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Paper 7
Date: March 22, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEIUTICALS, INC.,
Patent Owner.

IPR2023-00532
Patent 10,130,681 B2

Before JOHN G. NEW, SUSAN L.C. MITCHELL, and ROBERT A. POLLOCK, *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 of U.S. Patent No. 10,130,681 B2 (Ex. 1001, "the '681 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.*, IPR2022-01225, 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	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 3–11, 13, 14, 16–24, 26	102[2]	Dixon[3]
2	1, 3–11, 13, 14, 16–24, 26	102	Adis[4]
3	1, 3–11, 13, 14, 16–24, 26	102	Regeneron 2008[5]
4	1, 3–11, 13, 14, 16–24, 26	103	Dixon alone or in view of Papadopoulos[6] and/or Wiegand[7]

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the '601 patent issued has an effective filing date after that date, the AIA versions of §§ 102 and 103 apply.

[3] J.A. Dixon et al., *VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration*, 18(10) EXPERT OPIN. INVESTIG. DRUGS 1573–80(2009) ("Dixon") Ex. 1006.

[4] Adis R&D Profile, *Aflibercept: AVE 0005, AVE 005, AVE0005, VEGF Trap – Regeneron, VEGF Trap (R1R2), VEGF Trap-Eye*, 9(4) DRUGS R D 261–269 (2008) ("Adis") Ex. 1007.

[5] Press Release, *Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration*, April 28, 2008 ("Regeneron 2008") Ex. 1012.

[6] Papadopoulos et al. (US 7,374,758 B2, May 20, 2008) ("Papadopoulos") Ex. 1010.

[7] Wiegand et al. (US 7,531,173 B2, May 12, 2009) ("Wiegand") Ex. 1007.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
5	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Rosenfeld-2006[8], and if necessary, Papadopoulos and/or Wiegand
6	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Heimann-2007, and if necessary, Papadopoulos and/or Wiegand

Mylan IPR, Paper 21, 4–5, 28.

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 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

[8] P.J. Rosenfeld et al., *Ranibizumab for Neovascular Age-Related Macular Degeneration*, 355 (14) N. ENGL. J. MED. 1419–31; Suppl. App'x 1–17 (2006) ("Rosenfeld") Ex. 1058.

schedule. *Id.* As such, Petitioner asserts, the joinder will promote judicial efficiency in determining patentability of the '681 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.

Mot. 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 motion for joinder, 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 Motion for Joinder is GRANTED.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that trial is instituted in IPR2022-00257 on the following

grounds:

Ground 1: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 102 as anticipated by Dixon.

Ground 2: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 102 as anticipated by Adis.

Ground 3: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 102 as anticipated by Regeneron 2008.

Ground 4: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 103 as obvious over Dixon alone or in view of Papadopoulos and/or Wiegand.

Ground 5: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 103 as being obvious over Dixon in combination with Rosenfeld-2006, and if necessary, Papadopoulos and/or Wiegand.

Ground 6: Claims 1, 3–11, 13, 14, 16–24, and 26 of the '681 patent under 35 U.S.C. § 103 as being obvious over Dixon in combination with Heimann-2007, and if necessary, Papadopoulos and/or Wiegand.

FURTHER ORDERED that Petitioner's Unopposed Motion for Joinder with IPR20221-01225 is GRANTED;

FURTHER ORDERED that IPR2023-00532 is terminated and joined with IPR2022-01225, pursuant to 37 C.F.R. §§ 42.72, 42.122, wherein Celltrion 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 IPR2022-01225, 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 IPR2022-01225;

FURTHER ORDERED that the case caption in IPR2022-01225 for all further submissions shall be changed to add Celltrion, Inc. as a named Petitioner after the *Mylan* Petitioner, and a footnote shall be added to indicate the joinder of IPR2023-00532 to that proceeding, as shown in the attached sample case caption; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2022-01225.

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Joined Case Caption

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS, INC. and CELLTRION, INC.,
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REGENERON PHARMACEUTICALS, INC.,
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