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.: IPR2016-01340
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 ("the Teva/Fresenius Petition") of U.S. Patent No. 7,772,209 ("the '209 patent"). Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b), Teva and Fresenius request institution of *inter partes* review (IPR) and joinder with the IPR concerning the same patent in *Sandoz Inc. v. Eli Lilly and Company*, Case IPR2016-00318 (the "Sandoz IPR" or "IPR 318"), which was instituted on June 16, 2016. Joinder is appropriate because it will promote the efficient and consistent resolution of the validity of a single patent, and will not delay the Sandoz IPR trial schedule or prejudice the parties to that IPR. Sandoz has advised that they consent to Teva's and Fresenius's motion for joinder. Further, as detailed below, Teva, Fresenius and Sandoz have entered into a cooperation agreement for briefing and discovery in the event of the joinder of this IPR with the Sandoz IPR.

Teva's and Fresenius's request for joinder is timely, as it is submitted within one month of the June 16, 2016 institution of the Sandoz IPR. 37 C.F.R. §§ 42.22, 42.122(b).

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II. STATEMENT OF MATERIAL FACTS

Eli Lilly and Company ("Eli Lilly" or "Patent Owner") owns the '209 patent. Eli Lilly sued Teva and Fresenius for infringement of the '209 patent in 2010 and prevailed in the district court. That case is currently on appeal before the Federal Circuit (Case Nos. 2014-1455 and 2015-2067).

On June 16, 2016, the Board instituted Sandoz's IPR on the '209 patent on the following two grounds of unpatentability:

(1) obviousness of claims 1-22 over Calvert in view of Niyikiza I, Worzalla, EP 005 and the '974 Patent; and

(2) obviousness of claims 1-22 over Calvert in view of Niyikiza I, Hammond I, EP 005 and the '974 Patent.

(Sandoz IPR, Paper No. 21.).

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of like review proceedings, *e.g.* an IPR may be joined with another IPR. 37 C.F.R. § 42.122(a). The Board has discretion to join parties to an existing IPR. 35 U.S.C. § 315(c). In deciding whether to exercise its discretion, the Board considers factors including: (1) the movant's reasons why joinder is appropriate; (2) whether the new petition

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presents any new grounds of unpatentability; (3) what impact (if any) joinder would have on the trial schedule for the existing review; and (4) how briefing and discovery may be simplified. *Dell Inc. v. Network-1 Security Solutions, Inc.*, Decision on Motion for Joinder, IPR2013-00385, Paper No. 17 at 4 (July 29, 2013). The Board should consider "the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding." *Id.* at 10. Under this framework, joinder of the present IPR with the Sandoz IPR is appropriate.

B. Joinder is Appropriate Because the Teva/Fresenius Petition Contains No New Grounds of Unpatentability and Joinder Will Not Impact the Trial Schedule

Joinder will not impact the Board's ability to complete its review of the '209 patent in a timely manner, as Teva and Fresenius raise no issues or evidence that is not already before the Board in the Sandoz IPR. The Teva/Fresenius Petition seeks review of the same claims at issue in the Sandoz IPR (claims 1-22 of the '209 patent), based on the same grounds of unpatentability and combinations of prior art. Indeed, the Teva/Fresenius Petition is substantively identical to Sandoz's petition (Sandoz IPR, Paper No. 2). Further, Teva and Fresenius rely on the same exhibits and same expert declaration of Dr. Schiff that Sandoz submitted in IPR2016-00318. Given that Teva and Fresenius and Sandoz would be addressing

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the same prior art and grounds of unpatentability and Teva and Fresenius would rely on Sandoz's expert, Teva and Fresenius envision few, if any, differences in the petitioners' positions.

In such circumstances, the PTO anticipated that joinder would be granted as a matter of right. *See* CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) ("The Office anticipates that joinder will be allowed as of right – if an inter partes review is instituted on the basis of a petition, for example, a party that files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments.").

Because joinder will not introduce any new prior art, expert declarations, or grounds of unpatentability into the Sandoz IPR, joining Teva's and Fresenius's proceeding will not complicate the substantive issues already pending in the Sandoz IPR. Teva and Fresenius respectfully submit that the Patent Owner would thus not be prejudiced by the joinder.

In contrast, Teva and Fresenius would be prejudiced if joinder is denied. In order to permit Teva and Fresenius to protect their interests related to the validity and interpretation of the '209 patent claims, Teva and Fresenius should be permitted to participate in the Sandoz IPR. For example, allowing a joined *inter partes* review would avoid prejudice to Teva and Fresenius in the event that

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