

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

SANDOZ INC.,  
APOTEX INC., and 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,  
FRESENIUS KABI USA, LLC and WOCKHARDT BIO AG  
Petitioners,

v.

ELI LILLY & COMPANY,  
Patent Owner.

---

Case No: IPR2016-00318<sup>1</sup>  
Patent No. 7,772,209

---

**PATENT OWNER'S OBJECTIONS TO EVIDENCE**

---

<sup>1</sup> Cases IPR2016-01429, IPR2016-01393, and IPR2016-01340 have been joined  
with the instant proceeding.

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 Petitioner Sandoz Inc. on December 22, 2016 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.

Many of the exhibits served by Sandoz Inc. on December 22, 2016 were introduced at depositions in this proceeding, and Lilly objected to certain of those exhibits at the depositions as required by 37 C.F.R. § 42.64(a). Nothing contained herein shall be deemed to withdraw any of Lilly’s objections to deposition evidence or the requirement that evidence to cure those objections must have been provided during the deposition, *see id.*

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

**A. Exhibit 1063**

Lilly objects to Exhibit 1063 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 1063 contains a web page purportedly available to the public in 2001. Exhibit 1063 therefore bears no relevance to what the person of ordinary skill in the art would have known by the relevant date.

Therefore, Exhibit 1063 should be excluded under FRE 402 and 403. Lilly further objects to Exhibit 1063 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 1063 is therefore inadmissible under FRE 901, 1002, and 1003.

**B. Exhibit 1067**

Lilly objects to Exhibit 1067 under FRE 802 because it is inadmissible hearsay, specifically a portion of a demonstrative exhibit from a different proceeding, *Eli Lilly v. Teva Parenteral Meds., Inc. et al.*, 1:10-cv-01376-TWP-DKL (S.D. Ind.). Lilly further objects to Exhibit 1067 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time and needlessly presenting cumulative evidence in this compressed proceeding. Lilly further objects to Exhibit 1067 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 1067 is therefore inadmissible under FRE 901, 1002, and 1003. Lilly also objects to Exhibit 1067 because it is incomplete, and it therefore should be excluded under FRE 106, 401, 402, and 403.

**C. Exhibit 1071**

Lilly objects to Exhibit 1071 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 1071 contains a web page purportedly available to the public in 2016. Exhibit 1071 therefore bears no relevance to what the person of ordinary skill in the art would have known by the relevant date. Therefore, Exhibit 1071 should be excluded under FRE 402 and 403. Lilly further objects to Exhibit 1071 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 1071 is therefore inadmissible under FRE 901, 1002, and 1003.

**D. Exhibit 1074**

Lilly objects to Exhibit 1074, the transcript of the deposition of Dr. Bruce Chabner, as incomplete because Petitioner has not filed all exhibits introduced at the deposition, including the exhibits Lilly introduced on redirect. It therefore should be excluded under FRE 106, 401, 402, and 403.

**E. Exhibit 1075**

Lilly objects to Exhibit 1075, the reply 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 1078—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. 1075 at 36.

Lilly further objects to Exhibit 1075 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 1089. *See, e.g.*, Ex. 1075 at 18.

**F. Exhibit 1076**

Lilly objects to Exhibit 1076 under FRE 402 and 403 to the extent Petitioner relies on it as prior art or as reflecting the state of the prior art because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 1076 was created in 2000 by individuals at Lilly who had knowledge of the invention and was not available to the public; it therefore bears no relevance to what the person of ordinary skill in the art would have known by the relevant date.

**G. Exhibit 1077**

Lilly objects to Exhibit 1077 under FRE 402 and 403 to the extent Petitioner relies on it as prior art or as reflecting the state of the prior art because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 1077 was created on December 3, 1999 by individuals at Lilly who had knowledge of the invention and

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.