

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS INC.
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner.

Patent No. 10,888,601

Inter Partes Review No. IPR2024-00201

**PATENT OWNER'S OPPOSITION TO
PETITIONER'S MOTION FOR JOINDER**

Exhibit List

Exhibit Description	Exhibit #
Stipulation and Order Joining Biocon Biologics Inc. As Defendant (Dkt. 523) entered in <i>Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.</i> , NDWV-1-22-cv-00061 (June 5, 2023)	2001
Regeneron's Stipulation Regarding Summary Judgment and Case Narrowing (Dkt. 433) entered in <i>Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.</i> , NDWV-1-22-cv-00061 (Apr. 27, 2023)	2002

I. INTRODUCTION

Petitioner Biocon Biologics, Inc. (“Biocon”) seeks to join IPR2023-00739 and challenge certain claims of U.S. Patent No. 10,888,601 (the “’601 patent”). Biocon is the successor-in-interest of Mylan Pharmaceuticals, Inc. (“Mylan”), and has already fully 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 following the parties’ June 2023 trial is expected imminently. *See* Ex.2001, 2 (Stipulation joining Biocon). Mylan also previously challenged claims of the ’601 patent in IPR2022-01226, where a final written decision is expected in January, 2024.

Mylan/Biocon does not and cannot contend that any of the challenges presented by IPR2023-00739 were grounds that it did not or could not have raised in either the previous district court litigation or in IPR2022-01226. Yet, after a completed bench trial and IPR, Mylan/Biocon seeks the option to re-litigate overlapping claims (claims 11 and 19) before the PTAB via joinder. This serves no legitimate purpose and invites gamesmanship. Indeed, if the shoe were on the other foot and Biocon had challenged these claims and lost before the PTAB, Biocon would be barred by 35 U.S.C. § 315(e) from seeking to relitigate in the district court defenses it raised or could have raised before the PTAB. Consequently, Biocon should not be permitted a third bite at the apple. Patent

Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”) therefore opposes this joinder, and, for the reasons set forth below, submits that Biocon’s motion for joinder (and institution of its Petition) should be denied.

II. BACKGROUND AND RELATED PROCEEDINGS

A. This is the second IPR filed by Mylan/Biocon challenging the ’601 patent.

On July 1, 2022, Mylan filed a petition for review of the ’601 patent, challenging claims 1-9, 34-39, 41-43, and 45 in IPR2022-01226 (“the Mylan ’601 petition”). Biocon is a real-party-in-interest in those proceedings. *See Mylan Pharm. Inc. v. Regeneron Pharm. Inc.*, IPR2022-01226, Paper 48 at 1 (Apr. 10, 2023) (Pet. Updated Mandatory Notices). The Board instituted review on January 11, 2023. Review has proceeded through Oral Argument, and a Final Written Decision is expected in January 2024.

B. Mylan/Biocon challenged overlapping claims of the ’601 patent in parallel District Court litigation.

Regeneron sued Mylan (and Biocon, who was later joined) in district court on August 2, 2022, alleging infringement of, *inter alia*, a range of claims of the ’601 patent. *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D.W. Va.). Pursuant to the scheduling order in the case, Regeneron could only pursue 3 patents and 25 total claims at trial, and so ultimately narrowed the asserted ’601 patent claims down to claims 11 and 19 for the bench trial. Ex.1062, 2; Ex.2002, 2 (stipulation narrowing issues for trial). A two-week bench trial was

conducted in June 2023, and the parties have completed post-trial briefing. *See Regeneron*, 1:22-cv-00061-TSK (N.D.W. Va.). The Court has not yet issued its ruling.

III. ARGUMENT

Biocon's petition and motion for joinder should be denied for two reasons. First, 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. Second, joinder should be denied under *Fintiv*, as the sole purpose of Biocon's bid for joinder is to hedge against an adverse district court decision, which is expected to issue at any time. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential).¹

¹ Biocon's Petition would be time barred under 35 U.S.C. § 315(b) if it were not seeking joinder under 35 U.S.C. § 315(c). *See Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1328 (Fed. Cir. 2020); *Network-1 Tech. v. Hewlett-Packard Co.*, 981 F.3d 1015, 1020 (Fed. Cir. 2020). The Federal Circuit's interpretation of the time bar as it applies to joinder petitions may soon face Supreme Court review. *See* Petition for Writ of Certiorari, *VirnetX Inc. v. Mangrove Partners Master Fund, Ltd.*, No. 23-315 (Sep. 27, 2023). As such,

A. The Board Should Exercise Its Discretion to Deny Biocon's Inequitable Request for Joinder.

The Board has discretion over whether to institute IPR proceedings, even when the IPR petition is brought alongside a motion for joinder. *See Apple Inc. v. Uniloc 2017 LLC*, IPR2020-00854, Paper 9, at 4-5 (PTAB Oct. 20, 2020) (“That Petitioner seeks to join the 023 IPR does not obligate us to institute this proceeding without first considering whether to exercise discretion under § 314(a).”) Here, the Board should exercise its discretion and deny institution and joinder in view of the prior district court litigation involving Biocon.

IPR2023-00739 was instituted and will proceed with or without Biocon. However, allowing Biocon 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. And it would be plainly inequitable to subject Patent Owner to this serial harassment, the only purpose of which is for Biocon to hedge its bets and preserve another validity challenge, in the event it loses at the district court and Samsung settles out.

Regeneron reserves all rights to argue that Biocon's petition is time-barred, which is another basis for the Board to exercise its discretion and deny joinder.

The Board should not condone this gamesmanship. If Biocon had raised an IPR challenge before the district court litigation on these claims, proceeded to a final written decision, and lost, it would be statutorily estopped from challenging the same claims on patent and printed publication grounds. *See Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1297 (Fed. Cir. 2023). The legislative purpose behind estoppel is “to discourage ‘abusive serial challenges to patents’ and provide ‘faster, less costly alternatives to civil litigation to challenge patents.’” *Intuitive Surgical, Inc. v. Ethicon LLC*, 25 F.4th 1035, 1043 (Fed. Cir. 2022). The result should be no different here, simply because Biocon litigated at the district court first, before filing a copycat petition and seeking to join the IPR proceedings brought by Samsung. This is particularly true here, where Mylan, Biocon’s predecessor-in-interest, had every opportunity to file a timely IPR on the claims of the ’601 patent now challenged by Samsung, was familiar with all the relied-upon prior art through the litigation, and elected not to do so.

B. Biocon’s pending challenge to the ’601 patent in District Court weighs in favor of discretionary denial under *Fintiv*.

Consideration of the *Fintiv* factors also supports denial of Biocon’s me-too petition. Biocon argues that *Fintiv* should not apply, because it is willing to agree not to pursue “the specific grounds asserted in the Biocon Petition, or that reasonably could have been asserted in the Biocon Petition, against the currently Challenged Claims” in district court. Paper 3 at 48. Biocon’s stipulation rings

hollow, however, because all that remains in the district court litigation is for the Court to issue its opinion. In view of these circumstances, consideration of *Fintiv* is warranted, which further confirms that discretionary denial is appropriate.

***Fintiv* Factor 1: whether the Court granted or would be likely to grant a stay**

Trial has already taken place in the parallel litigation. The Court may rule at any time, including on the validity of overlapping claims 11 and 19. And no stay was issued previously. As to any future litigation, whether or not a court would issue a stay is conjecture. Just as the Board found in its Decision Granting Institution for the Samsung petition, this factor favors denial. *Samsung Bioepis Co. Ltd. v. Regeneron Pharms., Inc.*, IPR2021-00739, Paper 9 at 55 (PTAB Oct. 20, 2023).

***Fintiv* Factors 2 and 3: proximity of the Court’s trial date/investment in parallel proceeding by the Court and the parties**

In instituting review for the Samsung petition, the Board found that Factors 2 and 3 favor institution. *Samsung*, IPR2021-00739, Paper 9 at 58. But here, since Biocon is both the petitioner and a defendant in the parallel litigation, as described in Factor 5, these factors warrant closer scrutiny. There is no dispute that trial has already taken place, which weighs against institution. *See LG Electronics, Inc. et al. v. Ancora Techs. Inc.*, IPR2021-00581, Paper 16, at 8 (PTAB Jun. 10, 2021).

Additionally, Patent Owner, Biocon, and the District Court have invested a significant amount of time and money in the parallel proceedings involving the

'601 patent. In about a year, the parties engaged in discovery, claim construction, dispositive motions, a bench trial in June 2023, and post-trial briefing. These significant investments weigh in favor of denial. *See LG*, IPR2021-00581, Paper 16, at 8-9.

The Board may also consider delay under *Fintiv* factor three: “The third *Fintiv* factor also provides that a petitioner’s diligence or delay in filing a petition may be relevant. . . . If, however, the evidence shows that the petitioner did not file its petition expeditiously, such as at or around the same time that the patent owner responded to the petitioner’s invalidity contentions, or even if a petitioner cannot explain the delay in filing its petition, these facts have favored denial.” *See Snap, Inc. v. SRK Tech LLC*, IPR2020-00820, Paper 15, at 11 (PTAB Oct. 21, 2020) (precedential as to discretionary denial). Here, there can be no dispute that Biocon delayed filing its petition until after Mylan’s first IPR was heard and after the district court trial proceedings were completed. Biocon’s petition is time-barred absent joinder, and Biocon has not identified any proper purpose for bringing another challenge to the ’601 patent now at this late stage.

***Fintiv* Factor 4: overlap between issues raised in the petition and in the parallel proceeding**

Patent Owner previously argued that the overlap in substance, the similarity in the independent claims, and the use of the same prior art should tip this factor in favor of denial. *Samsung*, IPR2021-00739, Paper 8, 1-6. The Board determined,

however, that Factor 4 weighs in favor of institution, based on purported lack of overlap between certain claims challenged in Samsung's Petition and the litigation. *Samsung*, IPR2021-00739, Paper 9 at 58-60. But in the litigation, a larger subset of the '601 patent claims was at issue up until April 2023, including throughout discovery. *See* Ex.2002 (stipulation narrowing claims for trial). Although the Court may only rule on two claims, the overlap in *issues* is still significant and this factor should weigh in favor of discretionary denial.

Factor 5: whether petitioner and defendant in parallel proceeding are the same party

The parties agree that Biocon is a defendant in the parallel district court litigation, Paper 3 at 49, and therefore this factor weighs in favor of discretionary denial.

***Fintiv* Factor 6: other circumstances**

This factor contemplates any other circumstances that may be relevant to denial. "For example, factors unrelated to parallel proceedings that bear on discretion to deny institution include the filing of serial petitions [and] parallel petitions challenging the same patent" *Fintiv*, IPR2020-00019, Paper 11, at 16. As described above, this represents Biocon/Mylan's second petition challenging the '601 patent, and Biocon offers no explanation for why it waited to file until now. Moreover, the Samsung IPR will proceed regardless of whether Biocon is joined.

Thus, the potential impact of joinder would be if Samsung settles and Biocon steps into the role of primary petitioner. Such a result would be unfair to Patent Owner, who has already defended against two validity challenges mounted by Mylan/Biocon in prior proceedings. Biocon should not be allowed to continue to hedge against adverse results through a petition that would be time-barred, absent joinder. For this reason, and for those set forth above, discretionary denial under *Fintiv* is warranted.

IV. CONCLUSION

Patent Owner respectfully requests that the Board deny Petitioner's Motion for Joinder.

Dated: December 20, 2023

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR JOINDER and supporting materials were served as of the below date via email (by agreement) upon the following counsel of record for Petitioner:

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