an exhibit] qualifies as a prior art printed publication within the meaning of § 102(b)." *Chi. Mercantile Exch.,* CBM2014-00114, Paper 35 at 52. However, Lilly neglected to disclose that the panel then held 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*." *Id.* 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 just such an analysis—as performed in Teva's Motion—shows that EX1287 lacks sufficient foundation.

Finally, Lilly's argument that EX1287 is a "self-authenticating ancient document" also lacks merit. Opposition, 1-2. Lilly offers a conclusory assertion sans support that a Cambridge thesis purportedly from 1994 would qualify as an ancient document. *Id.* Lilly's assertion suffers from a critical flaw: 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 would be considered "ancient." Therefore, Lilly has not adequately authenticated EX1287 or established it as a self-authenticating document. The Board should exclude EX1287 from this record.

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