

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND
SAWAI PHARMACEUTICAL CO., LTD.
Petitioners,

v.

BIOGEN MA, INC.
Patent Owner.

Patent No. 8,399,514

Inter Partes Review IPR2019-00789

PETITIONER'S MOTION FOR JOINDER

37 C.F.R. § 42.122(b)

I. A STATEMENT OF THE PRECISE RELIEF REQUESTED

Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (“Sawai” or “Petitioners”) submit, concurrently with this motion, a petition for *inter partes* review (“Petition”) of claims 1-20 of U.S. Patent No. 8,399,514 (“the ’514 patent”) (Ex. 1001), assigned to Biogen MA Inc. (“Patent Owner”). Sawai respectfully requests joinder pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b) of the concurrently filed Petition with a pending *inter partes* review filed by Mylan Pharmaceuticals, Inc. (“Mylan”), *Mylan Pharmaceuticals Inc. v. Biogen MA Inc.*, IPR2018-01403 (“Mylan IPR”). Joinder is appropriate because it will promote an efficient and consistent resolution of the validity of a single patent and will not prejudice any of the parties to the Mylan IPR. Sawai’s request for joinder is timely because it was filed “no later than one month after the institution date of any *inter partes* review for which joinder is requested.” 37 C.F.R. § 42.122(b). Sawai’s IPR Petition is timely under 37 C.F.R. § 42.122, which provides that the time period set forth in 37 C.F.R. § 42.101(b) shall not apply when the petition is accompanied by a request for joinder. *See also* 35 U.S.C. § 315(b) (“The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).”).

II. BACKGROUND

On July 13, 2018, Mylan filed a petition for *inter partes* review challenging claims 1-20 of U.S. Patent No. 8,399,514, which was assigned Case No. IPR2018-01403. On February 6, 2019, the Board instituted review of claims 1-20 on 4 grounds: (1) Claims 1-20 of the '514 patent as obvious over the January 2006 Biogen Press Release in view of the Schimrigk 2004 Abstract; (2) Claims 1-20 of the '514 patent as obvious over Kappos 2006 in view of the Schimrigk 2004 Abstract; (3) Claims 1-20 of the '514 patent as obvious over Kappos 2006 in view of WO '342; and (4) Claims 1-20 of the '514 patent are obvious over Kappos 2006, Clinical Trials, Joshi '999, and ICH. IPR2018- 01403, Paper 12.

Today, concurrent with the instant motion for joinder, Sawai filed an IPR petition under Case No. IPR2019-00789 asserting the same grounds of unpatentability against the same patent claims as instituted in the Mylan IPR.

III. ARGUMENT

A. Legal Standard

The Board has authority to join as a party any person who properly files a petition for *inter partes* review to an instituted *inter partes* review.

35 U.S.C. § 315(c). A motion for joinder must be filed within one month of institution of any *inter partes* review for which joinder is requested.

37 C.F.R. § 42.122(b). In deciding whether to grant a motion for joinder, the Board considers several factors including: (1) the reasons why joinder is

appropriate; (2) whether the party to be joined has presented 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.

See, e.g., Hyundai Motor Co. v. Am. Vehicular Sciences LLC, IPR2014-01543, Paper 11 at 3 (Oct. 24, 2014); *Macronix Int'l Co. v. Spansion*, IPR2014-00898, Paper 15 at 4 (Aug. 13, 2014) (quoting *Kyocera Corp. v. Softview LLC*, IPR2013-00004, Paper 15 at 4 (April 24, 2013)).

B. The Relevant Factors Weigh in Favor of Joinder

Each of the four factors considered by the Board weighs in favor of joinder.

1. Joinder Is Appropriate

Joinder with IPR2018-01403 is appropriate because the Petition is limited to the same grounds instituted in the IPR2018-01403 petition. It also relies on the same prior art analysis and expert analysis submitted by Mylan. Indeed, the Petition raises grounds identical to those raised in the IPR2018-01403 petition, and does not include any new grounds not raised in that petition.

In order to further simplify the proceeding, Sawai will rely on the same declarants as Mylan, Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Rock, and Dr. Ian McKeague, should Mylan permit it. If Mylan allows Sawai to use the same declarants, then Sawai will withdraw the declarations of Dr. Baumhefner, Dr. Bainbridge, Ms. Rock, and Dr. Marks, and rely solely on the declarations and

testimonies of Mylan's declarants: Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Rock and Dr. Ian McKeague. The Board has previously acknowledged that such concessions on the part of a party seeking to join are sufficient to minimize the impact on the original proceeding. *See SAP America Inc. v. Clouding IP, LLC*, IPR2014-00306, Paper 13 at 4 (May 19, 2014). Further, Dr. Baumhefner, Dr. Bainbridge, Ms. Rock and Dr. Marks declarations submitted in support of the present Petition present substantively identical testimony to that of Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Jennifer Rock, and Dr. Ian McKeague, respectively, thus streamlining the issues for trial even if Mylan does not permit Sawai to rely directly on Dr. John R. Corboy, Dr. Leslie Z. Benet, Ms. Rock, and Dr. Ian McKeague.

Joinder is also appropriate because it will promote the just, speedy, and inexpensive resolution of patentability issues, including the determination of validity of the challenged claims of the '514 patent. For example, a final written decision on the validity of the '514 patent has the potential to minimize issues and potentially resolve any litigation altogether with respect to the '514 patent.

2. No New Grounds Are Presented

The Petition does not present any new ground of unpatentability. As mentioned above, the Petition presents for review only grounds from the petition in the Mylan IPR that have been instituted. The present Petition is based on the same

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