

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
APOTEX INC., APOTEX CORP.,
EMCURE PHARMACEUTICALS LTD.,
HERITAGE PHARMA LABS INC.,
HERITAGE PHARMACEUTICALS INC.,
GLENMARK PHARMACEUTICALS, INC., USA,
GLENMARK HOLDING SA,
GLENMARK PHARMACEUTICALS, LTD.,
MYLAN LABORATORIES LIMITED,
TEVA PHARMACEUTICALS USA, INC.
and FRESENIUS KABI USA, LLC,

Petitioners

v.

ELI LILLY AND COMPANY,

Patent Owner.

Case IPR2016-00318¹
U.S. Patent 7,772,209

PETITIONER SANDOZ INC.'S OBJECTIONS TO EVIDENCE

¹ Cases IPR2016-01340 and IPR2016-01429 have been joined with the instant proceeding.

Petitioner Sandoz Inc. (“Sandoz”) hereby objects pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence to the admissibility of the purported evidence listed below, which was served by Eli Lilly and Company (“Lilly”) in connection with its Patent Owner’s Response on September 30, 2016, in IPR2016-00318. Sandoz further objects to Lilly’s reliance on and citations to the evidence subject to the following objections.

I. Exhibit 2020 (1999 PDR)

Sandoz objects to Exhibit 2020 under Fed. R. Evid. 402 and 403 because it is irrelevant and its probative value is substantially outweighed by its potential to cause unfair prejudice and waste time or needlessly prolong the proceedings. Exhibit 2020 includes a date of 1999, but it is not clear when in 1999 this reference was published. In Lilly’s Patent Owner’s Response, Lilly asserts that the “relevant date for analyzing Sandoz’s obviousness arguments is June 29, 1999” Paper No. 36, PO Resp. at 13. It is not possible to determine whether Exhibit 2020 qualifies as prior art and thus it is unclear whether it has any relevance as to what a person of ordinary skill would have understood as of the relevant date for the obviousness inquiry.

II. Exhibit 2026 (Schiff Transcript)

Sandoz objects to Exhibit 2026 under Fed. R. Evid. 106 as an incomplete and inaccurate copy of the deposition transcript of Dr. Ronald Schiff as it omits Dr. Schiff's errata sheet, which was properly served on September 23, 2016.

III. Exhibit 2032 (ViDAL)

Sandoz objects to Exhibit 2032 under Fed. R. Evid. 901 and 902 as not being properly authenticated or self-authenticating. The certificate of translation indicates a publication date of 1988 for the 74th edition; however, the scanned cover page images indicate a copyright date of 1998. It is not clear whether this translation certification pertains to the translated material of Exhibit 2032.

IV. Exhibit 2044 (Boritzki)

Sandoz objects to Exhibit 2044 under Fed. R. Evid. 402 and 403 because it is irrelevant and its probative value is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings. Exhibit 2044 does not include any publication date and thus it has no relevance as to what a person of ordinary skill would have understood as of the relevant date for the obviousness inquiry.

V. Exhibit 2076 (Grem)

Sandoz objects to Exhibit 2076 under Fed. R. Evid. 402 and 403 because it is irrelevant and its probative value is substantially outweighed by its potential to

cause unfair prejudice, waste time, or needlessly prolong the proceedings. Exhibit 2076 lists a copyright date of “1999” but does not indicate on its face when in 1999 it was published. In Lilly’s Patent Owner’s Response, Lilly asserts that the “relevant date for analyzing Sandoz’s obviousness arguments is June 29, 1999” Paper No. 36, PO Resp. at 13. It is not possible to determine whether Exhibit 2076 qualifies as prior art and thus it is unclear whether it has any relevance as to what a person of ordinary skill would have understood as of the relevant date for the obviousness inquiry.

VI. Exhibit 2091 (Wall Street Journal Article)

Sandoz objects to Exhibit 2091 under Fed. R. Evid. 402, 403, and 802. Exhibit 2091 is an article listing a publication date of 2004, which is after the relevant June 30, 1999 date for the obviousness inquiry, and thus includes information that is irrelevant to obviousness of the patent at issue and its probative value is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings. Sandoz also objects to Exhibit 2091 under Fed. R. Evid. 802 to the extent Lilly’s Patent Owner’s Response relies on Exhibit 2091 for inadmissible hearsay purposes. Paper No. 36, PO Resp. at 58 (quoting Ex. 2091 at 3).

VII. Exhibit 2098 (Letter to FDA)

Sandoz objects to Exhibit 2098 under Fed. R. Evid. 402 and 403. Exhibit 2099 is not cited in the Patent Owner's Response or the accompanying declarations of Lilly's experts and should be excluded as irrelevant under Fed. R. Evid. 402 and 403. Sandoz reserves it right to submit additional objections to this exhibit if Lilly later cites or relies on this exhibit.

VIII. Exhibit 2099 (Letter to FDA)

Sandoz objects to Exhibit 2099 under Fed. R. Evid. 106, 402, 403, 901, and 902. Exhibit 2099 contains a number of unexplained redactions (*see, e.g.*, ELAP00007715), which call into question whether Exhibit 2099 is complete as required under Fed. R. Evid. 106 and is a true and correct copy of the document. As such, the document is also not sufficiently authenticated under Fed. R. Evid. 901 or 902. Finally, Exhibit 2099 is not cited in the Patent Owner's Response or the accompanying declarations of Lilly's experts and should be excluded as irrelevant under Fed. R. Evid. 402 and 403. Sandoz reserves it right to submit additional objections to this exhibit if Lilly later cites or relies on this exhibit.

IX. Exhibit 2101 (Letter to FDA)

Sandoz objects to Exhibit 2101 under Fed. R. Evid. 106, 402, 403, 901, and 902. Exhibit 2099. Exhibit 2101 contains an unexplained redaction (*see, e.g.*, ELAP00008711), which calls into question whether Exhibit 2101 is complete as is

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