

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2023-00532
U.S. Patent No. 10,130,681 B2

**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. 10,130,681 (“the ’681 Patent”) (IPR2023-00532) with *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2022-01225 (P.T.A.B.), filed July 1, 2022, and instituted on January 11, 2023 (“the Mylan IPR”). *See* IPR2022-01225, 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 '681 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 ’681 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.

1. No New Grounds of Unpatentability in the Petition

Celltrion's Petition does not assert any new grounds of unpatentability. It challenges the same claims (1, 3-11, 13-14, 16-24, and 26) of the '681 Patent based on the same arguments and analysis, prior art, evidence (including expert declarations), and five grounds of unpatentability as the Mylan IPR. *See, e.g., Hyundai*, IPR2014-01543, Paper 11, at 2-4; *Dell*, IPR2013-00385, Paper 17, at 6-10.

2. No Impact on the Schedule For the Existing IPR Proceeding

Because Celltrion's Petition raises no new grounds of unpatentability, and because a Scheduling Order has been established for the Mylan IPR less than one month ago, joinder should have no impact on the schedule of the Mylan IPR. *See LG v. Memory Integrity, LLC.*, IPR2015-01353, Paper 11, at 6 (Oct. 5, 2015) (granting IPR and motion for joinder where "joinder should not necessitate any additional briefing or discovery from Patent Owner beyond that already required in [the original IPR]"). Celltrion will adhere to all applicable deadlines set in the Scheduling Order for the Mylan IPR.

As discussed further below, Celltrion is willing to limit its participation in this proceedings to a "silent understudy." In the event that the Mylan IPR is terminated with respect to the Mylan Petitioner, only then does Celltrion intend to "step into the shoes" of the dismissed petitioner and materially participate in the

joined proceedings. Accordingly, for the reasons stated above, joinder of Celltrion to the Mylan IPR will not affect the Board's ability to complete its review and final decision within the statutory time limits under 35 U.S.C. § 316(a)(11) and 37 C.F.R. § 42.100(c).

3. Briefing and Discovery Will be Simplified

As a "silent understudy," Celltrion agrees that, if joined, the following conditions will apply so long as Mylan remains an active party, as previously approved by the Board in other joinder circumstances:

(a) all filings by Celltrion in the joined proceeding be consolidated with the filings of Mylan, unless a filing solely concerns issues that do not involve Mylan;

(b) Celltrion shall not be permitted to raise any new grounds not instituted by the Board in the Mylan IPR, or introduce any argument not already introduced by Mylan;

(c) With regard to taking of testimony, Celltrion will abide by 37 C.F.R. § 42.53 or any agreement between the Patent Owner and Mylan. *See DRL Pharms. Inc. v. Novartis AG*, IPR2015-00268, Paper 17, at 5-6 (PTAB Apr. 10, 2015) (finding the same proposed limitations "are consistent with the 'understudy' role that Petitioner agrees to assume, as well as Petitioner's assertion that its presence would not require introducing any additional arguments, briefing, or discovery.").

Celltrion also is willing to abide by any additional conditions the Board deems appropriate.

4. No Prejudice to Patent Owner

Joinder of Petitioner to the Mylan IPR will not create any additional burden on the Patent Owner. The Patent Owner need not expend any additional resources above and beyond those required in the current Mylan IPR. Moreover, joinder eliminates the need for the Patent Owner to participate in multiple, staggered *inter partes* review proceedings instituted upon identical grounds of unpatentability.²

III. Conclusion

For the foregoing reasons, Celltrion respectfully requests that its Petition for *inter partes* review of the '681 patent be granted and that the proceeding be joined with IPR2022-01225.

Respectfully submitted,

Dated: February 10, 2023

/Lora M. Green/
Lora M. Green, Lead Counsel
Reg. No. 43,541

² The argument that joinder may theoretically frustrate settlement between Mylan and Patent Owner is not a basis to deny joinder because that same possibility exists in every joinder situation. *Global Foundries U.S. Inc. v. Godo Kaisha IP Bridge 1*, IPR2017-00925 and IPR2017-00926, Paper 13, at 10 (June 9, 2017)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that I caused to be served a true and correct copy of the foregoing Motion for Joinder by overnight courier (Federal Express or UPS), on this 10th day of February 2023, on the Patent Owner at the correspondence address of the Patent Owner as follows:

Regeneron – Bozicevic Field & Francis LLP201
Redwood Shores Parkway
Suite 200
Redwood City, CA 94065

Regeneron Pharmaceuticals, Inc.
770 Old Saw Mill River Road
Tarrytown, NY 10591

And additional copies have been delivered to counsel for Patent Owner in IPR2022-01225, as follows:

Arnold & Porter Kaye Scholer LLP
3000 El Camino Real
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And to counsel for Petitioner Mylan Pharmaceuticals, Inc. in IPR2022-

01225, as follows:

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Respectfully submitted,

Dated: February 10, 2023

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