

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2022-00258
Patent No. 9,254,338

**MOTION FOR JOINDER UNDER 35 U.S.C. § 325(c)
AND 37 C.F.R. §§42.22 AND 42.222(b)**

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner, Celltrion, Inc. (“Celltrion” or “Petitioner”), respectfully requests joinder of the concurrently filed petition for *inter partes* review of U.S. Patent No. 9,254,338 (“the ’338 Patent”) (IPR2020-00258) with *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00881 (P.T.A.B.), filed May 5, 2021 and instituted on November 10, 2021 (“the Mylan IPR”). (See IPR2021-00881, Paper 21.) Celltrion has conferred with Mylan, and Mylan, including the real parties-in-interest identified in its petition, does not oppose this Motion for Joinder.

The instant Petition 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 supported by the same expert declarations) as the Mylan IPR. If joined Celltrion will assume a “silent understudy” role and will not take an active role in the *inter partes* review proceeding unless the Mylan Petitioner ceases to participate in the instituted IPR. Thus, the proposed joinder will neither unduly complicate the Mylan IPR nor delay its schedule. As such, the joinder will promote judicial efficiency in determining patentability in the Mylan IPR without prejudice to Patent Owner.

Although Celltrion is not otherwise time barred pursuant to 37 C.F.R. § 42.101(b), this Motion for Joinder, and accompanying Petition, are timely because they are filed less than one month after a decision instituting trial in the

Mylan IPR. 37 C.F.R. § 42.122(b) (“no later than one month after the institution date of any inter partes review for which joinder is requested.”). Accordingly, Celltrion respectfully requests that the Board grant this Motion for Joinder.

II. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review (IPR) proceedings. Joinder is governed by 35 U.S.C. § 315(c), which states:

(c) JOINDER. – If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

The AIA’s legislative history makes clear that joinder is to be liberally granted. 157 Cong. Rec. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). As joinder should be liberally granted, the factors *General Plastic Indus. Co. Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Pap. 19 at 16 (Sept. 6, 2017) favor

institution, as Celltrion has not previously filed a petition challenging the same claims of the '338 patent.¹

A motion for joinder should “(1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified.” *Dell Inc. v. Network-1 Sec. Solutions, Inc.*, IPR2013-00385, Paper 17 (PTAB July 29, 2013); *Hyundai Motor Co. v. Am. Vehicular Scis. 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)).

¹ The other factors are either also positive or neutral. For example, Factor 6, which is the “finite resources of the Board,” favors institution as Celltrion is advancing the same challenges, arguments, and evidence relied upon in the Mylan IPR. For the same reason, Regeneron’s Preliminary Response was not used as a roadmap for this Petition. And as discussed in the Motion, joinder would have no impact on the trial schedule for the Mylan IPR.

B. Celltrion's Motion for Joinder is Timely

A motion for joinder is timely if the moving party files within one month of institution of the inter partes review for which joinder is requested. 37

C.F.R. 42.122(b). Because Celltrion files this motion within one month after a decision on the institution of the Mylan IPR, this motion is timely.

C. Joinder is Appropriate

Joinder is appropriate because Celltrion's Petition does not raise any new grounds of unpatentability and does "not present issues that might complicate or delay" the Mylan IPR. *See Enzymotec Ltd. v. Neptune Techs & Bioresources, Inc.*, IPR2014-00556, Paper 19 (PTAB July 9, 2014). Celltrion's Petition is substantially identical to the petition in the Mylan IPR, challenging the same claims of the '338 Patent on the same grounds and relying on the same expert testimony. Thus, the only difference between Celltrion's Petition and the petition filed in the Mylan IPR are the sections on Real Party-In-Interest, Related Matters, and Counsel, which have been appropriately updated.

Joinder would, therefore, have little, if any, impact on the Mylan IPR, the schedule would not be affected, no additional briefing or discovery would be required, and no additional burdens would be placed on any party or the PTAB, as detailed below.

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