

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

U.S. Patent No. 12,168,036 to Graham
Issue Date: December 12, 2024
Title: Methods for Treating Angiogenic Eye Disorders
with High Doses of VEGF Receptor Fusion Proteins

Post Grant Review No. PGR2026-00039

**PETITIONERS' MOTION FOR JOINDER PURSUANT TO
35 U.S.C. § 325(C) AND 37 C.F.R. §§ 42.22 AND 42.222(B)**

TABLE OF CONTENTS

	<u>Page</u>
I. STATEMENT OF THE PRECISE RELIEF REQUESTED	1
II. STATEMENT OF MATERIAL FACTS.....	2
A. Biocon’s Motion for Joinder.....	2
B. Alvotech’s PGR	2
C. Biocon’s Petition and Proposed Role, Including Relevant Limitations	2
III. LEGAL STANDARDS	4
IV. STATEMENT OF REASONS FOR RELIEF REQUESTED.....	6
A. Biocon addresses below each factor considered by the Board in evaluating a motion for joinder, showing how each weighs in favor of joinder.....	6
B. Joinder Will Not Introduce Any New Grounds of Unpatentability	8
C. Joinder Will Not Impact the Alvotech PGR’s Trial Schedule	9
D. Joinder Will Simplify the Proceedings	10
E. The <i>General Plastic</i> Factors Are Not Relevant Here	11
V. CONCLUSION.....	12

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Alvotech USA, Inc. et al v. Regeneron Pharms. Inc.,</i> PGR2025-00085	<i>passim</i>
<i>Dell, Inc. v. Network-1 Security Solutions, Inc.,</i> IPR2013-00385, Paper 17 (July 29, 2013)	5
<i>General Plastic Indus. Co. v. Canon Kabushiki Kaisha,</i> PGR2016-01357, Paper 19 (PTAB Sept. 6, 2017)	11
<i>Netflix, Inc. v. Broadcom Corp.,</i> PGR2020-01423, Paper 7 (PTAB Mar. 11, 2021)	12
<i>Novartis AG,</i> IPR2015-00268, Paper 17	11
<i>Samsung Elecs. Co., Ltd. v. Raytheon Co.,</i> IPR2016-00962, Paper No. 12 (PTAB Aug. 24, 2016)	5
<i>Samsung Elecs Co., Ltd. v. Wepay Global Payments LLC</i> PGR2022-00045, Paper No. 9	5, 6
<i>Samsung Elecs. Co. v. Arendi S.A.R.L.,</i> IPR2014-01518, Paper 10 (PTAB Mar. 18, 2015)	7
<i>Sony Mobile Commc 'ns v. Ancora Tech.,</i> IPR2021-00663, Paper 17 (PTAB June 10, 2021)	6
<i>Sony Mobile Commc 'ns v. Ancora Tech.,</i> PGR2021-00663, Paper 17 (PTAB June 10, 2021)	11
Statutes	
35 U.S.C. § 112	8
35 U.S.C. § 321(c)	7
35 U.S.C. § 325(c)	1, 4

35 U.S.C. § 326(a)(11).....	9
35 U.S.C. § 326(b)	6
Leahy-Smith America Invents Act	4

Other Authorities

37 C.F.R. § 42.2(b)	6
37 C.F.R. §§ 42.22 and 42.222(b).....	1, 2
37 C.F.R. § 42.200(c).....	9
37 C.F.R. § 42.222(b)	2, 7, 8

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner Biocon Biologics, Inc. and Biocon Biologics Limited (together, “Biocon”) respectfully submits this Motion for Joinder, concurrently with a Petition for post grant review (“PGR”) of U.S. Patent No. 12,168,036 (“the ‘036 patent”) (“Petition”). Biocon requests its Petition for post grant review of the ‘036 patent be instituted and that Biocon be joined as a party pursuant to 35 U.S.C. § 325(c) and 37 C.F.R. §§ 42.22 and 42.222(b) with the post grant review proceeding in *Alvotech USA, Inc. et al v. Regeneron Pharms. Inc.*, PGR2025-00085 (the “Alvotech PGR”). The Alvotech PGR was instituted on March 3, 2026.

Biocon’s Petition is effectively a copy of the Alvotech PGR. It is based on grounds identical to those that formed the basis for the pending Alvotech PGR against the ‘036 patent, including the same prior art combinations supported by substantially the same evidence. *See* Alvotech PGR, Paper 10 (Institution of *Inter Partes* Review) (Mar. 3, 2026). Biocon further stipulates herein that if joinder is granted, it will take a limited “understudy” role in the same manner previously found to support joinder so long as Alvotech remains an active party. Joinder thus creates no additional burden for the Patent Trial and Appeal Board (the “Board”), Alvotech, or Patent Owner. Nor will it impact the schedule of the Alvotech PGR.

Accordingly, consistent with the Board’s consideration of prior joinder motions, Biocon submits that joinder will promote judicial efficiency. It will also

ensure that the currently pending grounds of unpatentability, which the Board found “compelling” in its Institution Decision, will most likely be seen through to the end, with Biocon playing a backstop role.

For these and the foregoing reasons, Biocon respectfully requests joinder be granted.

II. STATEMENT OF MATERIAL FACTS

A. Biocon’s Motion for Joinder

37 C.F.R. § 42.222(b) requires that “[a]ny request for joinder [] be filed, as a motion under § 42.22, no later than one month after the institution date of any post-grant review for which joinder is requested.” Alvotech’s PGR was instituted on March 3, 2026. Biocon timely moves for joinder under 37 C.F.R. §§ 42.22 and 42.222(b) because Biocon submits this motion within one month of March 3, 2026, the date on which the Alvotech PGR was instituted.

B. Alvotech’s PGR

Alvotech filed its PGR Petition on July 1, 2022 challenging claims 1-9, 34-39, 41-43, and 45 the ‘036 patent. The Alvotech PGR was instituted on January 11, 2023.

C. Biocon’s Petition and Proposed Role, Including Relevant Limitations

In its Petition, Biocon asserts the same grounds of unpatentability against the same claims based on the same prior art as the Alvotech PGR. *See* Alvotech PGR,

Papers 2 (Alvotech Petition), 10 (institution decision). Consistent with prior practice, Biocon has effectively copied Alvotech's PGR Petition, including the same analysis and exhibits. The only differences between Biocon's Petition and Alvotech's relate to the petitioner-specific information unrelated to the grounds presented in the petition, such as the introduction and mandatory notices. This is Biocon's first petition against the '036 patent.

Additionally, Biocon is submitting expert declarations that incorporate and adopt the same underlying expert opinions as Alvotech. More specifically, to preserve its rights in the event that the Alvotech PGR is settled or joinder is not granted, Biocon submits two short declarations of its own experts, Drs. Barrett Falconer and Jay Stewart, setting out their qualifications, noting their agreement with Alvotech's experts' analyses, and adopting them as their own. *See* Ex. 1067, Expert Declaration of Dr. Jay Stewart, in Support of Petition for Post Grant Review of U.S. Patent No. 12,168,036 ("Stewart Declaration"); Ex. 1068, Expert Declaration of Dr. Barrett Rabinow, in Support of Petition for Post Grant Review of U.S. Patent No. 12,168,036 ("Rabinow Declaration"). Neither Biocon, Dr. Stewart, nor Dr. Rabinow raise any new argument, analysis, or evidence.

Finally, Biocon will take an "understudy" role. For example, so long as Alvotech remains active in the Alvotech PGR, Biocon agrees to not file additional papers or additional pages to Alvotech's papers without a showing of good cause;

not present any new, additional, or supplemental arguments; and not present any arguments at oral hearings unless agreed to by Alvotech or requested by the Board. As part of that agreement, Biocon further agrees to consolidated filings for all substantive papers in the respective proceedings, unless a motion is made directed to Biocon alone. Additionally, Biocon agrees that consolidated discovery is appropriate given that it will take a subordinate role in the proceedings and have Alvotech take the lead in all discovery matters. Biocon agrees that Alvotech will manage any depositions, including questioning, and Alvotech will designate an attorney to conduct the cross-examination of any given witness produced by Patent Owner, within the ordinary time limits normally allotted by the rules for one party. Biocon will not receive any separate cross-examination or redirect time from that of Alvotech, unless Alvotech terminates its involvement in the joined deposition or oral hearing.

III. LEGAL STANDARDS

The Leahy-Smith America Invents Act permits joinder of PGR proceedings. The statutory provision governing joinder of PGR proceedings is 35 U.S.C. § 325(c), which reads as follows:

(c) JOINDER.— 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.

Motions for joinder should “(1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified.” *Dell, Inc. v. Network-1 Security Solutions, Inc.*, IPR2013-00385, Paper 17 (July 29, 2013), at 4.¹

The Board “routinely grants motions for joinder where the party seeking joinder introduces identical arguments and the same grounds raised in the existing proceeding.” *Samsung Elecs. Co., Ltd. v. Raytheon Co.*, IPR2016-00962, Paper No. 12 at 9 (PTAB Aug. 24, 2016) (quotations and citations omitted) *See Samsung Elecs Co., Ltd. v. Wepay Global Payments LLC* PGR2022-00045, Paper No. 9 (Granting “copycat” petitioner motion for joinder of a PGR because petition made no arguments in its petition that differ from those previously addressed).

¹ While this framework for assessing joinder was described in a motion to join IPR petitions, the factors are equally relevant to the PGR framework and Biocon could not find any case applying a different framework in the context of PGR petitions.

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Biocon addresses below each factor considered by the Board in evaluating a motion for joinder, showing how each weighs in favor of joinder.

1. Joinder is appropriate given Biocon's commitment to remain a silent understudy and not raise any new issues

Joinder is appropriate in this case because it is the most expedient way to secure the just, speedy, and inexpensive resolution of the two related proceedings. *See* 35 U.S.C. § 326(b); 37 C.F.R. § 42.2(b). Joinder will allow the Board to resolve the unpatentability of the challenged claims without any significant impact on the Alvotech PGR.

As noted above, Biocon's Petition is *identical* with respect to the grounds instituted in the Alvotech PGR. *See Sony Mobile Commc'ns v. Ancora Tech.*, IPR2021-00663, Paper 17 at 29-33 (PTAB June 10, 2021) (granting motion for joinder for challenge based on same grounds of unpatentability as first petition supported by essentially the same expert declaration) *See Samsung Elecs. Co., Ltd. v. Wepay Global Payments LLC* PGR2022-00045, Paper No. 9 (Granting "copycat" petitioner motion for joinder because petition made no arguments in its petition that differ from those previously addressed)..

Moreover, as set out above, Biocon agrees to consolidated filings and discovery and procedural concessions previously found supportive of joinder, so that in this matter Biocon will be bound by the schedule set forth in the Alvotech PGR

and its participation will only serve to streamline proceedings without any prejudice to any party. *See e.g., Samsung Elecs. Co. v. Arendi S.A.R.L.*, IPR2014-01518, Paper 10 at 6 (PTAB Mar. 18, 2015) (allowing joinder where movant takes a “limited understudy role” without a separate opportunity to actively participate).

Because this proceeding and the Alvotech PGR are effectively identical and Biocon agrees it will take an understudy role, granting joinder will thus not prejudice any party or have any significant impact on the Alvotech PGR.

2. Joinder is permissible under 37 C.F.R. § 42.222(b)

Biocon acknowledges that the '036 patent issued more than 9-months ago and would not ordinarily be available for a PGR. Under the present circumstances, however, Biocon believes that the '036 patent remains available for PGR under 37 C.F.R. §42.222(b). More specifically, because Alvotech submitted a PGR on the '036 patent within 9 months of the patent issuing, and the PGR was instituted on March 3, 2026, Biocon respectfully requests that it be permitted to join the instituted PGR as a party under 37 C.F.R. §42.222(b), which permits requests for joinder “no later than one month after the institution date of any post-grant review for which joinder is requested,” here April 3, 2026. Biocon believes that the issue of whether 37 C.F.R. § 42.222(b) permits a party to join a PGR proceeding that is not within the 9-month window for filing a PGR is one of first impression.

Allowing joinder to a PGR, even if the patent issued more than 9 months before the request for joinder is filed, will increase efficiency of proceedings before the patent office. Specifically, this approach allows a motion for joinder to be accompanied by a near identical petition covering the same grounds for challenging the patent. It also increases the odds that a PGR will remain active until the Board issues a final written decision.

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 (e.g., an *inter partes* review, which limits the types of grounds that can be brought (for example, no challenges under 35 U.S.C. § 112) or *ex parte* reexamination, which would proceed on a separate track with different filing requirements).

B. Joinder Will Not Introduce Any New Grounds of Unpatentability

Biocon's Petition contains the same grounds of unpatentability instituted in the Alvotech PGR. Indeed, Biocon's Petition is the same in all substantive aspects as the instituted Alvotech PGR, challenging the same claims of the '036 patent based on the same instituted grounds of unpatentability. Biocon's Petition contains the same analysis and exhibits, and effectively relies on the same expert opinions.

As noted above, if joinder is granted, Biocon is prepared to rely solely on the testimony of Alvotech's experts. Exs. 1003 and 1004. Only if Alvotech settles prior

to a final written decision would Biocon elect to rely on its own experts, Drs. Jay Stewart and Barrett Rabinow, who have reviewed and adopted the opinions set forth in the declarations of Alvotech's experts Drs. Falconer and D'Amico. The Stewart Declaration and Rabinow Declaration are both substantively identical to those putting forth the opinions of Drs. Falconer and D'Amico and do not alter or otherwise seek to supplement the opinions offered by Drs. Falconer and D'Amico.

C. Joinder Will Not Impact the Alvotech PGR's Trial Schedule

35 U.S.C. § 326(a)(11) and 37 C.F.R. § 42.200(c) provide that PGR proceedings should be completed and the Board's final decision issued within one year of institution of the review, with flexibility to extend the one-year period by up to six months for good cause, or in the case of joinder. *See* 35 U.S.C. § 326(a)(11); 37 C.F.R. § 42.200(c).

Joinder will not impact the Board's ability to complete its review in a timely manner and would have no impact on the Alvotech PGR schedule. Biocon's Petition does not present any new issues, arguments, or evidence for the Board or Patent Owner to address, and Biocon has further committed to consolidated filings with Alvotech.

Moreover, the difference between the filing date of Biocon's Petition and the Alvotech PGR is of no consequence should the proceedings be joined. The trial schedule for the Alvotech PGR would not need to be delayed to effect joinder based

on Patent Owners' preliminary response and Biocon's Petition. Indeed, because Biocon asserts identical grounds of unpatentability as those instituted in the Alvotech PGR, Patent Owner does not need to submit a preliminary response at all. Further, the Board does not need to extend any other deadlines following joinder for the same reason.

Accordingly, joinder does not impact any aspect of the trial schedule for the Alvotech PGR. Rather, a joint proceeding would allow the Board and parties to focus on the merits in one consolidated proceeding without unnecessary duplication of effort.

D. Joinder Will Simplify the Proceedings

Because Biocon relies on grounds of unpatentability that are identical to Alvotech's, the case is amenable to consolidated filings and discovery, which will simplify the briefing and discovery process.

In short, as long as the Alvotech PGR remains pending and Alvotech remains active following joinder, no additional briefing or discovery would be needed. Biocon will adopt an "understudy" or "second chair" role and would only assume

the primary role if Alvotech ceases to participate in the PGR. *See, e.g., Novartis AG*, IPR2015-00268, Paper 17, at 5.²

E. The *General Plastic* Factors Are Not Relevant Here

This is Biocon’s first petition against the claims of the ‘036 patent. Biocon has not coordinated with Alvotech or any other party regarding its Petition, and has never discussed its Petition with any other party other than to seek Alvotech’s position on whether it opposes this Motion for Joinder. Accordingly, the factors in *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, PGR2016-01357, Paper 19 at 17–18 (PTAB Sept. 6, 2017) (Paper 19), which relate to serial filings by the same party or by parties coordinating their filings, are not relevant here and do not weigh in favor of denying institution. *See Sony Mobile Commc’ns v. Ancora Tech.*, PGR2021-00663, Paper 17 at 11-15 (PTAB June 10, 2021) (finding factors weigh “strongly” in favor of institution of petition where joinder was sought and the joining party had not previously filed a challenge to the claims of the patent); *Netflix, Inc. v.*

² In the event that Alvotech ceases to participate and Biocon is required to rely on Drs. Stewart and Rabinow, there would be no impact on the Board’s ability to complete its review in a timely manner. Moreover, there would only be a modest impact on Patent Owner, given that Biocon’s contingent expert’s opinions are virtually identical to those already introduced and relied upon by Alvotech’s experts.

Broadcom Corp., PGR2020-01423, Paper 7 at 5-6 (PTAB Mar. 11, 2021) (finding prior petition filed by an unrelated petitioner irrelevant to institution).

V. CONCLUSION

For the foregoing reasons, Biocon respectfully requests that its Petition be instituted and the proceeding be joined with *Alvotech USA, Inc. et al v. Regeneron Pharms. Inc.*, PGR2025-00085. Although no additional fee is believed to be required for this Motion, the Commissioner is hereby authorized to charge any additional fees which may be required for this Motion to Deposit Acct. No. 501814.

Respectfully submitted,

Dated: April 02, 2026

/Scott Border/
Scott Border (lead counsel),
Reg. No. 77,744
Jovial Wong (backup counsel)
Reg. No. 60,115
Charles Klein
(*pro hac vice* to be submitted)
Mason Davenport
(*pro hac vice* to be submitted)
Winston & Strawn LLC
1901 L. Street, N.W.
Washington, D.C. 20036

Alison King
Reg. No. 76,897
Winston & Strawn LLC
300 N La Salle Dr Suite 4400
Chicago, IL 60654

*Counsel for Petitioner Biocon Biologics,
Inc.*

CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. §§ 42.6(e) and 42.205, I hereby certify that true and correct copies of the foregoing PETITIONER’S MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 325(c) AND 37 C.F.R. §§ 42.22 AND 42.222(b) were served on April 2, 2026 via FedEx Priority Overnight on Patent Owner at the correspondence address of record for U.S. Patent No. 12,168,036 as evidenced in Patent Center:

Schwabe W&W, PC / Regeneron Pharmaceuticals, Inc.
PacWest Center
1211 SW Fifth Avenue, Suite 1900
Portland, OR 97204
United States

Respectfully submitted,

Dated: April 02, 2026

/Scott Border/
Scott Border (lead counsel),
Reg. No. 77,744
Jovial Wong (backup counsel)
Reg. No. 60,115
Charles Klein
(pro hac vice to be submitted)
Mason Davenport
(pro hac vice to be submitted)
Winston & Strawn LLC
1901 L. Street, N.W.
Washington, D.C. 20036

Alison King
Reg. No. 76,897
Winston & Strawn LLC
300 N La Salle Dr Suite 4400

Chicago, IL 60654

*Counsel for Petitioner Biocon Biologics,
Inc.*