

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

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

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Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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

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 1082, 1098, 1240, 1247, 1261-1279, 1281-1288, 1290-1297, 1308, 1309, 1311, 1313-1318, 1320, 1327, and 1328 (the "Challenged Evidence"), filed by Petitioner Eli Lilly and Company ("Lilly") on September 10, 2019, with Lilly's Reply. Teva's Objections are filed within five business days of the Reply; 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.

## **IDENTIFICATION OF GROUNDS FOR OBJECTIONS**

### **A. Exhibits 1327 and 1328**

Exhibit 1327 purports to be the "Declaration of Dr. Joseph P. Balthasar, Ph.D." Teva objects to paragraphs 1-14, 79, and 80 in Exhibit 1327 under FRE 402 and FRE 403. Similarly, Exhibit 1328 purports to be the "Declaration of Dr. Andrew Charles, M.D." Teva objects to paragraphs 1-4, 95, and 96 of Exhibit 1328 under FRE 402 and 403. Lilly does not cite any of these paragraphs in its Reply, rendering Dr. Balthasar's and 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

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value, create unfair prejudice to Teva, and will only confuse the issues and waste the Board's time. Teva also objects to Exhibits 1325 and 1326 to the extent that they rely on evidence that is inadmissible under FRE 106, 402, 403, 901, 1001(e), and/or 1003, as described below.

**B. Exhibits 1082, 1098, 1110, 1240, 1247, 1263-1271, 1281-1288, 1290-1297, 1308, 1309, 1311, 1313-1318, and 1320**

Teva objects to exhibits 1082, 11098, 1110, 1240, 1247, 1263-1271, 1281, 1283-1288, 1290-1297, 1308, 1309, 1311, 1313-1318, and 1320 as lacking authentication under FRE 901. 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 exhibits 1082, 1087, 1098, 1110, 1240, 1247, 1263-1271, 1281-1288, 1290-1297, 1308, 1309, 1311, and 1313-1318 as incomplete. Each of these exhibits appears to be part of a larger work, rendering each exhibit inadmissible under FRE 106 and FRE 403.

Teva also objects to exhibits 1087, 1100, 1247, 1264, 1265, 1267-1271, 1281, 1286, 1293, 1296, 1311, 1313, 1314, 1316, 1317, and 1320 as irrelevant under FRE 401 through FRE 403. These exhibits are not cited in Lilly's reply, and several are published well after the filing date of the '211 patent. They are, therefore, irrelevant under FRE 401. Teva therefore objects to these exhibits under

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FRE 402. Teva also objects to these exhibits 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.

**C. Exhibits 1261, 1262, 1270-1279, 1284, 1287, 1308, 1311, and 1320**

Teva objects to exhibits 1261, 1262, 1272-1279, and 1320 as irrelevant under FRE 401 through FRE 403. These exhibits are not cited in Lilly's reply, and several are published well after the filing date of the '211 patent. There are, therefore, irrelevant under FRE 401. Teva therefore objects to these exhibits under FRE 402. Teva also objects to these exhibits 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 exhibits 1270, 1271, 1278, 1284, 1287, 1308 and 1311 under FRE 1001 through FRE 1003. For example, these documents have stray markings and other indicia that they are not original, or even clean copies of the original document. Accordingly, Teva objects to these exhibits for failure to comply with the best evidence rule.

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## CONCLUSION

To the extent Lilly fails to correct the defects associated with the Challenged Evidence in view of Teva's objections herein, Teva may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,  
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C



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