

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 No. IPR2018-01710
Patent No. 8,586,045

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

Table of Contents

I. Introduction.....1

II. Exhibit 1287 Is Admissible1

III. The Cross-Examination Transcripts of Teva’s Witnesses Are Admissible4

 A. Dr. Tomlinson’s Admissions Are Admissible4

 B. Dr. Stoner’s Admissions Are Admissible6

 C. Dr. Ferrari’s Admissions Are Admissible.....7

 D. Dr. Rapoport’s Admissions Are Admissible.....10

 E. Dr. Foord’s Admissions Are Admissible.....13

IV. All of Lilly’s Exhibits Are Admissible in Their Entirety.....13

V. Conclusion15

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. 2268, ¶¶ 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. 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; POR, 26-28. 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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.