

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 SUPPLEMENTAL
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 supplemental evidence listed below, which was served by Eli Lilly and Company (“Lilly”) on October 24, 2016, in IPR2016-00318. Sandoz further objects to Lilly’s reliance on and citations to the evidence subject to the following objections. Nothing contained herein shall be deemed to withdraw any objections in Sandoz’s Objections to Evidence previously served on Lilly on October 7, 2016.

I. Exhibit 2125 (Krinsky Declaration)

Sandoz objects to Exhibit 2125 under Fed. R. Evid. 402, 403, 602, 702, and 802, and as in violation of 37 C.F.R. § 42.53. Much of the content of Dr. Niyikiza’s testimony from a prior trial (Exhibit A to the Declaration) concerns topics that are not relevant or for which any relevance is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings and should thus be excluded under Fed. R. Evid. 402 and 403.

Sandoz further objects to the extent that Dr. Niyikiza’s trial testimony includes content over which he had no personal knowledge under Fed. R. Evid. 602 and for which he is not qualified to testify as an expert witness under Fed. R. Evid. 702.

Further, Dr. Niyikiza’s trial testimony is not only inadmissible hearsay in this proceeding under Fed. R. Civ. P. 802, but much of it constitutes double

hearsay, including at least one passage on which Lilly relies in its Patent Owner's Response. Paper No. 36, PO Resp. at 59 (quoting Ex. 2116² at 845).

Finally, Dr. Niyikiza's trial testimony should be excluded as in violation of the applicable regulations governing this proceeding, which require that "[u]ncompelled direct testimony must be submitted in the form of an affidavit" and that such testimony be subject to cross examination under 37 C.F.R. § 42.51(b)(1)(ii). 37 C.F.R. § 42.53(a).

Also, Exhibit 2125 describes Exhibits 2111-13 as true and correct copies of trial exhibits. However, this does not cure all of Sandoz's original objections to those Exhibits. *See* Paper 39, Sandoz's Objections at 5-7. Therefore, Sandoz maintains the following objections:

Sandoz objects to Exhibit 2111 under Fed. R. Evid. 402, 403, and 802. Sandoz objects to Exhibit 2111, which appears to be a non-public document concerning Lilly's development of antifolates, as irrelevant to the issue of whether the claimed invention would have been obvious based on the information publicly available in the prior art. Any purported probative value of this exhibit is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings and should thus be excluded under Fed. R.

² Exhibit 2116 contains excerpts from Dr. Niyikiza's trial testimony.

Evid. 402 and 403. Sandoz further objects to the statements in the document as impermissible hearsay under Fed. R. Evid. 802.

Sandoz objects to Exhibit 2112 under Fed. R. Evid. 402, 403, and 802.

Sandoz objects to Exhibit 2112, which appears to be a non-public document concerning Lilly's development of antifolates, as irrelevant to the issue of whether the claimed invention would have been obvious based on the information publicly available in the prior art. Any purported probative value of this exhibit is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings and should thus be excluded under Fed. R. Evid. 402 and 403. Sandoz further objects to the statements in the document as impermissible hearsay under Fed. R. Evid. 802.

Sandoz objects to Exhibit 2113 under Fed. R. Evid. 402, 403, and 802.

Sandoz objects to Exhibit 2113, which appears to be a non-public document concerning Lilly's development of antifolates, as irrelevant to the issue of whether the claimed invention would have been obvious based on the information publicly available in the prior art. Any purported probative value of this exhibit is substantially outweighed by its potential to cause unfair prejudice, waste time, or needlessly prolong the proceedings and should thus be excluded under Fed. R. Evid. 402 and 403. Sandoz further objects to the statements in the document as impermissible hearsay under Fed. R. Evid. 802.

II. Exhibit 2127 (Letter to FDA)

Exhibit 2127 removes the redactions from Exhibit 2099. However, this does not cure all of Sandoz's original objections to Exhibit 2099. *See* Paper 39, Sandoz's Objections at 4. Therefore, Sandoz maintains the following objections:

Sandoz objects to Exhibit 2099 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 its right to submit additional objections to this exhibit if Lilly later cites or relies on this exhibit.

III. Exhibit 2128 (Letter to FDA)

Exhibit 2128 removes the redactions from Exhibit 2101. However, this does not cure all of Sandoz's original objections to Exhibit 2101. *See* Paper 39, Sandoz's Objections at 4-5. Therefore, Sandoz maintains the following objections:

Sandoz objects to Exhibit 2101 under Fed. R. Evid. 402 and 403. Exhibit 2101 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 its right to submit additional objections to this exhibit if Lilly later cites or relies on this exhibit.

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