

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD.
AND SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioners,

v.

NOVO NORDISK A/S,

Patent Owner.

U.S. Patent No. 10,335,462 to Jensen
Issue Date: July 2, 2019
Title: Use of Long-Acting GLP-1 Peptides

Inter Partes Review IPR2024-00107

**PETITIONER'S MOTION FOR JOINDER
UNDER 35 U.S.C. § 315(c) and
37 C.F.R. §§ 42.22 AND 42.122(b)**

I. A STATEMENT OF THE PRECISE RELIEF REQUESTED

Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (“Sun” or “Petitioners”) submit, concurrently with this motion, a petition for *inter partes* review (the “Sun Petition”) of claims 1–10 of U.S. Patent No. 10,335,462 (“the ’462 patent”) (Ex. 1001), assigned to Novo Nordisk A/S (“Patent Owner”). Sun 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. Novo Nordisk A/S*, IPR2023-00724 (the “Mylan IPR”). Joinder is appropriate because Sun’s request is timely and 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. 37 C.F.R. § 42.122(b).

II. BACKGROUND

On March 16, 2023, Mylan filed a petition for *inter partes* review challenging claims 1–10 of U.S. Patent No. 10,335,462 (“the ’462 patent”), which was assigned Case No. IPR2023-00724. On October 4, 2023, the Board instituted review of claims 1–10 on five grounds: (1) Claims 1–3 of the ’462 patent as anticipated by WO421; (2) Claims 1–3 of the ’462 patent as anticipated by Lovshin; (3) Claims 1–10 of the ’462 patent as obvious over WO421 and the ’424 Publication; (4) Claims 1–10 of the ’462 patent as obvious over WO537 and Lovshin; and (5) Claims 1–10 of the

'462 patent as obvious over NCT657, NCT733, and the '424 Publication. IPR2023-00724, Paper 10.

Today, concurrent with the instant motion for joinder, Sun filed the Sun Petition, Case No. IPR2024-00107, that is substantially the same as the Mylan IPR: it involves the same patent, same claims, same grounds of unpatentability, and the same evidence (including the same prior art combinations) 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 the Mylan IPR is appropriate because the Sun Petition is limited to the same grounds instituted in Mylan's IPR2023-00724 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 IPR2023-00724 petition and does not include any new grounds not raised in that petition. As such, the Sun Petition does "not present issues that might complicate or delay" Mylan's IPR. *See Enzymotec Ltd. v. Neptune Techs & Bioresources, Inc.*, IPR2014-00556, Paper 19 (PTAB July 9, 2014).

In order to further simplify the proceeding, Sun will rely on the same declarants as Mylan, Dr. John Bantle, Dr. William J. Jusko, and Dr. Paul Dalby (collectively, the "Mylan Declarants"), should Mylan permit it. If Mylan allows Sun to use the Mylan Declarants, then Sun will withdraw the declarations of Dr. Melissa Weinberg, Dr. Craig Dyar, and Dr. Alekha K. Dash (the "Sun Declarants") and rely solely on the declarations and testimonies of the Mylan Declarants. Given Sun's reliance on Mylan's IPR Petition and Declarants, the primary difference between

Sun's and Mylan's Petitions are the sections on Real Party-In-Interest, Related Matters, and Counsel, which have been appropriately updated.

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. *Sawai USA, Inc. v. Biogen MA, Inc.*, IPR2019-00789, Motion for Joinder, Paper 2, at 4-5 (Mar. 5, 2019); *Teva Pharm. USA, Inc. v. Eli Lilly & Co.*, IPR2016-01343, Mot. for Joinder, Paper 3, at 8 (July 1, 2016) (offering same procedure); *Argentum Pharms. LLC v. Janssen Oncology, Inc.*, IPR2016-01317, Mot. for Joinder, Paper 3, at 6-7 (June 29, 2016) (same); *Argentum Pharms. LLC, v. Cosmo Techs., Ltd.*, IPR2016-01317, Mot. for Joinder, Paper 3, at 4-5 (Oct. 20, 2017) (same). Further, the declarations of the Sun Declarants submitted in support of the present Petition present substantively identical testimony to that of the Mylan Declarants, thus streamlining the issues for trial even if Mylan does not permit Sun to rely directly on the Mylan Declarants.

Even if, despite its best efforts with Mylan, Sun were required to proceed with its own Declarants, there would be no impact on the Board's ability to complete its review in a timely manner, in light of the substantially identical testimony between the Sun Declarants and the Mylan Declarants. In such a situation, there would be at most a modest impact on the Patent Owner given that little additional preparation would be needed for the deposition of the Sun Declarants beyond that required for



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