Trials@uspto.gov
571-272-7822

Paper 7
Date: February 9, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

REGENERON PHARMACEIUTICALS, INC.,
Patent Owner.

IPR2022-00301
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

Apotex Inc. ("Petitioner") has timely filed a Petition ("Apotex 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 1 ("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.

Apotex's Petition is substantially identical to Mylan's Petition, challenging the same patent and claims, based on the same grounds of

---

[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.

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 an "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 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 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:

> [A]grees to an "understudy" role and will not raise any additional issues in the joined proceeding so long as Mylan remains an active party. Joinder would thus create no additional burden for the Board, the Mylan IPR Petitioner, or Patent Owner. Nor should it impact the Mylan IPR schedule. As such, joinder will promote judicial efficiency in determining patentability of the '069 Patent 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 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 Motion for Joinder is GRANTED.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that trial is instituted in IPR2022-00301 on the following grounds:

Ground I: Claims 1 and 9–12 of the '069 patent under 35 U.S.C. § 102 as anticipated by Dixon.

Ground II: Claims 1 and 9–12 of the '069 patent under 35 U.S.C. § 102 as anticipated by Heier 2009.

Ground III: Claims 1 and 9–12 of the '069 patent under 35 U.S.C. § 102 as anticipated by Regeneron I.

Ground IV: Claims 1 and 8–12 of the '069 patent under 35 U.S.C. §§ 102 and or 103 as anticipated by or obvious over Dixon.

Ground V: Claims 1 and 8–12 of the '069 patent under 35 U.S.C. § 103 as being obvious over Heier 2009 and Mitchell or Dixon, and optionally, Papadopolous or Dix.

FURTHER ORDERED that Petitioner's Unopposed Motion for Joinder with IPR2021-000880 is GRANTED;

FURTHER ORDERED that IPR2022-00301 is terminated and joined with IPR2021-00880, 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 IPR2021-00880, 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 IPR2021-00880;

FURTHER ORDERED that the case caption in IPR2021-00880 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 IPR2022-00301 to that proceeding, as shown in the attached sample case caption; [8] and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2021-00880.

[8] The attached sample caption includes Petitioner Celltrion, based on our concurrently decided decision granting institution and granting the motion for joinder in IPR2022-00301.

FOR PETITIONER:

Teresa Stanek Rea
Deborah H. Yellin
Shannon M. Lentz
CROWELL & MORING LLP
trea@Crowell.com
dyellin@Crowell.com
slentz@Crowell.com

FOR PATENT OWNER:

Deborah E. Fishman
David A. Caine
Alice S. Ho
ARNOLD & PORTER KAYE SCHOLER LLP
deboarh.fishman@arnoldporter.com
david.caine@arnoldporter.com
alice.ho@arnoldporter.com

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.

_____

Case IPR2021-00880[1]
Patent 9,969,069 B2

_____

[1] IPR2022-00257 and IPR 2022-00301 have been joined with this proceeding.