

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.,
FRESENIUS KABI USA, LLC, and WOCKHARDT BIO AG,

Petitioners

v.

ELI LILLY AND COMPANY,

Patent Owner.

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

**PETITIONER SANDOZ INC.'S
UPDATED MANDATORY NOTICES
PURSUANT TO 37 C.F.R. § 42.8**

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

A. Real Party-In-Interest (UNCHANGED)

Sandoz Inc. is the real party-in-interest for the instant petition.

B. Related Matters (UPDATED)

1. Related Litigations

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '209 patent. Petitioner is a defendant in the following litigation involving the '209 patent: *Eli Lilly & Co. v. Sandoz Inc.*, No. 1:14-cv-2008 (S.D. Ind., filed December 5, 2014) (“Sandoz Litigation”). Sandoz has timely filed this petition pursuant to 35 U.S.C. § 315(b) within one year of the date “on which the petitioner . . . [was] served with [the] complaint alleging infringement of the patent” – December 15, 2014. Ex. 1053, Return of Service. The Patent Owner has also asserted the '209 patent in the following additional litigations in which Petitioner was not and is not a party: *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, No. 1:10-cv-1376 (S.D. Ind., filed October 29, 2010) (“Teva Litigation”); *Eli Lilly & Co. v. APP Pharmaceuticals, LLC*, No. 1:11-cv-942 (S.D. Ind., filed July 15, 2011); *Eli Lilly & Co. v. Accord Healthcare, Inc., USA*, No. 1:12-cv-86 (S.D. Ind., filed January 20, 2012); *Eli Lilly & Co. v. Apotex Inc.*, No. 1:12-cv-499 (S.D. Ind., filed April 17, 2012); *Eli Lilly & Co. v. Accord Healthcare Inc., USA*, No. 1:13-cv-335 (S.D. Ind., filed February 28, 2013); *Eli Lilly & Co. v. Sun Pharmaceutical Industries Ltd.*, No. 1:13-cv-1469 (S.D. Ind., filed September 13,

2013); *Eli Lilly & Co. v. Glenmark Generics Inc., USA*, No. 1:14-cv-104 (S.D. Ind., filed January 23, 2014); *Eli Lilly & Co. v. Nang Kuang Pharmaceutical Co., Ltd.*, No. 1:14-cv-1647 (S.D. Ind., filed October 8, 2014); *Eli Lilly & Co. v. Fresenius Kabi USA, LLC*, No. 1:15-cv-96 (S.D. Ind., filed January 23, 2015); *Eli Lilly & Co. v. Mylan Laboratories Ltd.*, No. 1:15-cv-1083 (S.D. Ind., filed July 10, 2015); *Eli Lilly & Co. v. Emcure Pharmaceuticals Ltd.*, No. 1:15-cv-1244 (S.D. Ind., filed August 7, 2015); *Eli Lilly & Co. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 1:16-cv-308 (S.D. Ind., filed Feb. 5, 2016); *Eli Lilly & Co. v. Biocon Ltd.*, No. 1:16-cv-469 (S.D. Ind., filed Feb. 26, 2016); *Eli Lilly & Co. v. Fresenius Kabi USA, LLC*, No. 1:16-cv-2960 (S.D. Ind., filed Nov. 1, 2016); and *Eli Lilly & Co. v. Hospira, Inc.*, No. 1:16-cv-3460 (S.D. Ind., filed Dec. 21, 2016).

Petitioner newly identifies the following additional litigations in which the Patent Owner has asserted the '209 patent and in which Petitioner was not and is not a party: *Eli Lilly & Co. v. Actavis LLC et al.*, No. 1:17-cv-982 (S.D. Ind., filed Mar. 30, 2017) and *Eli Lilly & Co. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-986 (S.D. Ind., filed Mar. 30, 2017).

2. Related Proceedings Before the Board

The '209 patent has also been challenged before the Board in the following proceedings in which Petitioner was not and is not a party: *Accord Healthcare, Inc., USA v. Eli Lilly & Co.*, IPR2013-356 (PTAB, filed June 14, 2013); *Neptune*

Generics, LLC v. Eli Lilly & Co., IPR2016-237 (PTAB, filed November 24, 2015); *Neptune Generics, LLC v. Eli Lilly & Co.*, IPR2016-240 (PTAB, filed November 24, 2015); *Wockhardt Bio AG v. Eli Lilly & Co.*, IPR2016-1335 (PTAB, filed June 30, 2016); *Wockhardt Bio AG v. Eli Lilly & Co.*, IPR2016-1337 (PTAB, filed June 30, 2016); *Wockhardt Bio AG v. Eli Lilly & Co.*, IPR2016-1393 (PTAB, filed July 8, 2016); *Apotex Inc. & Apotex Corp. v. Eli Lilly & Co.*, IPR2016-1190 (PTAB, filed July 1, 2016); *Apotex Inc. & Apotex Corp. v. Eli Lilly & Co.*, IPR2016-1191 (PTAB, filed July 1, 2016); *Apotex Inc. et al. v. Eli Lilly & Co.*, IPR2016-1429 (PTAB, filed July 14, 2016); *Teva Pharm. USA, Inc. & Fresenius Kabi USA, LLC v. Eli Lilly & Co.*, IPR2016-1340 (PTAB, filed July 1, 2016); *Teva Pharm. USA, Inc. & Fresenius Kabi USA, LLC v. Eli Lilly & Co.*, IPR2016-1341 (PTAB, filed July 1, 2016); and *Teva Pharm. USA, Inc. & Fresenius Kabi USA, LLC v. Eli Lilly & Co.*, IPR2016-1343 (PTAB, filed July 1, 2016). The Petitioners in IPR2016-1335, IPR2016-1190, and IPR2016-1341 have been joined with IPR2016-237. The Petitioners in IPR2016-1337, IPR2016-1191, and IPR2016-1343 have been joined with IPR2016-240. The Petitioners in IPR2016-1340, IPR2016-1393, and IPR2016-1429 have been joined with the instant proceeding. On October 1, 2013, the Board denied institution of Accord Healthcare Inc.'s petition in IPR2013-356 because the petition was not filed within the time limit imposed by 35 U.S.C.

§ 315(b). Neptune Generics, LLC's ("Neptune") two petitions are pending before the Board.

C. Lead and Back-Up Counsel (UNCHANGED)

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