

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.

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Case IPR2018-01423  
U.S. Patent No. 9,266,951

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**TEVA PHARMACEUTICALS INTERNATIONAL GMBH'S  
OBJECTIONS TO EVIDENCE**

*Mail Stop "PATENT BOARD"*  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Case IPR2018-01423

Patent No. 9,266,951

Patent Owner, Teva Pharmaceuticals International GmbH ("Teva"), objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 1004, 1005, 1031-1036, 1038-1052, 1055-1057, 1061, 1062, 1064-1077, 1081, 1082, 1089, 1090, 1095, 1098, 1101, 1136, 1143, and 1146-1154 (the "Challenged Evidence"), filed by Petitioner Eli Lilly and Company ("Lilly") on August 8, 2018, with Lilly's Petition for *Inter Partes* Review. Teva's Objections are filed within ten business days of the date of issuance of the Institution of *Inter Partes* Review; therefore, Teva's Objections to Evidence are timely under 37 C.F.R. § 42.64(b)(1). Teva files these Objections to provide notice to Lilly that Teva may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless cured by Lilly.

## **I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS**

### **A. Exhibit 1004**

Exhibit 1004 purports to be the "Declaration of Dr. Andrew C. Charles, M.D." Teva objects to paragraphs 31, 32, 65-72, 98, 157, 175-178 in Exhibit 1004 under FRE 402 and FRE 403. Lilly does not cite any of these paragraphs in its Petition, rendering Dr. Charles' testimony in these paragraphs irrelevant under FRE 401. Teva therefore objects to these paragraphs under FRE 402. Teva also objects to these paragraphs under FRE 403 because they have no probative value, create unfair prejudice to Teva, and will only confuse the issues and waste the

Board's time.

Teva also objects to paragraphs 18-26, 28, 31-45, 48-52, 54-56, 67-68, 75, 85, 99, 113, 122-123, 126, 129-130, 135-136, 142, 144-146, 149-150, 159-160, 163, 165, 168-169, 171-173 of EX1004 because these paragraphs rely on evidence that is inadmissible under FRE 402, 403, 901, 1001(e), and/or 1003. *See infra*.

**B. Exhibit 1005**

Exhibit 1005 purports to be the "Declaration of Dr. Alain P. Vasserot, Ph.D." Teva objects to paragraphs 21, 27, 54, 128-131 in Exhibit 1005 under FRE 402 and FRE 403. Lilly does not cite any of these paragraphs in its Petition, rendering Dr. Vasserot's testimony in these paragraphs irrelevant under FRE 401. Teva therefore objects to these paragraphs under FRE 402. Teva also objects to these paragraphs under FRE 403 because they have no probative value, create unfair prejudice to Teva, and will only confuse the issues and waste the Board's time.

Teva also objects to paragraphs 16-28, 30-47, 54-58, 77-78, 81, 83, 85, 87, 92-95, 97-98, 101, 106-107, 110, 113, 116-117, 120-121, 124-125 of EX1005 because these paragraphs rely on evidence that is inadmissible under FRE 402, 403, 901, 1001(e), and/or 1003. *See infra*.

**C. Exhibits 1031-1036, 1038-1050, 1052, 1055-1057, 1061, 1062, 1064-1077, 1081, 1082, 1089, 1090, 1095, 1098, and 1101**

Teva objects to Exhibits 1031-1036, 1038-1050, 1052, 1055-1057, 1061,

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1062, 1064-1077, 1081, 1082, 1089, 1090, 1095, 1098, and 1101 as lacking authentication under FRE 901. In particular, Teva objects to Exhibits 1031-1034, 1036, 1038-1050, 1052, 1055-1057, 1061, 1062, 1064-1077, 1081, 1082, 1089, 1090, 1095, 1098, and 1101 under FRE 901 because Lilly fails to provide sufficient evidence indicating the origin or publication of these documents, and accordingly fails to provide sufficient information regarding their authenticity. Teva objects to Exhibits 1033, 1035, 1043, 1047, 1050, 1055, and 1074 under FRE 901 because these Exhibits are stamped with a label or other markings not consistent with being the claimed document. Teva further objects to Exhibits 1034, 1040, 1041, 1045, 1046, 1065, 1067, 1074, 1081, 1089 because these Exhibits purport to be published at one date, yet have markings indicating that they were recently downloaded at a later date. Collectively, these Exhibits are inadmissible under FRE 901 because Lilly has failed to provide sufficient evidence indicating the origin of the documents and has not provided sufficient information regarding their authenticity. Further, these Exhibits are not self-authenticating under FRE 902.

Teva also objects to these Exhibits because they are not a "duplicate" as defined by FRE 1001(e) insofar as each exhibit is not "a copy . . . which accurately reproduces the original." Thus, under FRE 1003, these Exhibits are inadmissible because they are not a "duplicate."

**D. Exhibit 1051**

Exhibit 1051 purports to be a copy of "Sigma-Aldrich, Biochemicals & Reagents for Life Science Research" catalog. Neither the Petition nor Lilly's experts has established that EX1051 was publicly available before November 14, 2005, the priority date of U.S. Patent No. 9,266,951. Patent Owner therefore objects to Exhibit 1051 as irrelevant under FRE 402 and unfairly prejudicial under FRE 403.

**E. Exhibits 1136, 1143, and 1146-1154**

Exhibits 1136, 1143, and 1146-1154 purport to be excerpts from the File History of U.S. Patent Nos. 8,597,649 (EX1136), 8,586,045 (EX1143), and 9,266,951 (EX1146-EX1154). Teva objects to these Exhibits under FRE 403 because they are incomplete documents, with only select portions of the whole presented as exhibits. These exhibits are therefore misleading and confusing, and create unfair prejudice to Teva. Teva also objects to these Exhibits under FRE 1002 because as an "excerpt," they are not the original file history document. For the same reason, Teva objects to these Exhibits under FRE 1003 because they are not duplicates of the original file history documents.

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