

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2022-00257
Patent 9,969,069 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and
SUSAN L.C. MITCHELL, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314
Granting Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

Celltrion, Inc. (“Petitioner”) has timely filed a Petition (“Celltrion Petition”) requesting an *inter partes* review of claims 1 and 8–12 of U.S. Patent No. 9,969,069 B2 (Ex. 1001, “the ’069 patent”). Paper 2 (“Pet.”). Petitioner also timely filed a Motion for Joinder (the “Motion” or “Mot.,” Paper 3) to join this proceeding with *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880, filed May 5, 2021, and instituted on November 10, 2021 (the “*Mylan IPR*”). See *Mylan IPR*, Paper 21. In an email to the Board on December 20, 2021, Patent Owner Regeneron Pharmaceuticals Inc. (“Patent Owner”)¹ communicated that it waives filing a Preliminary Response to the Petition. See Ex. 3001.

For the reasons set forth below, we (1) institute *inter partes* review based on the same grounds as instituted in the *Mylan IPR*, and (2) GRANT Petitioner’s Motion for Joinder, subject to the conditions detailed herein.

II. INSTITUTION OF INTER PARTES REVIEW

In the *Mylan IPR*, we instituted trial on the following grounds:

¹ In its Mandatory Notices, Patent Owner identifies itself as the real party-in-interest. Paper 6, 2.

| Ground | Claims Challenged | 35 U.S.C. § | Reference(s) |
|--------|-------------------|-------------|--|
| I | 1, 9–12, | 102 | Dixon ² |
| II | 1, 9–12 | 102 | Heier 2009 ³ |
| III | 1, 9–12 | 102 | Regeneron I ⁴ |
| IV | 1, 8–12 | 102/103 | Dixon |
| V | 1, 8–12 | 103 | Heier 2009, Mitchell ⁵ or Dixon, optionally Papadopolous ⁶ or Dix ⁷ |

Mylan IPR, Paper 21, 3, 4, 49.

Celltrion’s Petition is substantially identical to Mylan’s Petition, challenging the same patent and claims, based on the same grounds of unpatentability, and relying upon the same evidence (including the same

² James A. Dixon et al., “VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration,” 18(10) *Expert Opin. Investig. Drugs* 1573–1580 (2009) (Ex. 1006, “Dixon”).

³ J.S. Heier, *Intravitreal VEGF Trap for AMD: An Update*, October 2009 *RETINA TODAY* 44–45 (2009) (“Heier 2009”) Ex. 1020.

⁴ Press Release, *Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion*, April 30, 2009 (“Regeneron I”) Ex. 1028.

⁵ P. Mitchell et al., *Ranibizumab (Lucentis) in Neovascular Age-Related Macular Degeneration: Evidence from Clinical Trials*, 94(2) *Br. J. Ophthalmol.* 2–13 (2010) (“Mitchell”) Ex. 1030.

⁶ Papadopoulos et al. (US 7,374,758 B2, May 20, 2008) (“Papadopolous”) Ex. 1010.

⁷ Dix et al., (US 2006/0217311 A1, May 20, 2008) (“Dix”) Ex. 1033.

prior art combinations supported by the same expert declaration) as the *Mylan* IPR. *See* Mot. 1. Petitioner seeks only institution of the same claims and grounds for which the Board instituted in the *Mylan* IPR. *Id.*

Patent Owner has waived filing a Preliminary Response in this proceeding. Ex. 3001. Therefore, at this stage and in this proceeding, Patent Owner has not raised any arguments in response to the substantive grounds of the *Mylan* Petition. Petitioner undertakes, if the Petition and Motion are granted, to 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. Pet. 3. Petitioner contends that the proposed joinder will neither unduly complicate the *Mylan* IPR nor delay its schedule. *Id.* As such, Petitioner asserts, the joinder will promote judicial efficiency in determining patentability of the '069 patent in the *Mylan* IPR without prejudice to Patent Owner. *Id.*

In view of these representations by Petitioner, and having reviewed the Celltrion Petition, we determine that, under the current circumstances, it is appropriate to exercise our discretion to institute *inter partes* review of the challenged claims based upon the same grounds authorized and for the same reasons discussed in our Institution Decision in the *Mylan* IPR. *See Mylan* IPR, Paper 21.

III. JOINDER OF *INTER PARTES* REVIEWS

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 35 U.S.C. § 315(c), which governs joinder of *inter partes* review proceedings:

(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.

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: set forth the reasons joinder is appropriate; identify any new grounds of unpatentability asserted in the petition; and explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview, LLC*, IPR2013-00004, Paper 15 at 4 (PTAB Apr. 24, 2013); *see also*, USPTO, *America Invents Act (AIA) Frequently Asked Questions*,” available at: uspto.gov/patents/laws/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review_3244 (last visited February 2, 2022).

Petitioner timely filed its Joinder Motion within one month of the institution of the *Mylan* IPR, as required by 37 C.F.R. § 42.122(b). In the motion, Petitioner explains that it 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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.