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Paper No. 10
Entered: October 4, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX INC., APOTEX CORP.,
EMCURE PHARMACEUTICALS LTD.,
HERITAGE PHARMA LABS INC.,
HERITAGE PHARMACEUTICALS INC.,
GLENMARK PHARMACEUTICALS, INC.,
USA, GLENMARK HOLDING SA,
GLENMARK PHARMACEUTICALS, LTD, and
MYLAN LABORATORIES LIMITED,
Petitioner,

v.

ELI LILLY & COMPANY
Patent Owner.

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Case IPR2016-01429
Patent 7,772,209 B2

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Before MICHAEL P. TIERNEY, JACQUELINE WRIGHT BONILLA, and TINA E. HULSE, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review and Grant of Motion for Joinder
*37 C.F.R. § 42.108; 37 C.F.R. § 42.122(b)*

## I. INTRODUCTION

Apotex Inc. et al.[1] (collectively, "Petitioner" or "Apotex"), filed a Petition requesting an *inter partes* review of claims 1–22 of U.S. Patent 7,772,209 B2 (Ex. 1001, "the '209 patent"). Paper 2 ("Pet."). Concurrent with the filing of the Petition, Petitioner filed a Motion for Joinder seeking to join the current proceeding to IPR2016-00318.[2] Motion for Joinder, Paper 3. Patent Owner and Petitioner filed a Joint Notice of Stipulation Concerning Joinder that states, among other things, that Patent Owner waives its right to file a Preliminary Response to the Petition. Paper 9. We have jurisdiction under 35 U.S.C. § 314.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in challenging claims 1–22 of the '209 patent. We authorize an *inter partes* review to be instituted as to those claims. Our Decision to Institute in this proceeding is consistent with our institution of *inter partes* review in IPR2016-00318. IPR2016-00318, Paper 14 ("'318 Inst. Dec.").

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[1] 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.

[2] Sandoz Inc. ("Sandoz") v. Eli Lilly & Company ("Patent Owner"), IPR2016-00318.

Additionally, all parties have stipulated that, subject to our approval, Apotex shall join the proceeding with Sandoz designated as Lead Petitioner and that Apotex will act as a silent understudy and will not file any papers or exhibits in the Joined Proceeding, except *pro hac vice* motions and administrative filings. Paper 9, 2–3. For the reasons provided below, we grant Apotex's Motion for Joinder and exercise our discretion to join Apotex and the present proceeding to the IPR2016-00318 proceeding.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Proceedings

The '209 patent is the subject of litigation in the Southern District of Indiana, including *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc*., Case No. 1:10-cv-1376. Pet. 2–3.

The '209 patent also has been challenged in the following instituted *inter partes* reviews IPR2016-00237 and IPR2016-00240 by Neptune Generics, LLC, and in IPR2016-00318 by Sandoz Inc. Several parties, including Petitioner, seek to join the instituted reviews. Specifically, in addition to the current case, IPR2016-01393 (Wockhardt) and IPR2016-01340 (Teva and Fresenius) seek to join IPR2016-00318. Also, IPR2016-01190 (Apotex Inc. and Apotex Corp.), IPR2016-01335 (Wockhardt) and IPR2016-01341 (Teva and Fresenius) seek to join IPR2016-00237. Additionally, IPR2016-01191 (Apotex Inc. and Apotex Corp.), IPR2016-

01337 (Wockhardt) and IPR2016-01343 (Teva and Fresenius) seek to join IPR2016-00240.

B. The '209 Patent

The '209 patent claims priority benefit of a series of applications, the earliest of which was filed on June 30, 2000. Ex. 1001, 1:2–10.

Rapidly-dividing cancer cells generally have a higher folate requirement than normal cells. Declaration of Ron D. Schiff, Ex. 1004 ¶ 29. Antifolates are a well-studied class of antineoplastic agents that "inhibit one or several key folate-requiring enzymes of the thymidine and purine biosynthetic pathways." Ex. 1001, 1:19–20, 1:36–41. As antifolates interfere with DNA synthesis, antifolates are used as chemotherapeutic drugs to treat certain types of cancer. Ex. 1004 ¶ 28.

A limitation on the use of antifolate drugs is "that the cytotoxic activity and subsequent effectiveness of antifolates may be associated with substantial toxicity for some patients." Ex. 1001, 1:62–64. Homocysteine levels have been shown to be a predictor of cytotoxic events related to the use of certain antifolate enzyme inhibitors. *Id*. at 2:16–26. The '209 patent states that folic acid has been shown to lower homocysteine levels. *Id*. Additionally, the patent states that it was known in the art to treat and prevent cardiovascular disease with a combination of folic acid and vitamin B12. *Id*. at 2:50–54.

The '209 patent describes "[a] method of administering an antifolate to a mammal in need thereof." Ex. 1001, abstract. The method is said to improve the therapeutic utility of antifolate drugs by administering a methylmalonic acid ("MMA") lowering agent, such as vitamin B12, to the

host undergoing treatment. *Id*. at 2:37–46. The '209 patent also states that a combination of a MMA lowering agent, such as B12, and folic acid "synergistically reduces the toxic events associated with the administration of antifolate drugs." *Id*. at 2:47–50

The term antifolate is said to encompass "chemical compound[s] [that] inhibit[] at least one key folate-requiring enzyme of the thymidine or purine biosynthetic pathways." *Id*. at 4:28–34. Pemetrexed disodium is the most preferred antifolate for the '209 patent. *Id*. at 4:28–43. Pemetrexed is also referred to in the art as a "multitargeted antifolate" ("MTA"). Ex. 1004 ¶ 35.

C. Illustrative Claims

The '209 patent contains twenty-two claims, all of which are challenged by Petitioner. Independent claim 1 is directed to a method for administering pemetrexed disodium to a patient in need thereof, where folic acid and a MMA lowering agent, such as B12, is administered, followed by administering an effective amount of the pemetrexed disodium. Independent claim 12 is written in a Jepson claim format, where the preamble defines the admitted prior art as administering pemetrexed disodium to a patient in need of a chemotherapeutic treatment. Independent claim 12 further recites specific dosage amounts of folic acid and vitamin B12 that are administered to the patient prior to the first administration of the pemetrexed disodium. Dependent claim 2 requires the MMA lowering agent of claim 1 to be vitamin B12 and the remaining dependent claims recite various dosages of folic acid and B12, and times for administering folic acid. Certain claims also require the administration of cisplatin to the patient.

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