

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION**

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1073	<i>Biocon Launches First US Manufacturing Facility in Cranbury, NJ</i> , (Sept. 15, 2025) https://finance.yahoo.com/news/biocon-launches-first-us-manufacturing-084341359.html (last accessed July 7, 2026)
1074	<i>Syngene Expands Global Footprint with \$36.5M Baltimore Bet</i> , (Mar. 17, 2025) https://www.bioprocessintl.com/facilities-capacity/syngene-expands-global-footprint-with-36-5m-baltimore-bet (last accessed July 7, 2026)
1075	<i>Biocon Biologics and Civica Expand Partnership and Launch Private-Label Insulin</i> , https://bioconbiologicsus.com/news/press-releases/biocon-biologics-and-civica-expand-partnership-and-launch-private-label-insulin/ (last accessed July 7, 2026)
1076	<i>Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices</i> (Apr. 2025), https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/ (last accessed July 7, 2026)
1077	<i>United States-India Joint Leaders' Statement</i> (February 13, 2025) https://www.whitehouse.gov/briefings-statements/2025/02/united-states-india-joint-leaders-statement/ (last accessed July 7, 2026)
1078	<i>Memorandum from John A. Squires, Under Sec'y of Com. for Intell. Prop. & Dir. of the U.S. Patent & Trademark Off., to All PTAB Users, Additional Discretionary</i>

	<i>Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings</i> , (Mar. 11, 2026), https://www.uspto.gov/sites/default/files/documents/Additional_Discretionary_Institution_Considerations_US_Manufacturing_and_Small_Business_Use_of_AIA_Proceedings.pdf (“Memorandum of J. Squires”)
1079	Exec. Order No. 14273, “Lowering Drug Prices by Once Again Putting Americans First” 90 Fed. Reg. 16,441 (Apr. 15, 2025).

I. INTRODUCTION

Patent Owner’s request for discretionary denial is rooted in the fact that Regeneron is a U.S. company and Petitioners Biocon Biologics, Inc. and Biocon Biologics Limited (“Biocon”) are “foreign-owned companies seeking to invalidate the ’036 patent to market a biosimilar competitor” to Patent Owner’s drug, Eylea HD®. This argument falls short, as it ignores the significant investment that Biocon has made in U.S. pharmaceuticals and manufacturing.

Biocon is committed to investing in American manufacturing, creating American jobs, and delivering affordable medicines to American patients.¹ While it is true that it began abroad, Biocon has increasingly expanded its operations in the U.S. and plans to continue doing so into the future.² In September 2024, Biocon opened its North American headquarters in New Jersey’s biopharma corridor.³ Biocon subsequently launched its first U.S. manufacturing facility in Cranbury, New Jersey in September 2025.⁴ And Biocon’s affiliate, Syngene International, invested

¹ EX1071, Decl. of D. Taneja at ¶ 17.

² *Id.* at ¶¶ 9, 11, 14.

³ EX1072, *Biocon Biologics Opens North America Headquarters in New Jersey’s Biopharma Corridor*, (Sept. 13, 2024), <https://www.bioconbiologics.com/our-stories/biocon-biologics-opens-north-america-headquarters-in-new-jerseys-biopharma-corridor/> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 3.

⁴ EX1073, *Biocon Launches First US Manufacturing Facility in Cranbury, NJ*, (Sept. 15, 2025) <https://finance.yahoo.com/news/biocon-launches-first-us-manufacturing-084341359.html> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 9.

\$36.5 million in a new facility in Baltimore, Maryland also in 2025.⁵ Through its partnership with Civica, Biocon has expanded access to affordable insulin products for American patients—directly advancing the Trump Administration’s priority of lowering prescription drug costs.⁶ Biocon has thus heeded the Administration’s call to expand Indian manufacturing capacity in the U.S. for critical medicines,⁷ showing itself to be a company that invests in domestic production and brings lower-cost alternatives to market for the benefit of American consumers.

Beyond Biocon’s significant investments in U.S. manufacturing and pharmaceuticals, the Director should reject Patent Owner’s request because this proceeding involves a joinder petition by which Biocon seeks to join a post-grant review that has already been instituted. Specifically, Patent Owner already sought discretionary denial of proceedings challenging the ’036 patent in PGR2025-00085

⁵ EX1074, *Syngene Expands Global Footprint with \$36.5M Baltimore Bet*, (Mar. 17, 2025) <https://www.bioprocessintl.com/facilities-capacity/syngene-expands-global-footprint-with-36-5m-baltimore-bet> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 11.

⁶ EX1075, *Biocon Biologics and Civica Expand Partnership and Launch Private-Label Insulin*, <https://bioconbiologicsus.com/news/press-releases/biocon-biologics-and-civica-expand-partnership-and-launch-private-label-insulin/> (last accessed June 24, 2026); EX1076, *Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices* (Apr. 2025), <https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/>.

⁷ EX1077, *United States-India Joint Leaders’ Statement* (February 13, 2025) <https://www.whitehouse.gov/briefings-statements/2025/02/united-states-india-joint-leaders-statement/> (last accessed June 24, 2026).

and the Director rejected that request and instituted post-grant review. The Director should not reach a different conclusion here. Biocon's petition is substantively identical to the petition the Director already instituted, and the Director should permit Biocon to join the already-instituted proceeding.

II. ARGUMENT

A. This Proceeding Is a Joinder Petition in an Already-Instituted PGR, and the Discretionary Factors Do Not Warrant Denial

Biocon seeks joinder with PGR2025-00085 pursuant to 35 U.S.C. § 325(c) and 37 C.F.R. § 42.222(b). Biocon's petition is substantively identical to the Alvotech petition that the Director already instituted. *See* Pet. at 1. On March 3, 2026, the Director granted institution in PGR2025-00085 after "review of discretionary considerations," finding that the petitioner showed "it is more likely than not that at least one of the claims challenged in the petition is unpatentable." Notice of Decisions on Institution, PGR2025-00085, Paper 10 (Director Mar. 3, 2026). As a copycat petition seeking joinder with an already-instituted proceeding presenting the same grounds and the same prior art, Biocon's petition should be favored for institution.

This is now Patent Owner's second opportunity to seek discretionary denial of proceedings challenging the '036 patent—and this attempt, like the last, does not warrant denial. In PGR2025-00085, Patent Owner argued that the Director should deny institution under 35 U.S.C. § 325(d), contending that the prior art and

arguments in the petition had already been presented to the Patent Office during prosecution. *See* Patent Owner’s Discretionary Denial Brief, PGR2025-00085, Paper 6. The Director rejected those arguments and instituted the proceeding.

A joinder petition is not an occasion to give Patent Owner successive opportunities to seek discretionary denial. The purpose of joinder under 35 U.S.C. § 325(c) is to allow additional parties to participate in an already-instituted proceeding. This is especially true where, as here, the joinder petitioner’s substantive challenge is identical to the one the Director has already found meritorious.

Moreover, institution of Biocon’s petition is consistent with the Administration’s goal of reversing the “off-shoring trends” described in the Director’s March 2026 memo on additional discretionary institution proceedings.⁸

Biocon has never engaged in offshoring. Rather, Biocon began abroad and has increasingly engaged in onshoring by expanding its investments in domestic manufacturing.⁹ Biocon has also successfully brought lower-cost biosimilar medicines to American patients, including through its partnership with Civica to

⁸ EX1078, *Memorandum from John A. Squires, Under Sec’y of Com. for Intell. Prop. & Dir. of the U.S. Patent & Trademark Off., to All PTAB Users, Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings*, (Mar. 11, 2026), https://www.uspto.gov/sites/default/files/documents/Additional_Discretionary_Institution_Considerations_US_Manufacturing_and_Small_Business_Use_of_AIA_Proceedings.pdf (“Memorandum of J. Squires”).

⁹ *See generally* EX1071, Decl. of D. Taneja (describing the steps Biocon has taken to increase its U.S. footprint and activities).

deliver affordable insulin in furtherance of the Administration’s stated priority of lowering prescription drug costs.¹⁰ Denying institution of a meritorious joinder petition filed by such an entity would be inconsistent with these policy objectives.

B. Biocon Is a Significant Investor in U.S. Manufacturing and the American Economy

Biocon has made—and continues to make—substantial investments in the United States, including investments in domestic manufacturing, precisely the type of activity the Director has indicated he will weigh in considering institution. Even if the Director were to evaluate using the recent discretionary factors anew—despite the prior institution decision in PGR2025-00085—those factors do not support discretionary denial.

The Director has stated that he will consider “the extent to which any products accused of infringement in a parallel proceeding are manufactured in the United States or are related to investments in American manufacturing operations.”¹¹ The Director has also stated the following three factors when considering PGR proceeding institution: (1) the extent to which any products accused of infringement in a parallel proceeding are manufactured in the United States or are related to

¹⁰ EX1079, Exec. Order No. 14273, “Lowering Drug Prices by Once Again Putting Americans First” (Apr. 15, 2025); EX1076, White House, Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices (Apr. 2025), <https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/>.

¹¹ EX1078, *Memorandum of J. Squires*.

investments in American manufacturing operations; (2) the extent to which any products made, sold, or licensed by the patent owner that compete with the accused products are manufactured in the United States; and (3) whether the petitioner is a small business that has been sued for infringement of the patent at issue.¹²

Biocon’s growing domestic manufacturing presence and concrete capital investments in U.S. facilities demonstrate that Biocon is precisely the type of entity whose interests the Director has indicated he will protect—not penalize.

Patent Owner characterizes Biocon as a “foreign-owned” company with only a “recent and limited” U.S. presence. Paper No. 9 at 10. This is misleading. Biocon Biologics has opened a spate of U.S. based operations, starting with its North American headquarters in New Jersey’s biopharma corridor—one of the nation’s most important centers of pharmaceutical research, development, and production.¹³ This headquarters serves as the nerve center for Biocon’s expanding U.S. commercial and manufacturing operations.

Biocon similarly launched its first U.S. manufacturing facility in Cranbury, New Jersey in just September 2025—a direct investment in U.S. domestic

¹² *Id.*

¹³ EX1072, *Biocon Biologics Opens North America Headquarters in New Jersey’s Biopharma Corridor*, (Sept. 13, 2024), <https://www.bioconbiologics.com/our-stories/biocon-biologics-opens-north-america-headquarters-in-new-jerseys-biopharma-corridor/> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 3.

pharmaceutical manufacturing capacity.¹⁴ This U.S. manufacturing site is a state-of-the-art oral solid dose facility with an annual capacity of up to 2 billion tablets.¹⁵ Biocon's investment in two major facilities reflects Biocon's commitment to increasingly expand its manufacturing operations in the United States, for American patients, using American workers. Indeed, through its U.S. operations, Biocon currently employs about 230 full-time employees across its facilities in the United States.¹⁶ This includes teams across sales and marketing, key account management, manufacturing, quality, regulatory, and other personnel.¹⁷

Additionally, Biocon Ltd.'s subsidiary Syngene International expanded its global footprint with a \$36.5 million facility in Baltimore, Maryland—representing a direct, substantial capital investment in American biopharmaceutical manufacturing and research infrastructure.¹⁸

Thus, Biocon and its affiliated entities are investing millions of dollars in U.S.-based operations, creating American jobs and contributing to expand domestic

¹⁴ EX1073, *Biocon Launches First US Manufacturing Facility in Cranbury, NJ*, (Sept. 15, 2025) <https://finance.yahoo.com/news/biocon-launches-first-us-manufacturing-084341359.html> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 9.

¹⁵ EX1071, Decl. of D. Taneja at ¶ 9.

¹⁶ *Id.* at ¶ 13.

¹⁷ *Id.*

¹⁸ EX1074, *Syngene Expands Global Footprint with \$36.5M Baltimore Bet*, (Mar. 17, 2025) <https://www.bioprocessintl.com/facilities-capacity/syngene-expands-global-footprint-with-36-5m-baltimore-bet> (last accessed July 7, 2026); *see also* EX1071, Decl. of D. Taneja at ¶ 11.

pharmaceutical manufacturing capacity. These are not aspirational plans—they are concrete investments already underway, demonstrating Biocon’s sustained commitment to American manufacturing. And Biocon’s efforts are not complete. Over the course of the next few years, Biocon is looking to invest up to 250 million dollars in manufacturing and allied activities in the United States.¹⁹

With regard to Biocon’s aflibercept product (a biosimilar of Regeneron’s Eylea® products) specifically, a large part of the manufacturing activities, including final testing and release, will happen in the United States through U.S. contract manufacturing organizations.²⁰

Given the above, even if the director considers the new discretionary factors here, they weigh against denial. *See, e.g., Tesla, Inc. v. Bulletproof Property Management, LLC*, IPR2026-00204, Paper 14 at 5 (June 15, 2026) (considering evidence that petitioner “manufactures the accused products in America” and finding the evidence “persuasive”).

As for the specific factors laid out in the Director’s memorandum—none of them apply here because there is no parallel proceeding and therefore there are no products accused of infringement and no products that compete with any accused products.

¹⁹ EX1071, Decl. of D. Taneja at ¶ 14.

²⁰ *Id.* at ¶ 10.

In sum, the discretionary framework was designed to address concerns about entities that “neither manufacture in the United States, nor are making American manufacturing investment” from gaining tactical advantages through AIA proceedings.²¹ Biocon does not fit that description. Biocon is actively investing in American manufacturing, with concrete capital committed to facilities in New Jersey and Maryland, and Biocon is providing affordable medicines to American consumers. Biocon’s ability to compete fairly—including its ability to challenge weak patents that may improperly extend market exclusivity beyond the scope of legitimate patent protection—is a crucial part of protecting this investment and promoting and permitting future investment.²²

Regeneron’s argument effectively asks the Director to use the discretionary framework as a sword to prevent any foreign challenger from testing the validity of Regeneron’s patents. But the Director’s stated concerns are directed at companies that “neither manufacture in the United States, nor are making American manufacturing investment.”²³ Biocon is not one of those companies.

²¹ EX1078, *Memorandum of J. Squires*.

²² EX1071, Decl. of D. Taneja at ¶ 16.

²³ *Id.*

III. CONCLUSION

For the above reasons, Biocon respectfully requests that the Director reject Patent Owner's request to discretionarily deny institution of this proceeding.

Respectfully submitted,

Dated: July 7, 2026

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CERTIFICATION OF PAGE LIMIT

The undersigned certifies that this Discretionary Denial Brief complies with the 20-page limit provided in Section III.C.iii of the Interim Director Discretionary Process guidance available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Date: July 7, 2026

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

The undersigned hereby certifies that on July 7, 2026, I caused true and correct copies of the following materials:

- Petitioners' Opposition to Patent Owner's Request for Discretionary Denial for Institution
- Exhibits 1071-1079

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