

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.

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Case No. IPR2018-01712  
Patent No. 9,884,908

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**PETITIONER'S OPPOSITION TO  
PATENT OWNER'S MOTION TO EXCLUDE**

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## **I. Introduction**

Teva's Motion should be denied, as it raises meritless challenges to evidence undermining its theories in this proceeding. For example, Teva incorrectly attempts to exclude Dr. Tan's thesis (Ex. 1287/1287A) despite the "low bar" for document authentication, improperly relying on printed-publication case law. The Board should also decline Teva's attempt to exclude *more than 20 admissions* in its own experts' cross-examination transcripts under FRE 403. Finally, there is no basis to exclude any of Lilly's evidence regardless of whether it was directly cited in briefing.

## **II. Exhibit 1287 Is Admissible**

Teva incorrectly seeks to exclude Exhibit 1287/1287A, the doctoral thesis of Dr. Keith Tan, under FRE 901. Mot., 2-7. Lilly has more than met the standard for authentication under FRE 901, which is a "low bar" that is satisfied by "evidence sufficient to support a finding that the item is what the proponent claims it is." *Fox Factory, Inc. v. SRAM, LLC*, IPR2017-00472, Paper 64 at 64 (PTAB Apr. 18, 2018).

Here, Teva does not dispute that Exhibit 1287 is Dr. Tan's doctoral thesis. *See* Paper 38 at 2 (referencing Ex. 1287 as a "dissertation by Dr. Tan"). Mr. Carney also fully authenticates the thesis, explaining how he obtained it directly from the University of Cambridge Library and how it was catalogued. Ex. 1307, ¶¶ 6-19. The content of Exhibit 1287 also mirrors Tan 1994 and Tan 1995, further confirming that it is Dr. Tan's 1994 thesis. *See, e.g.*, Ex. 1287, 194-97, 209-10, 222-23, 247; Ex.

1021, 708-09; Ex. 1022, 565, 568, 571; FRE 901(b)(4); *Minerva Surgical, Inc. v. Hologic, Inc.*, IPR2016-00868, Paper 63 at 53 (PTAB Dec. 15, 2017) (appearance, contents, substance, and circumstance of an item may authenticate). Additionally, because Exhibit 1287 is a Cambridge thesis authored in 1994, obtained from Cambridge Library, it is a self-authenticating ancient document. FRE 901(b)(8).

Establishing public accessibility or prior-art status is unnecessary for authenticating Exhibit 1287, contrary to Teva's arguments. Mot., 2-7. Indeed, challenging public availability is not properly raised in a motion to exclude, and Teva has not challenged the *admissibility* of any evidence supporting public availability, e.g., the Carney declaration. *Chi. Mercantile Exch., Inc. v. 5th Mkt., Inc.*, CBM2014-00114, Paper 35 at 52 (Aug. 18, 2015). Rather, Teva explicitly and improperly argues the "sufficiency" of the evidence for proving public availability, which the Board prohibits. Trial Practice Guide, 79 (Nov. 2019) ("A motion to exclude . . . may not be used to challenge the sufficiency of the evidence to prove a particular fact."); Mot., 2 (citing *Conoco Inc. v. Dep't of Energy*, 99 F.3d 387, 391-92 (Fed. Cir. 1996), which analyzed "business records" under FRE 803(6), not public accessibility).

Moreover, instead of relying on Exhibit 1287 as an asserted reference or prior art, Lilly cites Exhibit 1287 for reasons that do not require any showing of public availability. For example, Exhibit 1287 rebuts Teva's purported personal knowledge that co-authors of the Tan references never considered developing therapeutic anti-

CGRP antibodies (Ex. 2270, ¶¶ 147, 152), as Dr. Tan wrote that there was “no reason” not to investigate *humanized* anti-CGRP antibodies for treating diseases such as migraine. Ex. 1287, 247; Reply, 6, 15-16. Public availability is not required to admit Exhibit 1287 to rebut Teva’s purported *personal*—not public—knowledge.

Lilly also cites Exhibit 1287 to rebut Teva’s argument that minor, transient side effects would diminish an expectation to treat migraine with an anti-CGRP antibody. Reply, 15-16; POR, 27-29. With first-hand knowledge of the blood pressure results in Tan 1995, Dr. Tan proposed developing and using humanized anti-CGRP antibodies as “therapeutic agents” for migraine. Ex. 1287, 209, 222-23, 247. Public availability is not required to admit Exhibit 1287 for the rebuttal purpose of demonstrating that *actual researchers* in the field before November 2005 were urging humanization and therapeutic uses of anti-CGRP antibodies.

Nevertheless, even if it were necessary to establish Exhibit 1287 as a printed publication, Mr. Carney’s declaration establishes public accessibility. Dr. Tan’s thesis was authored and submitted to the Cambridge Library in 1994, stamped by the Library, and would have been cataloged and shelved about one month later. Ex. 1307, ¶¶ 14-15. Teva disputes that the Library used electronic MARC records (Mot., 4-5), but Mr. Carney established that the Library *actually indexed* Exhibit 1287 in its electronic MARC records by 2002, at the latest. Ex. 1307, ¶¶ 16-17. Teva’s remaining criticisms of Mr. Carney’s declaration, including his direct

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