UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.

&

FRESENIUS KABI USA, LLC

PETITIONERS

v.

ELI LILLY AND COMPANY,

Patent Owner

CASE NO.: IPR2016-01341
PATENT NO. 7,772,209
FILED: JULY 11, 2007
ISSUED: AUGUST 10, 2010
INVENTOR: CLET NIYIKIZA

TITLE: ANTIFOLATE COMBINATION THERAPIES

Motion for Joinder
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 and 42.122(b)

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Teva Pharmaceuticals USA, Inc. ("Teva") and Fresenius Kabi USA, LLC ("Fresenius") respectfully submit this Motion for Joinder, together with a petition for *inter partes* review of U.S. Patent No. 7,772,209 ("the '209 patent") ("the Teva/Fresenius petition"). Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. § 42.22, and 37 C.F.R. § 42.122(b), Teva and Fresenius request institution of an *inter partes* review ("the Teva/Fresenius IPR") and joinder of this proceeding with *Neptune Generics, LLC v. Eli Lilly and Company*, Case IPR2016-00237 (the "Neptune IPR" or "IPR 237") which was instituted on June 3, 2016. This Motion for Joinder is timely under 37 C.F.R. §§ 42.22 and 42.122(b), as it is submitted within one month of June 3, 2016, the date on which the Neptune IPR was instituted. *See* Neptune IPR, Paper No. 13. It is also narrowly-tailored to the same claims, prior art, and grounds of unpatentability that are the subject of the Neptune IPR.[1] In addition, Teva and Fresenius are willing to streamline discovery and briefing. Accordingly, joinder is appropriate because it will not prejudice the parties to the Neptune IPR and will promote the efficient resolution of the question of validity of a patent in a

[1] The second sentence of each of sections VI.B.1., VI.B.2., and VI.B.3. has been slightly modified from Neptune's petition for accuracy purposes, but such modifications do not substantively change any of Neptune's arguments.

single proceeding. Absent joinder, Teva and Fresenius will be prejudiced because their interests may not be adequately represented in the Neptune IPR.

II. STATEMENT OF MATERIAL FACTS

1. Eli Lilly and Company ("Lilly" or "Patent Owner") owns U.S. Patent 7,772,209. There is no current district court patent litigation between Eli Lilly and Teva or Fresenius with respect to the '209 patent. Teva and Fresenius were previously sued by Eli Lilly with respect to the '209 patent. *Eli Lilly and Company v. Teva Parental Medicines, Inc., et al*., INSD-1:10-cv-01376 (filed Oct. 29, 2010). That suit is currently on appeal at the Federal Circuit. (*Eli Lilly and Company v. Teva Parenteral Medicines*, No. 15-2067 (Fed. Cir.) (filed Sept. 21, 2015).

2. On November 24, 2015, Neptune filed its petition for *inter partes* review seeking cancellation of claims 1-22 of the '209 patent. (Neptune IPR, Paper No. 1.)

3. The Neptune IPR petition included the following ground for challenging the validity of the '209 patent:

Ground 1: Claims 1-22 are obvious in view of Niyikiza, U.S. 5,217,974, and EP 0 595 005.

4. On March 4, 2016, Patent Owner filed a Preliminary Response. (Neptune IPR, Paper No. 10.)

5. On June 3, 2016, the Board instituted review of claims 1–22 of the ’209 patent in the Neptune IPR. (Neptune IPR, Paper No. 13.)

6. On June 3, 2016, the Board entered a scheduling order in the Neptune IPR setting various dates, including the oral argument set for February 7, 2017. (Neptune IPR, Paper No. 14.) On June 17, 2016, the Board entered a revised scheduling order in the Neptune IPR changing various dates, including moving the oral argument to March 7, 2017. (Neptune IPR, Paper No. 15.)

7. The Teva/Fresenius petition in this proceeding proposes that claims 1–22 of the ’209 patent should be cancelled in view of Ground 1, as set forth in the Neptune IPR petition.

8. The Teva/Fresenius petition in this proceeding presents the identical grounds on which the Neptune IPR was instituted.

9. The Teva/Fresenius petition in this proceeding proposes the same claim construction positions as the petition in the Neptune IPR, and relies upon the same prior art.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review proceedings. The statutory provision governing joinder of *inter partes* review proceedings is 35 U.S.C. § 315(c), which reads as follows:

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