

IN THE 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 IPR2018-01710
U.S. Patent No. 8,586,045

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

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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 1098, 1261-1279, 1281-1288, 1290-1297, 1300-1304, 1308-1311, 1313-1318, 1331-1338, and 1343-1349 (the "Challenged Evidence"), filed by Petitioner Eli Lilly and Company ("Lilly") on October 4, 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 1337 and 1338

Exhibit 1337 purports to be the "Declaration of Dr. Joseph P. Balthasar, Ph.D." Teva objects to paragraphs 1-14, 88, and 89 in Exhibit 1337 under FRE 402 and FRE 403. Similarly, Exhibit 1338 purports to be the "Declaration of Dr. Andrew Charles, M.D." Teva objects to paragraphs 1-4, 145, and 146 of Exhibit 1338 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 value, create unfair prejudice to Teva, and will only confuse the issues and waste the Board's time. Teva also objects to Exhibits 1337 and 1338 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 1098, 1263-1271, 1281-1288, 1290-1297, 1308-1311, 1313-1318, 1331-1336, and 1347-1349

Teva objects to exhibits 1098, 1263-1271, 1281, 1283-1288, 1290-1297, 1308-1311, 1313-1318, 1331-1336, and 1347-1349 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 1098, 1263-1271, 1281-1288, 1290-1297, 1308-1311, 1313-1318, 1331-1336, and 1347-1349 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 1098, 1264-1265, 1267-1271, 1286, 1291-1293, 1296, 1311, 1313, 1314, 1316, 1317, 1331, 1335-1336, 1344, and 1347-1349 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 '045 patent.

They 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.

C. Exhibits 1261, 1262, 1270-1279, 1284, 1287, 1308, 1311, and 1349

Teva objects to exhibits 1261, 1262, and 1272-1279 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 '045 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, 1311, and 1349 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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