

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SANDOZ INC.,  
Petitioner,

v.

ELI LILLY & COMPANY,  
Patent Owner.

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Case No: IPR2016-00318  
Patent No. 7,772,209

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE**

Patent Owner Eli Lilly & Company (“Lilly”) hereby objects pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”) to the admissibility of certain purported evidence served by Sandoz Inc. in connection with its Petition for *Inter Partes* Review. The exhibits objected to, and grounds for Lilly’s objections, are listed below. Lilly also objects to Petitioner’s reliance on or citations to any objected evidence in its papers.

**I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS**

**A. Exhibit 1002**

Lilly objects to Exhibit 1002 because it has not been properly authenticated under FRE 901, is not self-authenticating under FRE 902, and is not a “duplicate” as defined by FRE 1001(e). Exhibit 1002 is therefore inadmissible under FRE 901, 1002, and 1003.

**B. Exhibit 1004**

Lilly objects to Exhibit 1004, the declaration of Dr. Ron D. Schiff, under FRE 402 to the extent it includes or relies on irrelevant or inadmissible information and under FRE 403 to the extent that it includes or relies on information—such as Exhibit 1031—the probative value of which is substantially outweighed by the danger of unfair prejudice, wasting time, or needlessly presenting cumulative evidence. *See, e.g.*, Ex. 1004 at 50, 52.

Lilly further objects to Exhibit 1004 under FRE 901, 1002, and 1003 on the basis that it cites or relies on exhibits that have not been properly authenticated or lack foundation, such as Exhibit 1002. *See, e.g.*, Ex. 1004 at 12. Lilly further objects to Exhibit 1004 for failing to comply with 37 C.F.R. § 42.53.

Lilly further objects to Appendix D of Exhibit 1004 under FRE 401 and 402 as irrelevant, as unfairly prejudicial, needlessly cumulative, and wasting time under FRE 403, because it has not been properly authenticated under FRE 901 and is not self-authenticating under FRE 902, and as inadmissible hearsay under FRE 801 and 802. Appendix D of Exhibit 1004 is a claim chart summarizing Petitioner's positions regarding other exhibits and, therefore, is not admissible evidence in this proceeding, including because it does not tend to make a fact more or less probable so as to be relevant evidence and is thus irrelevant and inadmissible under FRE 401. Under the rules, claim charts such as Appendix D of Exhibit 1004 may be included in a Petition, but are counted toward the page (now word) limits; the submission of a claim chart as an appendix to an exhibit is an improper attempt to evade those limits, and Appendix D of Exhibit 1004 should not be considered. Lilly further objects to Appendix D of Exhibit 1004 under FRE 402 as irrelevant and as unfairly prejudicial, needlessly cumulative, and wasting time under FRE 403 to the extent that this exhibit is not expressly relied on in Petitioner's Petition for *Inter Partes* Review. Lilly further objects to Appendix D of Exhibit 1004

because it is a claim chart whose author and source have not been identified, and thus it has not been properly authenticated under FRE 901 and is not self-authenticating under FRE 902. Lilly further objects to Appendix D of Exhibit 1004 as inadmissible hearsay under FRE 801 and FRE 802 because it is an out-of-court statement being offered to prove the truth of the matter asserted by a declarant who has not been identified and is not available for cross examination.

**C. Exhibit 1008**

Lilly objects to Exhibit 1008 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 1008 is date stamped September 8, 1999, and, therefore, bears no relevance to what the person of ordinary skill in the art would have known by the relevant date. Therefore, Exhibit 1008 should be excluded under FRE 402 and 403.

**D. Exhibit 1022**

Lilly objects to Exhibit 1022 under FRE 402 as irrelevant and as unfairly prejudicial, needlessly cumulative, and wasting time under FRE 403 to the extent that this exhibit is not expressly relied on in Petitioner's Petition for *Inter Partes* Review or Dr. Schiff's declaration.

**E. Exhibit 1024**

Lilly objects to Exhibit 1024 because it has not been properly authenticated under FRE 901, is not self-authenticating under FRE 902, and is not a "duplicate"

as defined by FRE 1001(e). Exhibit 1024 is therefore inadmissible under FRE 901, 1002, and 1003.

**F. Exhibit 1026**

Lilly objects to Exhibit 1026 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 1026 does not have a discernable publication date and Petitioner has not established that it is prior art. Absent such a showing, it bears no relevance to what the person of ordinary skill in the art would have known by the relevant date. Therefore, Exhibit 1026 should be excluded under FRE 402 and 403. Lilly further objects to Exhibit 1026 for failing to comply with 37 C.F.R. § 42.53. Lilly further objects to Exhibit 1026 because it has not been properly authenticated under FRE 901, is not self-authenticating under FRE 902, and is not a “duplicate” as defined by FRE 1001(e). Exhibit 1026 is therefore inadmissible under FRE 901, 1002, and 1003.

**G. Exhibit 1027**

Lilly objects to Exhibit 1027 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 1027 does not have a publication date and Petitioner has not established that it is prior art. Absent such a showing, it bears no relevance to what the person of ordinary skill in the art would have known by the

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