

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS, INC. AND BIOCON BIOLOGICS LIMITED,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: PGR2026-00039
U.S. Patent No. 12,168,036

PATENT OWNER'S OPPOSITION TO
PETITIONERS' MOTION FOR JOINDER

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I. Introduction

Patent Owner Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”) files the present opposition under 37 C.F.R. §§ 42.23-42.25 and respectfully requests that the Board deny the Motion for Joinder (Paper 3, “Motion” or “Mot.”) filed by Biocon Biologics, Inc. and Biocon Biologics Limited (“Biocon” or “Petitioners”).

First, Biocon’s Petition requesting post-grant review (“PGR”) of Regeneron’s U.S. Patent 12,168,036 (the “’036 patent”) is untimely, and the Board can neither institute PGR nor join the present proceeding to the PGR proceeding brought by Alvotech USA Inc. and Alvotech hf. (“Alvotech”). *See* PGR2025-00085. Remarkably, Biocon’s Motion never once cites the statute governing the filing deadline for a PGR petition, 35 U.S.C. § 321(c). The plain text of that statute prohibits the filing of a PGR petition “later than the date that is 9 months after the date of the grant of the patent.” Biocon undisputedly filed its Petition more than nine months after the ’036 patent issued; thus, by statute, its Petition is time-barred. Biocon’s Motion references the joinder regulation for PGR proceedings, 37 C.F.R. § 42.222(b), but that rule does not override the governing statute. Rather, it merely sets forth the deadline by which a “request for joinder must be filed.”

Biocon’s misunderstanding of the law is confirmed by comparison to the corresponding *inter partes* review (“IPR”) statute and regulation. The IPR statute

expressly provides that the one-year IPR bar “shall not apply to a request for joinder,” 35 U.S.C. § 315(b), and the corresponding regulation likewise provides that the one-year bar “shall not apply when the petition is accompanied by a request for joinder,” 37 C.F.R. § 42.122(b). By contrast, the statute and regulation governing the nine-month PGR bar contain no such limitation. *See* 35 U.S.C. § 321(c); 37 C.F.R. § 42.222(b). Biocon’s Petition thus is untimely under the governing statute and regulation.

Second, any interpretation of the PGR joinder regulation that would permit joinder of an untimely PGR petition lacks support in the regulation’s plain text. As explained, the PGR statute mandates a nine-month bar for filing a PGR petition, and unlike the corresponding IPR statute, it creates no exception to that time period including for joinder of untimely filed petitions. *See* 35 U.S.C. § 321(c). Biocon’s reading of 37 C.F.R. § 42.222(b) to create such an exception for untimely PGRs would run afoul of the clear statutory text, rendering that regulation invalid.

Finally, if the Board nonetheless were to join the Biocon proceeding to the Alvotech one, it should require Biocon to abide by additional limitations on its participation to ensure that it plays a true understudy role. Specifically, Biocon should not be permitted separately to depose Regeneron’s witnesses and should be required to make its own declarants available for deposition. In the event the Board does not require Biocon to make its declarants available for deposition, Biocon

should be bound by the testimony of Alvotech’s declarants.

II. Legal Standards

“A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent. . . .” 35 U.S.C. § 321(c). The Director has discretion to grant joinder—that is, to consolidate multiple PGR proceedings—when multiple PGR petitions have been “*properly* filed” against a particular patent. *Id.* § 325(c) (emphasis added); *see id.* (“If more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.”). By regulation, however, “[a]ny request for joinder must be filed . . . no later than one month after the institution date of any post-grant review for which joinder is requested.” 37 C.F.R. § 42.222(b).

Even in the context of nearly identical copycat petitions, moreover, joinder of a post-grant proceeding is not a “matter of right.” *Unified Patents, Inc. v. PersonalWeb Techs. LLC*, IPR2014-00702, Paper 12, at 4 (P.T.A.B. July 24, 2014). A petitioner requesting joinder bears the burden of establishing entitlement to joinder. *See* 37 C.F.R. § 42.20(c). The Board “determine[s] whether to grant joinder on a case-by-case basis, taking into account the particular facts of each case.” *Harmonix Music Sys., Inc. v. Princeton Digital Image Corp.*, IPR2015-00271, Paper

15, at 3 (P.T.A.B. June 2, 2015). The Board specifically considers any prejudice to the patent owner, *id.* at 7, and any briefing and discovery inefficiencies, complications, or delays that could arise from joinder, *Chegg Inc. v. Netsoc, LLC*, IPR2019-01165, Paper 19, at 6 (P.T.A.B. Jan. 13, 2020).

III. Argument

A. The Petition Is Untimely, and the Present Proceeding May Not Be Joined to the Alvotech Proceeding

The Board should deny the Motion, because Biocon’s Petition is untimely. The ’036 patent issued on December 17, 2024. Alvotech filed a petition requesting PGR of that patent on September 17, 2025, exactly nine months after patent issuance. *See* PGR2025-00085, Paper 2. Biocon, however, did not file its Petition until April 2, 2026, *see* PGR2026-00039, Paper 1, almost sixteen months after the ’036 patent issued, and roughly seven months after the deadline for filing a PGR petition had elapsed. *See* 35 U.S.C. § 321(c). Because a PGR petition “may only be filed not later than the date that is 9 months after the date of the grant of the patent,” and Biocon did not file the Petition within that timeframe, its Petition is untimely, not properly filed, and may not be instituted or joined. *Id.*; *see also Apple Inc. v. RFCyber Corp.*, PGR2022-00003, Paper 10, at 8 (P.T.A.B. Mar. 24, 2022) (“Institution of post-grant review is barred when a petition is filed more than 9 months after the challenged patent is granted.”).

Biocon, however, seeks to avoid the straightforward application of § 321(c)

to its untimely Petition, never citing that statutory provision or attempting to reconcile its nine-month statutory bar with the timing of its Petition. Biocon instead notes that “Alvotech’s PGR was instituted on March 3, 2026,” and that it moved for joinder on April 2, 2026, “within one month of . . . the date on which the Alvotech PGR was instituted.” Mot. 2. According to Biocon, even though “the ’036 patent issued more than 9-months ago and would not ordinarily be available for a PGR[,] . . . because Alvotech submitted a PGR on the ’036 patent within 9 months of the patent issuing, . . . the PGR was instituted on March 3, 2026,” and Biocon filed its Motion within a month of institution, it may “be permitted to join the instituted PGR as a party under 37 C.F.R. §42.222(b).” Mot. 7. In other words, Biocon claims that the nine-month time bar does not apply to petitions that are themselves untimely but that nevertheless are filed within one month of institution of a timely petition and are accompanied by a request for joinder. *See id.*

There is no support for Biocon’s position. Section 321(c) sets the deadline by which a PGR petition must be filed (*i.e.*, within nine months of patent issuance), and § 42.222(b) sets the deadline by which a joinder request must be filed for PGR petitions (*i.e.*, within one month of institution of another proceeding). There is no textual basis for the notion that § 42.222(b)’s joinder provision somehow operates to override § 321(c)’s time bar. To the contrary, any such interpretation of § 42.222(b) would render it invalid. *See infra* § III.C. The most straightforward

reading of these provisions—and the only one that is consistent with their text and the governing statutes—is that § 42.222(b) authorizes joinder of a PGR proceeding for which the petition was properly filed within nine months of patent issuance to an already-instituted PGR proceeding, so long as the joinder motion is filed within one month of institution of the earlier-filed proceeding. *See, e.g., Early Warning Servs., LLC v. Wepay Glob. Payments LLC*, PGR2022-00031, Paper 28 (P.T.A.B. Dec. 20, 2022) (granting joinder where both PGR petitions were filed within 9-month window and joinder was requested within 1 month of institution).

Comparing the analogous IPR and PGR provisions confirms that a request for joinder does not exempt a PGR petition from the requirement that it be filed within nine months of patent issuance. The IPR statute contains three pertinent provisions:

(1) it creates a time bar:

“An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner . . . is served with a complaint alleging infringement of the patent.”;

(2) it authorizes 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”; and

(3) it creates a joinder exception to the one-year time bar:

“The time limitation set forth in the preceding sentence shall not

apply to a request for joinder under subsection (c).”

35 U.S.C. § 315(b)-(c). The statute thus provides that an untimely IPR petition accompanied by a joinder request is nevertheless “properly file[d]” and may be joined to another, instituted IPR proceeding. *Id.*

In contrast, the relevant PGR statutory provisions expressly accomplish items (1) and (2) but *do not* contain provision (3). The PGR statutory provisions:

(1) set forth a time bar in § 321(c):

“A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent” ; and

(2) provide for joinder in § 325(c):

“If more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.”

But *nowhere* do they contain a provision analogous to (3) above. Biocon identifies no provision exempting PGR petitions accompanied by joinder motions from the nine-month time bar. There is none to be found. Absent any PGR counterpart to the explicit time-bar exception for IPR joinder requests, it is clear that a PGR petition is “properly filed” and thus eligible for joinder only if it is timely. Biocon’s untimely Petition is ineligible for joinder to the Alvotech proceeding.

B. Biocon’s Interpretation Would Thwart Congress’ Decision To Segregate PGRs and IPRs

Biocon advances several policy arguments in support of its position. They are unavailing. Resort to policy simply cannot overcome the clear text of the statutes and regulations at issue here. Even so, Biocon’s policy arguments fall especially flat because they flaunt *Congress’* intended policy of ensuring that patents are never simultaneously eligible for both PGR and IPR.

Biocon argues that permitting joinder of untimely filed petitions “will increase efficiency of proceedings before the patent office” by “allow[ing] a motion for joinder to be accompanied by a near identical petition covering the same grounds for challenging the patent” and “increas[ing] the odds that a PGR will remain active until the Board issues a final written decision.” Mot. 8. “Conversely, if 37 C.F.R. § 42.222(b) were interpreted to not allow a motion for joinder to be filed simultaneously with a petition, potential petitioners would be required to pursue other less-efficient avenues” such as “[IPR] . . . or *ex parte* reexamination” *Id.*

These arguments fail for at least two reasons. First, “policy arguments cannot supersede the clear statutory text.” *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 192 (2016). And the text at issue here is clear: The PGR statute never sets forth any exception to its time bar for joinder requests, while the IPR statute does. “Had Congress wanted to include a [joinder exception to the PGR time bar], it certainly knew how to do so.” *Polselli v. IRS*, 598 U.S. 432, 439 (2023). The

assumption is that “Congress ‘acts intentionally and purposely’ when it ‘includes particular language in one section of a statute but omits it in another section of the same Act,’” so the fact that the IPR time-bar provision “expressly” sets forth an exception for joinder requests “strongly suggests that Congress deliberately omitted a similar [exception] with respect to [PGR joinder requests].” *Id.* (citation omitted).

Second, Biocon’s policy arguments fly in the face of Congress’ policy choices. To wit, Congress plainly decided as a matter of policy that PGR should be available only for recently issued patents and that other mechanisms like IPR should be available only for earlier-issued patents. *See* 35 U.S.C. § 311(c) (“A petition for inter partes review shall be filed after the later of either . . . the date that is 9 months after the grant of a patent; or . . . the date of the termination of [an instituted] post-grant review.”); *id.* § 321(c) (“A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent . . .”). Congress’ decision not to permit joinder of untimely PGR petitions is entirely consistent with its intention—as expressed not only by §§ 311(c) and 321(c) but also the legislative history of the America Invents Act (“AIA”)¹—to limit the availability

¹ *See also, e.g.*, 157 Cong. Rec. H4480-01, H4495 (“Post-grant review . . . allows third parties, *for a limited window of 9 months after a patent is issued*, to submit evidence that the patent should not have been granted in the first place. . . . If the evidence shows that the patent is valid, then the patent is made stronger and more

of PGR to *recently issued patents*, and to ensure that patents are not simultaneously eligible for PGR and IPR. “To create a [PGR time-bar exception for joinder requests] here would impermissibly second-guess Congress’ decision not to [permit joinder of untimely filed PGR petitions].” *Nestle USA, Inc. v. Doe*, 593 U.S. 628, 639 (2021). Accordingly, Biocon’s policy arguments are no basis for disregarding the clear statutory text and permitting the use of joinder requests as an end run around Congress’ decision, as a matter of policy, that PGRs must be filed within nine months of patent issuance and that IPRs can only be filed thereafter.

C. Any Interpretation of 37 C.F.R. § 42.222 Permitting Joinder in These Circumstances Would Render the Regulation Invalid

Biocon calls on the Board to interpret “37 C.F.R. § 42.222(b) [as] . . . allow[ing] a motion for joinder to be filed simultaneously with a petition” that is

certain by surviving a post-grant review.” (emphasis added)); 157 Cong. Rec. S5370-01, S5375 (“Section 6 of the [AIA] amends the Patent Act to create a post-grant review procedure *available for a limited time* . . . after the date a patent is granted. Section 6 also amends existing inter partes reexamination procedures to make them available *after the period of time for post-grant review has passed*” (emphases added)); H.R. REP. 112-98, 47-48, 2011 U.S.C.C.A.N. 67, 78 (“The intent of the post-grant review process”—which provides a “new, *early-stage*[,] . . . *time-limited*, . . . procedure”—“is to enable *early challenges to patents*, while still protecting the rights of inventors and patent owners against new patent challenges unbounded in time and scope.” (emphases added)).

filed more than nine months after a patent has issued. Mot. 8. The Board should decline Biocon's invitation. Such an interpretation would render that regulation invalid as contrary to the plain text of 35 U.S.C. § 321(c).

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Accordingly, an "agency does not have authority to pass regulations that are inconsistent with the meaning of a statute." *New Jersey v. Bessent*, 149 F.4th 127, 144 (2d Cir. 2025) (citation omitted). Any such regulations may be "set aside" as "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

In enacting the AIA, Congress created a new mechanism for challenging patents (PGR) but explicitly restricted its availability to the first nine months after patent issuance. *See* 35 U.S.C. § 321(c). PGR may not be instituted on petitions filed after those nine months have elapsed. *See id.*; *Apple*, PGR2022-00003, Paper 10, at 8. At the same time, Congress created the IPR mechanism, which is available only after the PGR window has closed. *See* 35 U.S.C. § 311(c). By design, a patent is at no point simultaneously eligible for both PGR and IPR.

Furthermore, Congress knew how to create a time-bar exception for joinder requests, and it did so for IPRs, but not for PGRs. *See id.* §§ 315(b)-(c), 321(c), 325(c). Therefore, the clear implication of the absence of any explicit time-bar

exception for joinder requests for PGR petitions is that there is no such exception, such that PGR petitions must be filed within nine months of patent issuance or not at all. *See Polsell*, 598 U.S. at 439. The absence of any exception to the PGR time bar for joinder requests, moreover, preserves the congressionally mandated sequencing of a patent's eligibility for PGR first and IPR second, in that it forecloses institution or joinder of petitions that are filed outside the window for PGR and within the window for IPR. *See* 35 U.S.C. §§ 315(b)-(c), 321(c), 325(c).

Accordingly, the text is clear: There is no exception to the nine-month PGR bar for untimely petitions filed within one month of institution of a timely petition. The Board has not previously had reason to address this issue. In *Apple*, for example, the Board determined only that the relevant joinder motion was untimely. *See Apple*, PGR2022-00003, Paper 10, at 8 (“In view of the above, we do not waive the one-month period to file a motion for joinder under 37 C.F.R. § 42.222(b) and therefore deny Petitioner’s Motion for Joinder as untimely.”). The Board should decline Biocon’s request to improperly “engraft onto the statute an exception Congress chose not to create.” *Honig v. Doe*, 484 U.S. 305, 325 (1988). If the Board holds otherwise, Regeneron intends to challenge 37 C.F.R. § 42.222(b) under the Administrative Procedure Act as inconsistent with the relevant statutory provisions.

D. If the Board Grants Biocon’s Motion, It Should Impose Additional Limitations on Biocon’s Participation in the Alvotech Proceeding

If the Board were to grant Biocon’s motion, however, it should require Biocon

to abide by additional limitations on its participation in the PGR to ensure that it is truly serving as an “understudy.” Biocon represents that it is willing to “take a limited ‘understudy’ role in the same manner previously found to support joinder so long as Alvotech remains an active party,” Mot. 1, and has agreed to several limitations on its participation, *see* Mot. 3-4. But those conditions permit Biocon to maintain a more active role than is typically allowed of silent understudies.

For example, Biocon has not offered to limit its participation in the Alvotech PGR in each of the ways that the Board has found necessary in other proceedings. To ensure that joinder does not introduce inefficiencies, complicate briefing and discovery, and prejudice Regeneron, the following additional conditions—to the extent not already subsumed by those conditions to which Biocon has agreed, *see* Mot. 3-4—should be imposed so long as Alvotech remains an active party in PGR2025-00085: (1) Alvotech will be subject to the page limits for a single party when filing papers on behalf of itself and Biocon. *Aurobindo Pharma U.S.A. Inc. v. AstraZeneca AB*, IPR2016-01117, Paper 12, at 11 (P.T.A.B. Oct. 21, 2016). (2) Biocon must obtain prior Board authorization to file any paper or to take any action on its own in the Alvotech PGR, with the exception of *pro hac vice* motions, updated mandatory notices, and similar administrative filings that do not constitute argument or evidence relating to the merits. *Ericsson Inc., v. Uniloc 2017 LLC*, IPR2020-00376, Paper 16, at 10 (P.T.A.B. May 22, 2020). (3) Biocon will not serve

discovery requests in connection with the Alvotech PGR. *Aurobindo*, IPR2016-01117, Paper 12, at 6. (4) Counsel for Biocon will not participate in a speaking role in any of the following in the Alvotech PGR: (A) telephonic conference before the Board, (B) oral argument, and (C) depositions, including by participating in the questioning of any witness or the defense of any witness, unless the witness being deposed is one of Biocon's declarants. *Teva Pharm. USA, Inc. v. Eli Lilly & Co.*, IPR2016-01340, Paper 8, at 3 (P.T.A.B. Aug. 22, 2016), Paper 9, at 11 (P.T.A.B. Oct. 6, 2016); *Dr. Reddy's Labs., Inc. v. Horizon Pharma USA, Inc.*, IPR2018-01341, Paper 21, at 7 (P.T.A.B. Apr. 19, 2019); *LG Elecs., Inc. v. Fundamental Innovation Sys. Int'l LLC*, IPR2018-00461, Paper 10, at 5-6 (P.T.A.B. May 29, 2018). (5) Biocon will continue to refrain from "present[ing] any new issues, arguments, or evidence," or any grounds other than those presented in Alvotech's petition. Mot. 9. (6) Biocon must agree to be bound by any agreement between Regeneron and Alvotech concerning discovery or depositions.

In addition, Biocon has reserved the right "to rely on its own experts" "if Alvotech settles prior to a final written decision." Mot. 8-9. This reservation is not appropriate to the joinder posture. Biocon should be required to make its declarants available for deposition in the event of joinder, so that if Alvotech's proceeding terminates then the PGR may proceed apace. Alternatively, if its declarants are not deposed, Biocon should be bound by the deposition testimony of Alvotech's experts

to the same extent as Alvotech, consistent with the Board’s joinder decisions in analogous scenarios. *See Am. Honda Motor Co. v. Neo Wireless, LLC*, IPR2023-00791, Paper 11, at 13, 17 (P.T.A.B. Oct. 10, 2023) (ordering joinder where petitioner agreed to “not rely on expert testimony beyond that submitted by the Volkswagen IPR Petitioner unless the Volkswagen IPR Petitioner is terminated from the case prior to any necessary depositions”); *Mercedes-Benz USA, LLC v. Neo Wireless, LLC*, IPR2023-00079, Paper 11, at 11, 14 (P.T.A.B. May 5, 2023) (same).

Joinder must not create inefficiencies or complications and should not prejudice Regeneron. These conditions will ensure the efficient and orderly resolution of the proceedings if they are joined—indeed, the Board has previously required similar covenants as a condition of joinder. *See, e.g., Dr. Reddy’s*, IPR2018-01341, Paper 21, at 7. These safeguards are of a kind to which Biocon already has suggested it would agree, Mot. 6, and are necessary to prevent prejudice and to “ensure the just, speedy, and inexpensive resolution of [this] proceeding” in the event of joinder. *Central Security Grp. v. Ubiquitous Connectivity, LP*, IPR2019-01610, Paper 12, at 6 (P.T.A.B. Feb. 26, 2020).

IV. Conclusion

For the foregoing reasons, Regeneron respectfully requests that the Board deny Biocon’s request for joinder of its untimely filed Petition.

Date: April 30, 2026

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CERTIFICATION UNDER 37 C.F.R. § 42.24(a)(1)(v)

The undersigned certifies that Patent Owner's Opposition to Petitioners' Motion for Joinder complies with the 15-page limit provided in 37 C.F.R. § 42.24(a)(1)(v).

Date: April 30, 2026

/David I. Berl/

David I. Berl

Reg. No. 72,751

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE
(37 C.F.R. § 42.6(e))

The undersigned hereby certifies that on April 30, 2026, I caused true and correct copies of the following materials:

- Patent Owner's Opposition to Petitioners' Motion for Joinder

to be served via e-mail on the following:

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