

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS INC.,
Petitioner,

v.

REGENERON PHARMACUTICALS, INC.,
Patent Owner.

IPR2024-00201
Patent 10,888,601 B2

Before JOHN G. NEW, ROBERT A. POLLOCK, and RYAN H. FLAX,
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

Biocon Biologics Inc. (“Petitioner”) has timely filed a Petition seeking *inter partes* review of claims 10–12, 17–19, 21, 25–28, and 33 of U.S. Patent No. 10,888,601 B2 (Ex 1001, “the ’601 patent”). Paper 3 (“Pet.”). Petitioner also timely filed a Motion for Joinder (the “Motion” or “Mot.,” Paper 2), seeking to join this proceeding with *Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00739 (the “-00739 IPR”), filed March 26, 2023, and instituted on November 10, 2021. *See* -00739 IPR, Papers 1, 9. Patent Owner Regeneron Pharmaceuticals Inc. (“Patent Owner”) has filed an Opposition (“Opp.”) to Petitioner’s Motion for Joinder. *See* Paper 10.

For the reasons set forth below, we: (1) institute *inter partes* review based on the same grounds as instituted in the -00739 IPR; and (2) GRANT Petitioner’s Motion for Joinder, subject to the conditions detailed herein.

II. INSTITUTION OF *INTER PARTES* REVIEW

A. *Petition and Motion for Joinder*

In the -00739 IPR, we instituted trial on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
2 ¹	10–12, 18, 19, 21, 26–28	103 ²	2009 Press Release ³ , Shams ⁴
3	10–12, 18, 19, 21, 26–28	103	2009 Press Release, Elman ⁵
6	17, 25, 33	103	2009 Press Release, Elman, CATT ⁶ , PIER ⁷

¹ All of the claims challenged in Grounds 1, 4, and 5 of the -00739 IPR were subsequently disclaimed by Patent Owner. *See* -00739 IPR, Paper 6 at 1, n.1. We therefore did not institute *inter partes* review with respect to those Grounds.

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 Press Release, Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (September 14, 2009) (the “2009 Press Release”) Ex 1009.

⁴ Shams (WO 2006/047325 A1, May 4, 2006) (“Shams”) Ex 1010.

⁵ M.J. Elman et al., *Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema*, 117(6) OPTHALMOL. 1064–1077.e35 (2010) (“Elman”) Ex 1006.

⁶ CATT Patient Eligibility Criteria, retrieved from: https://web.archive.org/web/20100713035617/http://www.med.upenn.edu/cpob/studies/documents/CATTEligibilityCriteria_000.pdf (“CATT”) Ex 1018.

⁷ C.D. Regillo et al., *Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1*, 145(2) AM. J. OPTHALMOL. 239–48 (2008) (“PIER”) Ex 1004.

-00739 IPR, Paper 9 at 5, 62.

Petitioner's Petition is substantially identical to Petitioner Samsung Bioepis Co. Ltd.'s ("Samsung") Petition in the -00739 IPR, 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 and supported by the same expert declaration) as the -00739 IPR. *See* Pet. 1; Mot. 1–2, 6–7. Petitioner seeks only institution of the same claims and grounds for which the Board instituted in the -00739 IPR. *Id.* at 7.

Petitioner timely filed its Joinder Motion within one month of the institution of the -00739 IPR, as required by 37 C.F.R. § 42.122(b). In its Motion for Joinder, Petitioner undertakes to assume a "silent understudy" role, and will not take an active role in the *inter partes* review proceeding unless Samsung ceases to participate in the instituted -00739 IPR. Mot. 6–7. Petitioner contends that the proposed joinder will neither unduly complicate the -00739 IPR, nor delay its schedule. *Id.* at 8. As such, Petitioner asserts, the joinder will promote judicial efficiency in determining patentability of the challenged claims of the '601 patent in the -00739 IPR without prejudice to Patent Owner. *Id.*

B. Patent Owner's Opposition

Patent Owner first asserts that Petitioner is the successor-in-interest of Mylan Pharmaceuticals, Inc. ("Mylan"), and has litigated the validity of claims of the '601 patent in district court in *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D.W. Va.), where a decision has recently been reached. Opp. 1 (citing Ex 2001, 2). Patent Owner also notes that Mylan challenged claims of the '601 patent in *Mylan Pharms Inc.*

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v. Regeneron Pharms., Inc., IPR2022-01226 (the “-01226 IPR”), in which a Final Written Decision was entered on January 9, 2024.

Patent Owner contends that following the bench trial in district court, Petitioner now seeks to re-litigate before the Board overlapping claims (claims 11 and 19) *via* joinder. Opp. 1.

Patent Owner presents two arguments as to why the Board should deny institution of *inter partes* review and joinder: (1) the Board should exercise its discretion and deny Biocon’s joinder motion, because it would be unfair and prejudicial to Patent Owner for Biocon’s third attack on the ’601 patent to proceed; and (2) joinder should be denied under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential), as the alleged purpose of Biocon’s bid for joinder is to hedge against an adverse district court decision. Opp. 3.

With respect to its first argument, Patent Owner contends that the -00739 IPR, which Petitioner seeks to join, was instituted and will proceed with or without Petitioner. Opp. 4. Patent Owner argues that allowing Petitioner to challenge the validity of claims of the ’601 patent in a “me-too” petition, after it has fully litigated validity of some of the same claims before the district court serves no legitimate purpose. Patent Owner also alleges that joinder would be inequitable to permit Petitioner to preserve another validity challenge to the ’601 patent, in the event that Patent Owner prevails in the district court and Samsung settles the -00739 IPR. *Id.*

With respect to its second argument, Patent Owner argues that the balance of the *Fintiv* factors weigh in favor of the Board exercising its discretion to deny institution and joinder. Opp. 6. With respect to *Fintiv* factor 1, Patent Owner argues that trial has already taken place in the parallel

district court litigation with respect to overlapping claims 11 and 19 of the '601 patent.⁸ Patent Owner points to our finding in the -00739 IPR that *Fintiv* factor 1 thus favors denial. *Id.*

With respect to *Fintiv* factors 2 and 3, Patent Owner repeats that trial in the parallel district court litigation has already taken place, and that Patent Owner, Petitioner and the district court have invested a significant amount of time and money in the parallel proceedings involving the '601 patent, both of which circumstances weigh in favor of denial. Opp. 6–7. Patent Owner also notes that Petitioner's petition is Biocon's petition is time-barred absent joinder, and Petitioner has not identified any proper purpose for bringing another challenge to the '601 patent now at this stage. *Id.* at 7.

With respect to *Fintiv* factor 4, Patent Owner argues that, although challenged claims 11 and 19 of the '601 patent are at issue in the parallel district court litigation, a larger subset of the '601 patent claims was at issue up until April 2023, including throughout discovery. Opp. 8 (citing Ex 2002). Patent Owner argues that, despite the narrowing of the claims challenged in the district court litigation, the overlap in issues is still significant and *Fintiv* factor 4 should thus weigh in favor of discretionary denial. *Id.*

As to *Fintiv* factor 5, Patent Owner notes that the parties agree that Petitioner, as successor-in-interest to Mylan, is a defendant in the parallel district court litigation, which weighs in favor of denial. Opp. 8 (citing Paper 3 at 49).

⁸ Claims 11, 19, and 27 are the only claims of the '601 patent at issue in the parallel district court litigation. *See* Ex 2002, 2.

Finally, with respect to *Fintiv* factor 6, Patent Owner contends that the Petition represents Petitioner/Mylan's second petition challenging the '601 patent, and Petitioner offers no explanation for why it waited to file its Petition until now. Opp. 8. Furthermore, argues Patent Owner, the -00739 IPR will proceed regardless of whether or not Petitioner is joined. *Id.* However, Patent Owner argues, should Samsung settle in the -00739 IPR, Samsung settles and Petitioner steps into the role of primary petitioner, such a result would be inequitable to Patent Owner, who has already defended against two validity challenges mounted by Mylan/Petitioner in prior proceedings. *Id.* at 9.

C. Analysis

We explained in our Institution Decision in the -00739 IPR, why we concluded that Samsung had demonstrated a reasonable likelihood of prevailing at trial in showing that the challenged claims are unpatentable. *See, generally,* -00739 IPR, Paper 9 ("Inst. Dec."). The present Petition advances essentially identical arguments, challenging the same claims over the same combinations of prior art. We consequently adopt the same reasoning as in our -00739 Institution Decision, and conclude that Petitioner is similarly likely to prevail in demonstrating the unpatentability of the same challenged claims.

With respect to Petitioner's Motion for Joinder, an *inter partes* review may be joined with another *inter partes* review, subject to the provisions of 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: (1) set forth the reasons joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; and (3) 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](https://www.uspto.gov/patents/laws/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review_3244) (last visited February 2, 2022).

We are persuaded by Petitioner’s arguments that joinder in these circumstances is appropriate. Petitioner undertakes to act as a “silent understudy” in the joined *inter partes* reviews and to take no active role in the joined *inter partes* reviews, unless Samsung ceases to act as a party. Mot. 6–7. The challenged claims and grounds of the Petition are identical to those of the -00739 IPR. *Id.* at 7. Petitioner’s Motion is timely and should have no effect upon the trial schedule established for the -00739 IPR. *Id.* at 8.

Although Patent Owner is correct that certain claims of the ’601 patent were previously challenged in the -01226 IPR, those challenged

claims related to the treatment of age-related macular degeneration (claims 1–9, 34–39, 41–43, 45), whereas the challenged claims in both the -00739 IPR and in the present Petition relate to treatment of diabetic retinopathy (claims 10–12, 18, 19, 21, 26–28, and 33). Pet. 1; Inst. Dec. 4–5, 62. As is readily apparent, there is no overlap between these sets of challenged claims in the -01226 IPR and the -00739 IPR.

Similarly, and as Patent Owner acknowledges, only claims 11 and 19 were at issue in the parallel district court litigation. Consequently, and far from allowing Petitioner “multiple bites at the apple” as Patent Owner argues, the validity of claims 10, 12, 18, 21, 26–28, and 33 of the ’601 patent have been challenged in but a single prior proceeding, the currently-instituted -00739 IPR, which Petitioner now seeks to join as a “silent understudy.” If, as Patent Owner hypothesizes, we were to deny Petitioner’s Motion for Joinder, and if Samsung should subsequently reach a settlement with Patent Owner in the -00739 IPR, the remaining claims of the ’601 patent would stand unchallenged. Conversely, instituting *inter partes* review in the present proceeding, but denying joinder, would invoke needlessly repetitive litigation of the same challenged claims upon the same Grounds as the -00739 IPR.

As for the *Fintiv* factors, we considered Patent Owner’s arguments in the Institution Decision of the -00739 IPR, and we find the substantially same arguments in Patent Owner’s Opposition no more persuasive upon repetition. *See* Inst. Dec. 55–61. Again, we emphasize that although trial may have concluded in the district court litigation, as well as in the -01226 IPR, there nevertheless remains a substantial number of ’601 patent claims that have been challenged *only* in the -00739 IPR. We conclude that this

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fact warrants exercise of our discretion to institute *inter partes* review and to grant Petitioner's Motion for Joinder of the present *inter partes* review with the -00739 IPR.

Having reviewed the Petition, as well as Petitioner's representations in its Motion for Joinder, and having also considered Patent Owner's Opposition, we determine that, under the current circumstances, it is appropriate 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 -00739 IPR (*see generally* Inst. Dec.) and to grant Petitioner's Motion for Joinder.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that trial is instituted in IPR2024-00204 on the following grounds:

Ground2: Claims 10–12, 18, 19, 21, and 26–28 of the '601 patent under 35 U.S.C. § 103 as obvious over 2009 Press Release and Shams.

Ground3: Claims 10–12, 18, 19, 21, and 26–28 of the '601 patent under 35 U.S.C. § 103 as obvious over 2009 Press Release and Elman.

Ground6: Claims 17, 25, and 33 of the '601 patent under 35 U.S.C. § 103 as obvious over 2009 Press Release, Elman, CATT, and PIER.

FURTHER ORDERED that Petitioner's Motion for Joinder with IPR2023-00739 is GRANTED;

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FURTHER ORDERED that IPR2024-00201 is terminated and joined with IPR2023-00739, pursuant to 37 C.F.R. §§ 42.72, 42.122, in which Biocon will maintain a secondary role in the proceeding, unless and until Samsung ceases to participate as a petitioner in the *inter partes* review;

FURTHER ORDERED that the Scheduling Order in place for IPR2023-00739, 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 IPR2023-00739;

FURTHER ORDERED that the case caption in IPR2023-00739 for all further submissions shall be changed to add Biocon Biologics Inc. as a named Petitioner after the Samsung Petitioner, and a footnote shall be added to indicate the joinder of IPR2024-00201 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 IPR2023-00739.

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Joined Case Caption

UNITED STATES PATENT AND TRADEMARK OFFICE

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SAMSUNG BIOEPIS CO. LTD. and BIOCON BIOLOGICS INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

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¹ IPR2024-00204 has been joined with IPR2023-00739.