

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2022-00298
Patent 9,254,338 B2

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

Apotex, Inc. (“Petitioner”) timely filed a Petition (“Apotex 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 1 (“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. Apotex’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 Apotex 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 ground 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 decisions to institute the same grounds in the *Mylan* IPR, we determine that Petitioner Apotex 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*.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 3–11, 13, 14, 16–24, and 26 of U.S. Patent No. 9,254,338 B2 is instituted in IPR2022-00298 on the six grounds asserted in the Petition, and set forth above in Section II:

FURTHER ORDERED that Petitioner’s Unopposed Motion for Joinder with IPR2021-000881 is *granted*;

FURTHER ORDERED that IPR2022-00298 is terminated and joined with IPR2021-00881, pursuant to 37 C.F.R. §§ 42.72, 42.122, wherein Apotex will maintain a secondary role in the proceeding, unless and until Mylan ceases to participate as a petitioner in the *inter partes* review;

FURTHER ORDERED that the Scheduling Order in place for IPR2021-00881, along with modifications appropriately stipulated to by the parties, shall govern the joined proceeding;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2021-00881;

FURTHER ORDERED that the case caption in IPR2021-00881 for all further submissions shall be changed to add Apotex, Inc. as a named Petitioner after the *Mylan* Petitioner, and a footnote shall be added to indicate the joinder of IPR2022-00298 to that proceeding, as shown in the attached sample case caption;⁹ and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2021-00881.

⁹ The attached sample caption includes Petitioner Celltrion, based on our concurrently decided decision granting institution and granting the motion for joinder in IPR2022-00258.

IPR2022-00298
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Joined Case Caption

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., CELLTRION, INC., and
APOTEX, INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2021-00881¹⁰
Patent 9,254,338 B2

¹⁰ IPR2022-00258 and IPR 2022-00298 have been joined with this proceeding.