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 No. IPR2018-01426
Patent No. 9,890,211

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

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I.   Introduction

Teva's Motion 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, relying exclusively and improperly 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 Lilly's briefing. Teva's Motion to Exclude should be denied.

II.   Exhibit 1287 Is Admissible

Teva incorrectly seeks to exclude Exhibit 1287/1287A, the doctoral thesis of Dr. Keith Tan, under FRE 901. Mot., 1-7. 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, conceding that it is what it purports to be. *See* Paper 43 at 2 (referencing Ex. 1287 as a "dissertation by Dr. Tan"); *Minerva Surgical, Inc. v. Hologic, Inc.*, IPR2016-00868, Paper 63 at 53 (PTAB Dec. 15, 2017) ("the appearance, contents, [and] substance . . . of the item, taken together with all the circumstances," 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). Thus, there is no basis to exclude Exhibit 1287 under FRE 901.

Every case cited in Teva's challenge to Exhibit 1287 analyzes public accessibility for *prior art purposes.* Mot., 1-7. Challenging public availability, however, is not properly raised in a motion to exclude. *Chi. Mercantile Exch., Inc. v. 5th Mkt., Inc.*, CBM2014-00114, Paper 35 at 52 (Aug. 18, 2015). Regardless, Teva fails to establish why public availability is necessary for authenticating Exhibit 1287.

Lilly does not rely on Exhibit 1287 in its obviousness ground, and Lilly does not rely on it as prior art. Rather, Lilly cites Exhibit 1287 for purposes that do not require any showing of public accessibility. For example, Exhibit 1287 rebuts Teva's purported personal knowledge that co-authors of the Tan references never considered antibody humanization (Ex. 2214, ¶¶ 70, 76), as Dr. Tan wrote that there was "no reason" why *humanized* anti-CGRP antibodies should not be investigated. Ex. 1287, 247; Reply, 11. A showing of a public availability is not required to admit Exhibit 1287 as rebutting Teva's purported *personal*—not public—knowledge.

Lilly also cites Exhibit 1287 to rebut Teva's argument that minor, transient side effects would have deterred humanization of anti-CGRP antibodies. POR, 24-26, 40-41. With first-hand knowledge of the blood pressure results in Tan 1995, Dr. Tan proposed humanizing anti-CGRP antibodies to use 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 notwithstanding Teva's hypothetical, unsupported concerns.

Nevertheless, even if it were necessary to establish Exhibit 1287 as a printed

publication, Michael Carney's declaration (Ex. 1307) 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), 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 outreach to the Library, ignore that both the 1994 shelving date and the 2002

MARC record date occurred *years* before Teva's earliest filing date.

Thus, the Board should admit Exhibit 1287 as authenticated under FRE 901,

and credit the Tan Thesis as a printed publication to the extent necessary.

III.   The Cross-Examination Transcripts of Teva's Witnesses Are Admissible

Seeking to insulate its witnesses from their damaging cross-examination

testimony, Teva asserts that numerous portions of its own experts' transcripts should

be excluded under FRE 403 based on form and scope objections. Teva has conducted

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