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Paper 35
Date: February 9, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

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IPR2022-00258
Patent 9,254,338 B2

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

FRANKLIN, *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") timely filed a Petition ("Celltrion Petition") requesting an *inter partes* review of claims 1, 3–11, 13, 14, 16–24, and 26 of U.S. Patent No. 9,254,338 B2 (Ex. 1001, "the '338 patent"). Paper 2 ("Pet."). Petitioner also timely filed a Motion for Joinder ("Joinder Motion") to join this proceeding with *Mylan Pharms., Inc. v. Regeneron Pharms, Inc.*, IPR2021-00881, filed May 5, 2021, and instituted on November 10, 2021 (the "*Mylan* IPR"). Paper 3 ("Mot."); *see Mylan* IPR, Paper 21. In an email to the Board on December 20, 2021, Regeneron Pharmaceuticals, Inc. ("Patent Owner")[1] communicated that it waives filing a Preliminary Response to the Petition. 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 Joinder Motion, subject to the conditions detailed herein.

## II. INSTITUTION OF *INTER PARTES* REVIEW

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

| **Claims Challenged** | **35 U.S.C. §** | **Reference(s)** |
|---|---|---|
| 1, 3–11, 13, 14, 16–24, 26 | 102 | Dixon[2] |
| 1, 3–11, 13, 14, 16–24, 26 | 102 | Adis[3] |

[1] In its Mandatory Notices, Patent Owner identifies itself as the real party-in-interest. Paper 6, 2.
[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] Adis Data Information BV, "Aflibercept," 9(4) *Drugs R&D* 261–269 (2008) (Ex. 1007, "Adis").

| Claims Challenged | 35 U.S.C. § | Reference(s) |
|---|---|---|
| 1, 3–11, 13, 14, 16–24, 26 | 102 | Regeneron 2008[4] |
| 1, 3–11, 13, 14, 16–24, 26 | 102 | NCT-795[5] |
| 1, 3–11, 13, 14, 16–24, 26 | 102 | NCT-377[6] |
| 1, 3–11, 13, 14, 16–24, 26 | 103 | Dixon, Papadopoulos,[7] Dix[8] |

*Mylan* IPR, Paper 21, 6, 40. 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 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 Joinder

[4] Press Release, Regeneron, "Bayer and Regeneron Dose First Patient in Second Phase 3 Study for VEGF Trap-Eye in Wet Age-Related Macular Degeneration" (May 8, 2008) (Ex. 1013, "Regeneron 2008").
[5] Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009), https://clinicaltrials.gov/ct2/show/NCT00509795 (Ex. 1014, "NCT-795").
[6] VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), https://clinicaltrials.gov/ct2/show/NCT00637377 (Ex. 1015, "NCT-377").
[7] Papadopoulos et al., US 7,374,758 B1, issued May 20, 2008, (Ex. 1010, "Papadopoulos").
[8] Dix et al., US 2006/0217311, issued Sept. 28, 2006 (Ex. 1033, "Dix").

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 '388 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 Joinder 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.

Mot. 3, 1. As discussed in the Institution Decision, Section II *supra*, the instituted grounds in this proceeding are the same as that instituted in the *Mylan* IPR.

Having considered the unopposed Joinder Motion, and our decision to institute the same grounds in the *Mylan* IPR, we determine that Petitioner Celltrion has established persuasively that joinder is appropriate and will have little to no impact on the timing, cost, or presentation of the trial on the instituted ground. Thus, in consideration of the foregoing, and in the manner set forth in the following Order, the Joinder Motion is *granted*.

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