

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BICARA THERAPEUTICS, INC.,
Petitioner,

v.

THE JOHNS HOPKINS UNIVERSITY,
Patent Owner.

PGR2026-00025
Patent 12,295,968

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

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I. INTRODUCTION

JHU seeks discretionary denial based on demonstrably incorrect claims regarding ownership of Bicara and overstatements about what the named inventors of the '968 Patent disclosed when they filed this family of patents. The Board should reject these arguments and allow Bicara's petition to be considered on its merits.

JHU's real party-in-interest ("RPI") argument rests on a mathematical error. JHU double-counts the shares beneficially owned by Biocon affiliates, artificially inflating the alleged control. As of the relevant period for the RPI analysis (and contrary to JHU's assertions), Biocon-affiliated entities and Kiran Mazumdar-Shaw did not own the largest block of Bicara stock and their collective percentage of Bicara's stock was not "over 20%"—it decreased from 11.6% to 9.7%.

JHU's descriptions of the '968 Patent similarly belie the facts. JHU portrays the '968 Patent as a long-established research asset undergirding decades of institutional investment, surrounded by settled expectations, and threatened by a foreign actor seeking to exploit the patent system for competitive gain. Each element of that portrayal is false. JHU's own prosecution record tells the real story. After fourteen years of prosecution, JHU introduced the challenged claims targeting a specific subgenus of fusion proteins only after Bicara's \$362 million IPO. The Examiner issued a Notice of Allowance roughly five weeks after JHU's amendment without any § 112 scrutiny, but as set forth in the petition, these subgenus claims

lack any basis in the specification. JHU cannot have settled expectations regarding claims directed at subject matter it did not invent, but are instead designed to attempt to capture Bicara's lead investigational product, ficerafusp alfa (BCA101).

Bicara is a U.S.-incorporated, U.S.-listed, U.S.-headquartered company conducting U.S. clinical trials of BCA101 to obtain FDA approval in the U.S. The record weighs strongly against the Board exercising its discretion to deny Bicara's petition, which raises arguments that were not considered by the Examiner and are supported by two precedential Federal Circuit decisions issued after patent issuance. JHU's request for discretionary denial should therefore be rejected.

II. DISCRETIONARY DENIAL IS NOT WARRANTED

A. The Petition Identifies All Real Parties-in-Interest in This PGR

JHU's claim that the petition failed to identify all RPIs is based on factual errors. Neither "Biocon"¹ nor Kiran Mazumdar-Shaw is an RPI. Bicara accurately identified itself as the only RPI.

1. JHU Miscalculates the Shares That Biocon and Ms. Mazumdar-Shaw Control

JHU's entire RPI argument rests on its assertions (at 6, 9): (i) "that Biocon and

¹ JHU does not explicitly specify which "Biocon" entity it deems is the missing RPI, although it suggests that Biocon Ltd. ("Biocon") is the missing RPI. Nevertheless, neither Biocon Ltd. nor any other Biocon-affiliated entity is an RPI for this PGR.

Ms. [Kiran] Mazumdar-Shaw still collectively own the largest block of Bicara stock” and (ii) that “they own over 20% of Bicara’s stock (*see* EX2007 at 47; EX2021 at 2) and therefore have ‘working control’ of Bicara and can affect its corporate decision-making.” Both assertions are wrong. JHU’s calculations inappropriately double-count shares owned by Biocon-affiliated entities and those owned by Ms. Mazumdar-Shaw. The SEC filing relied upon by JHU makes clear that the number of shares identified as “beneficially owned” by Ms. Mazumdar-Shaw include the shares that are also separately listed as owned by Biocon-affiliated entities. Adding these together (as JHU incorrectly does) double-counts over 5.5 million shares.

JHU relies on the section on “Principal Stockholders” in Bicara’s Schedule 14A (EX2007) submitted to the SEC, providing a table of “the beneficial ownership of our common stock as of April 14, 2025” for certain stockholders.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Greater-than-five Percent Stockholders:		
Entities affiliated with Biocon ⁽¹⁾	5,523,897	10.1 %
Entities affiliated with RA Capital Management, L.P. ⁽²⁾	6,955,993	12.8 %
	*	*
Kiran Mazumdar-Shaw ⁽¹¹⁾	6,328,894	11.6 %

Paper-6, 6 (excerpted, citing EX2007, 47 (emphases added by JHU)). JHU’s argument simply adds the shares owned by “Entities affiliated with Biocon” and Kiran Mazumdar-Shaw to arrive at its alleged “over 20%” collective ownership. The footnotes to this chart, however, explain that these numbers overlap and cannot be added together. This filing reported that the “Entities affiliated with Biocon”

beneficially owned 5,523,897 shares and Kiran Mazumdar-Shaw beneficially owned 6,328,894 shares, with footnotes 1 and 11 referring to these entries, respectively. EX2007, 47-49. Footnote 1 explains that the 5,523,897 shares listed for “Entities affiliated with Biocon” consist of 4,443,122 shares held by Biocon Ltd. and 1,080,775 shares held by Biocon Pharma Inc., and that Kiran Mazumdar-Shaw—a Bicara board member and managing member of both Biocon entities—“may be deemed to beneficially own the shares held by Biocon Ltd. and Biocon Pharma.” *Id.* Footnote 11 then expressly cross-references footnote 1—stating “See footnote 1 above. *In addition*, consists of . . .”—and lists the non-overlapping additional shares: 324,552 shares held by Glentech International, 432,736 by Carica Investments, 16,669 held personally by Ms. Mazumdar-Shaw, and 31,040 subject to underlying options exercisable within 60 days of April 14, 2025. *Id.* The sum of non-overlapping shares specified in footnote 11 (804,997) combined with the shares in footnote 1 (5,523,897) equals the number of shares listed for Kiran Mazumdar-Shaw in the table: 6,328,894. Therefore, Kiran Mazumdar-Shaw’s reported 11.6% ownership includes the 10.1% beneficially owned by the Biocon-affiliated entities in row 1 (*i.e.*, 5,523,897 shares). *Id.* The correct percentage of shares beneficially owned by Kiran Mazumdar-Shaw and Biocon-affiliated entities together was 11.6%.

Based on an accurate reading of Bicara’s SEC filings, (i) the Biocon-affiliated entities and Kiran Mazumdar-Shaw do ***not*** own the largest block of Bicara stock and

(ii) their collective percentage of Bicara's stock is **not** over 20%. As of April 14, 2025, the collective percentage of Bicara's shares beneficially owned by Biocon entities and Kiran Mazumdar-Shaw was less than the 12.8% of shares beneficially owned by entities affiliated with RA Capital Management, L.P. ("RA Capital"). EX2007, 47-49. Bicara's latest Schedule 14A, filed April 27, 2026 (EX1099), reflects a similar breakdown, except with a decrease in the collective percentage of shares beneficially owned by Biocon-affiliated entities and Ms. Mazumdar-Shaw. As of April 15, 2026, the collective percentage of Bicara's shares beneficially owned by Biocon entities and Kiran Mazumdar-Shaw was 9.7%, which was less than the 11.1% and 10.1% of shares beneficially owned by entities affiliated with RA Capital and T. Rowe Price Investment Management, Inc., respectively. *Id.*, 39-41.

2. Neither Biocon Nor Ms. Mazumdar-Shaw Are RPIs

JHU argues that Biocon and Kiran Mazumdar-Shaw are missing RPIs based on two factors: whether they (1) are "clear beneficiar[ies] that ha[ve] a preexisting ... relationship" with Bicara (Paper-6, 5-7 citing *Entegris, Inc. v. Inpria Corp.*, IPR2025-00267, Paper-33 at 8 (PTAB Jan. 27, 2026)) and (2) "exercised or could have exercised control over [Bicara's] participation" in the PGR (Paper-6, 8-11 citing *VirnetX Inc. v. Mangrove Partners Master Fund, Ltd.*, 778 F. App'x 897, 902 (Fed. Cir. 2019)). These arguments fail because they both heavily rely on JHU's miscalculation of the collective ownership of Bicara's shares by Biocon entities and

Ms. Mazumdar-Shaw. Analyzing the accurate factual record, these factors establish that neither Biocon nor Ms. Mazumdar-Shaw is an RPI—neither is a clear beneficiary of this proceeding, nor could either exercise control over the petition.

(a) Biocon and Ms. Mazumdar-Shaw Are Not “Clear Beneficiaries”

The RPI inquiry evaluates the relationship between the parties as it exists at the time of institution, including those that arise after the petition is filed. *Power Integrations, Inc. v. Semiconductor Components Indus., LLC*, 926 F.3d 1306, 1316 (Fed. Cir. 2019). JHU heavily relies on Bicara’s origins as a wholly-owned subsidiary of Biocon Ltd., but these outdated facts are irrelevant. Biocon is no longer Bicara’s parent company. Bicara has been an independent, publicly-traded U.S. biopharmaceutical company since long before the ’968 Patent issued. EX1098, ¶¶7, 12. By 2021, Bicara was operating “as a standalone company under an independent management team.” EX1097, 15. In that fiscal year, Biocon “ceded control to [Bicara’s] Board and Management.” *Id.* In 2024, Bicara became a publicly-traded company on the Nasdaq Global Market, greatly disseminating its ownership. EX1098, ¶9. During the relevant time period (and years before), contrary to JHU’s suggestions, Bicara has operated independently from Biocon. *Id.*, ¶¶7, 12-15.

Biocon and Ms. Mazumdar-Shaw are thus not “clear beneficiaries” of this PGR. At most, Biocon is positioned as one of Bicara’s suppliers for the product that the ’968 Patent attempts to capture. Bicara holds a fully paid-up license from Biocon

regarding BCA101, with no ongoing milestone or royalty payments. EX1100, 128. The only ongoing payments from Bicara to Biocon related to this product would be under research-services and supply agreements, which position Biocon as a supplier. Paper-6, 7 (citing EX2007, 45). Any tangential benefit to Biocon from Bicara enabling a launch of BCA101 would be similar to the supplier relationships that the Board has found insufficient to create an RPI. *E.g., Toshiba Memory Corp. v. Anza Tech., Inc.*, IPR2018-01597, Paper-56 at 14-17 (PTAB Mar. 12, 2020) (supplier relationships within corporate family insufficient without ownership or control).

(b) Biocon and Ms. Mazumdar-Shaw Do Not Control this PGR

Neither Biocon nor Ms. Mazumdar-Shaw “exercised or could have exercised control” over Bicara’s participation in this PGR. *Cf.* Paper-6, 8. As Ryan Cohlhepp, Bicara’s President and Chief Operating Officer and a member of its board of directors (“Board”), explains, Bicara was operating independently from Biocon by 2021. EX1098, ¶¶1, 7. Bicara has its own executive leadership team, its own Board, its own employees, its own management structure, and its own in-house legal function. *Id.*, ¶12. Bicara funds, controls, and directs this PGR—Bicara independently desired review of the ’968 Patent and independently authorized, funded, and directed the filing of this proceeding. *Id.*, ¶¶16, 19. The decision to bring this PGR was made by Bicara’s employees and executive officers and was not subject to a vote by Bicara’s Board or shareholders. *Id.*, ¶17. All strategy decisions

in this proceeding—including decisions regarding grounds, expert selection, and litigation strategy—have been made by Bicara in consultation with outside counsel retained by Bicara. *Id.*, ¶18. Neither Ms. Mazumdar-Shaw nor Biocon nor any Biocon-affiliated entity has funded, controlled, or directed this PGR. *Id.*, ¶¶20-21. Apart from Ms. Mazumdar-Shaw’s non-employee director role, no officer, director, employee, or representative of Biocon or any Biocon-affiliated entity has served as an executive officer or director of Bicara between the issuance of the ’968 Patent and the present. *Id.*, ¶15. Ms. Mazumdar-Shaw’s director seat is no different in kind from the seats held by other stockholders’ representatives on Bicara’s Board of ten directors, and none of these stockholders have sufficient shares to control the activity of Bicara. *Id.*, ¶¶13-14; *VirnetX*, 778 F. App’x 897 at 902-03.² No one else controls or could have exercised control over this PGR; only Bicara controls this proceeding.

JHU (again) mischaracterizes Bicara’s SEC filing to assert (at 8-9) that Biocon could have exercised control over Bicara’s participation in this PGR. Bicara’s 10-Q states that certain stockholders “will be able to exert significant control *over matters*

² See EX1099, 39. RA Capital has beneficially owned more shares of Bicara than Biocon entities and Ms. Mazumdar-Shaw collectively during the relevant time period, and has a representative on the Board. *Supra* pp. 3-5; EX1099, 13, 39. There is no dispute that RA Capital is not an RPI.

subject to stockholder approval.” EX2008, 89 (emphasis added). JHU emphasizes (at 8-9) only the language “able to exert significant control,” but ignores the context of the disclosure. This PGR was not a “matter subject to stockholder approval,” making the potential “significant control” irrelevant to this analysis. EX1098, ¶17.

Delaware law similarly does not support JHU’s arguments. As described above, Biocon entities and Ms. Mazumdar-Shaw collectively owned 9.7-11.6% of Bicara’s shares during the relevant period, not “over 20%,” which confirms they are not a “control group,” “interested shareholder,” or “controlling stockholder” even under JHU’s interpretation of the law. Paper-6, 9-11 (citing Del. cases and dictionary referring to 15-20% or more of stock ownership). Notably, however, JHU failed to account for the March 2025 amendments to the Delaware General Corporations Laws (“DGCL”), directly contradicting JHU’s positions. *See* 8 *Del. C.* § 144(e)(2)(c) (controlling stockholders are those that “own[] or control[] at least $\frac{1}{3}$ *in voting power*” and meet other requirements (emphasis added)); *Rutledge v. Clearway Energy Grp. LLC*, 2026 WL 548504, at *1 (Del. Feb. 27, 2026) (explaining the 2025 amendments to the DGCL “redirect[ed] the [] judicial development of the concept of control by defining the term controlling stockholder.” (modified)). Under the amended law, Biocon and Ms. Mazumdar-Shaw fall well short of the “at least $\frac{1}{3}$ in voting power” required to be a controller.

B. JHU Has No Settled Expectations in the ’968 Patent

“[P]etitions for [PGR] are favored because they must be filed no later than nine months from the grant of the patent..., are close in time to examination, and occur before expectations in the patent rights are strongly settled.” *Toyota Motor Corp. v. Autoconnect Holdings LLC*, PGR2025-00041, Paper-9 at 2 (Director Sept. 8, 2025); *see also Straumann USA, LLC v. Smart Denture Conversions, LLC*, PGR2025-00054, Paper-11 at 2 (Director Oct. 17, 2025). The ’968 Patent issued on May 13, 2025, and Bicara filed this petition on February 10, 2026.

As the Board has repeatedly confirmed, patent age is the primary driver of settled expectations. *See, e.g., Amgen, Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper-9 at 2-4 (Director July 24, 2025) (cited by JHU); *Dabico Airport Sols. Inc. v. Axa Power Aps*, No. IPR2025-00408, Paper-21 at 3 (Director June 18, 2025) (cited by JHU). In *Amgen*, petitioner filed IPR petitions challenging three patents. IPR2025-00601, Paper-9 at 2. The Director denied institution for the two petitions directed at patents that had been in force for seven and six years, respectively. *Id.*, 3. By contrast, the Director found no settled expectations for the patent that had been in force for only about three years. *Id.*, 2. The ’968 Patent is even younger than the patent for which the Director in *Amgen* found no settled expectations.

JHU attempts to manufacture evidence of settled expectations, but each of its arguments fails. JHU’s evidence of settled expectations focuses on the “’789 Bedi IP” family as a whole, not the specific claims of the ’968 Patent, and much of the

evidence pre-dates the issuance of the '968 Patent. This is not coincidence. JHU has not developed products that are covered by the challenged claims and therefore must resort to looking to the other family members. The '968 Patent is not a research asset, but merely a blocking instrument that lacks any legitimate reliance interest. The settled expectations analysis favors Bicara. *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper-17 at 8-9 (Director May 14, 2026) (precedential).

1. The Extended Patent Family Cannot Establish Settled Expectations for the Challenged Claims

Even accepting JHU's argument that settled expectations could arise from a family of continuation patents, JHU cannot have settled expectations regarding claims directed to subject matter not found in those earlier applications. Contrary to JHU's assertion (at 13), the '968 Patent is not the product of "routine and predictable continuation practice" and "refining claims based on the original disclosure." *Cf.* Paper-6, 12-13. After prosecuting this family for more than 14 years, the challenged claims were introduced by amendment on December 23, 2024—just months after Bicara's IPO. *Compare* EX1002, 434-36, *with* EX1101. These claims reflect a shift from broad genera and functional disclosures to narrower subgenus claims that lack any basis in the specification. These claims target, for the first time, a moiety comprising an antibody or antibody fragment comprising only amino acids 1-119 of one sequence (SEQ ID NO: 2) and the entirety of another sequence (SEQ ID NO: 71). As explained in the petition, this subject matter is not disclosed in the

specification. The relevant inquiry here is whether there are settled expectations regarding the challenged claims, not other members of the patent family. *See, e.g.*, March 2025 Workload Management Memorandum (“settled expectations of the parties, such as the length of time *the claims* have been in force” (emphasis added)).

Further, JHU’s reliance on the double patenting rejection during prosecution of the ’968 Patent is misplaced. JHU argues (at 12-13) that “the public-facing scope of the family’s claims . . . was established no later than the 2016 issuance of the ’044 patent,” but the prosecution record shows that JHU significantly amended or newly added all of the challenged claims *after* the double patenting rejection. EX1002, 433-40. The Examiner withdrew the rejection in view of a terminal disclaimer without comment on the scope of these new claims. *Id.*, 464. Thus, this rejection cannot be evidence of equivalence between the issued claims and any earlier patent.

2. Alleged Family-Level Investments Are Insufficient

JHU’s alleged investment also fails to establish settled expectations here because it addresses the patent family as a whole—not the claims of the ’968 Patent—and predates the ’968 Patent entirely. JHU points to grants and investments all before the application that led to the ’968 Patent was even filed. EX2023, 1 (as of 2022); EX2024, 1 (as of 2018). As the Board found in *Amgen*, only a strong, claim-specific showing justifies denial—a showing JHU has not made and cannot make. IPR2025-00601, Paper-9 at 2-3 (denying discretionary denial where patent

owner failed to explain “how an extraordinary amount of investment, time, and resources ... correlates to settled expectations” in the challenged claims). While JHU alleges that Y-Trap has developed “certain molecules within the 789 Bedi IP,” it tellingly provides no evidence of any molecules covered by the challenged claims. *Cf.* EX2017 (no mention of any EGFR/TGF-beta binding fusion proteins).

This lack of evidence is unsurprising. The claims of the '968 Patent were strategically added to try to capture Bicara's BCA101 product. Settled expectations cannot attach to claims deliberately drafted to attempt to capture a competitor's existing product in clinical development. Based on publicly-available sources, Bicara has found no evidence that Y-Trap or the named inventors of the '968 Patent are developing a product covered by these claims, nor has JHU provided any. Public sources on Y-Trap's alleged development are sparse. Y-Trap's own website consists of only about 50 words and three links to its email. EX1102.

3. Y-Trap-JHU License Does Not Support Settled Expectations

JHU asserts that “Y-Trap took a license to the '968 patent's family,” but provides no evidence of the terms of that license. Paper-6, 1, 16-17. Tellingly, JHU does not state *when* Y-Trap took that license. Looking to allegations in the district court litigation Y-Trap brought (“Y-Trap action”), Y-Trap alleged that “In July 2016, Y-Trap procured an exclusive license from JHU to the '789 Bedi IP.” EX2020, ¶41; *id.* ¶¶38, 80. Even if accepting these allegations as true, the license predates the '968

Patent and it was taken by an entity co-founded by the inventors. Y-Trap cannot have structured a business decision around claims that did not exist when the license was taken, particularly when those claims find no support in the parent specification.

4. Biocon's Prior Conduct Does Not Establish Settled Expectations Here

JHU's prior conduct argument fails because it relies solely on activity prior to issuance of the challenged claims. JHU never explains why conduct before issuance of the '968 Patent and related to different subject matter is relevant to this analysis. First, even if JHU and Y-Trap's allegations that Biocon attempted to license the "'789 Bedi IP" family in 2012 were true, this conduct cannot generate settled expectations in claims that did not exist until December 2024. Paper-6, 14-15. No licensing attempt predating a patent's existence can tether settled expectations to claims that would not appear for another twelve years, particularly claims lacking written description and enablement in the parent disclosures. Second, JHU's reliance on Indian Patent Office proceedings fails for the same reason—that decision concerned different subject matter at issue in a non-U.S. application and issued before the December 2024 claim amendments that introduced the claims at issue here. EX1103. Notably, JHU does not provide documentary support for its positions. JHU relies on allegations from the Y-Trap action, citing the district court's acceptance of Y-Trap's allegations as true solely for Rule 12 purposes. Paper-6, 15-16. These allegations are not facts upon which the Board should rely.

C. JHU's Remaining Arguments Fail—These Factors Support Bicara**1. The Petition's Merits Are Strong and the Petition Is PGR Eligible**

The merits of the unpatentability challenges raised in the petition are strong, are fully supported by record evidence, were not previously considered by the USPTO, and are reinforced by recent, precedential Federal Circuit decisions. Because the claimed priority applications that share a common specification with the '968 Patent fail to satisfy both the written description and enablement requirements of 35 U.S.C. § 112, the '968 Patent is PGR eligible.

The petition presents six grounds of unpatentability, all challenging the claims that JHU added in December 2024—without specification support—just months after Bicara's IPO. On written description (Ground 1), the common specification does not adequately describe particular claim limitations or the claim limitations together as a whole. Pet., 23-53. For enablement (Ground 2), the '968 Patent discloses the concept of certain fusion proteins but provides little to no actual demonstration of which ones to make, how to make them, or whether the subgenera as claimed will bind EGFR. *Id.*, 53-86. As for Grounds 3-6, JHU resorted to contorted claim drafting in its attempt to capture BCA101. Claims 2-8 are unpatentable for improper dependency and for indefiniteness because claims 2 and 3 contradict, and do not narrow, the respective claim(s) from which they depend, resulting in nonsensical claims. *Id.*, 86-91.

The USPTO has never considered the challenges raised in Bicara’s petition. The prosecution of the ’968 Patent consisted of a single office action, a single response, and a Notice of Allowance issued five weeks later. The sole office action, dated December 3, 2024, raised only a double patenting rejection and an indefiniteness rejection directed at original claims 2-3 on grounds different from those in the petition for claim rejections. EX1002, 398-413. In response on December 23, 2024, JHU significantly amended claims 1 and 2 and added the claims that issued as claims 3-9, which were not previously presented. EX1002, 434-36. The Examiner issued a Notice of Allowance roughly one month later, without any § 112 scrutiny. EX1002, 459, 464-65.

Additionally, two precedential Federal Circuit decisions issued after the ’968 Patent’s issuance—*Seagen Inc. v. Daiichi Sankyo Co.*, 160 F.4th 1322 (Fed. Cir. Dec. 2025), and *Duke Univ. v. Sandoz Inc.*, 160 F.4th 1305 (Fed. Cir. Nov. 2025)—weigh against discretionary denial. These decisions clarify the written description (both decisions) and enablement (*Seagen*) standards underlying Grounds 1 and 2, and constitute new judicial precedent bearing on patentability. See Director’s March 2025 Workload Management Memorandum. For example, both decisions found that broad disclosures without sufficient blaze marks directed to a specific subgenus are inadequate to satisfy written description—the same deficiency established by the petition with respect to all nine claims of the ’968 Patent. *Seagen*, 160 F.4th at 1330

(“As [the Federal Circuit has] consistently held, a patent’s disclosure of a ‘broad genus,’ without more, is inadequate to satisfy the written description requirement for claims directed to a ‘particular subgenus or species contained therein.’” (citation omitted)); *Duke*, 160 F.4th at 1312 (“[T]he patent must ‘provide sufficient blaze marks’ to direct a skilled artisan to the claimed subgenus.” (citation omitted)).

Finally, JHU’s cursory argument against PGR eligibility is without merit. As a threshold matter, JHU only addresses written description and entirely fails to rebut the petition’s enablement challenge. *E.g.*, *CSIRO v. BASF Plant Sci. GmbH*, PGR2020-00033, Paper-11 at 9 (PTAB Sep. 10, 2020) (“[A] patent claiming the benefit of a priority application filed before March 16, 2013 must have written description support in, and be enabled by, the earlier-filed application to avoid PGR-eligibility.”). As for written description, JHU provides (at 3-5) a conclusory statement that “the specification provides written description support for the claims,” but its only support is its single, color-coded figure and quote piecing together no less than four disparate parts of the specification and a comparison to only claim 9. JHU does not address claim 1 or any of the dependent claims of the ’968 Patent. JHU’s alleged support confirms—rather than cures—the lack of written description. As the Federal Circuit has confirmed, written description cannot be satisfied by piecing together scattered disclosures with hindsight. *E.g.*, *Pet.*, 23-26 (summarizing legal standards). JHU’s color-coded picking-and-choosing to reconstruct claim 9 is visual proof of

impermissible hindsight and is insufficient for written description. These substantial § 112 deficiencies establish PGR eligibility and strongly favor institution.

2. Institution Serves Domestic Economic and Public Health Interests

JHU invokes “[c]ompelling economic, public health, [and] national security interests” as a basis for discretionary denial, but the argument fails on the facts.

As established above, Bicara is an independent, publicly-traded U.S. biopharmaceutical company. Bicara is incorporated in Delaware and headquartered in Massachusetts, with over 90% of its roughly 100 employees based in the U.S. EX1098, ¶¶4-6. It is publicly traded on a U.S. securities exchange. *Id.*, ¶9. Its shareholder base is predominantly American, including U.S. institutional investors RA Capital, T. Rowe Price, Invus Public Equities, and FMR LLC. EX1099, 39-40. The American investors who participated in Bicara’s first and second public offerings, raising \$362 million and over \$172 million, respectively, are economic beneficiaries of Bicara’s success. EX1101; EX1104. JHU asks the Director to treat these American interests as a “foreign” concern. They are not.

Bicara’s sole clinical-stage product, ficerafusp alfa (BCA101), is being developed and studied in clinical trials in the U.S. EX1105 (Bicara’s sponsored U.S. clinical trials). The patients enrolled in those trials are American patients. In October 2025, FDA granted Breakthrough Therapy Designation (“BTD”) to BCA101 in combination with pembrolizumab for the first line treatment of patients

with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma. EX1106, 1. FDA's BTB process is designed to expedite the development and review of drugs intended to treat a serious condition that show substantial improvement over available therapies. *Id.*; EX1107. This pivotal clinical trial has initiated Phase 3. EX1109, 1; EX1108. JHU's invocation of national interest as a reason to shield its patent from Bicara because of Bicara's history with Biocon rings hollow. JHU's framing of a U.S.-incorporated, U.S.-listed, U.S.-headquartered company conducting U.S. clinical trials as a "foreign interest" cannot withstand scrutiny. Bicara is committed to bringing BCA101 to market to treat U.S. patients and is seeking to avoid any potential impediments. EX1106, 1. The domestic economic and public health interests favor institution.

3. There Is No Parallel Litigation and No Unexplained Inconsistency

There is no "parallel litigation" here, which weighs heavily against discretionary denial. *Magnolia*, IPR2026-00097, Paper-17 at 3. As JHU stated in its Mandatory Notices, "[t]he '968 patent is mentioned in a footnote in a counterclaim" in the Y-Trap action—it has not been asserted in that action. Paper-4, 2. It is undisputed that the validity of the '968 Patent is not at issue in the Y-Trap action. As a result, unlike in *Tesla*, neither party has taken claim construction positions related to the '968 Patent. *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper-18 at 3 (Director Nov. 5, 2025). Here, JHU's alleged "inconsistent

positions” concern *separate* parties and *separate* legal issues. *Cf. Magnolia*, IPR2026-00097, Paper-17 at 4, 8. As the petition explains, the counterclaim seeking correction of inventorship was brought by Biocon, not Bicara, and the inventorship issues are distinct from the unpatentability grounds raised here. There is also no inconsistency—Biocon alleges that employees of Biocon invented BCA101; Bicara asserts that the JHU ’968 Patent does not support the subgenus of claims targeting that molecule (as argued here). Both can be true, and if the patent survives review here, the Biocon employees are required to be named as inventors (as argued in the Y-Trap action). Lastly, JHU’s alternative argument that Bicara might move to terminate this PGR if Biocon’s inventorship claim succeeds is pure speculation and is not a cognizable basis for denying institution of new patentability challenges.

D. Additional Discretionary Factors Favor Institution

As explained above, additional discretionary factors favor institution, including: (i) no other forum is adjudicating the validity of the challenged claims, (ii) new judicial precedent (*Seagen* and *Duke*) has issued since claim issuance that may affect patentability, and (iii) this PGR raises six, well-founded grounds that were never considered by the USPTO.

III. CONCLUSION

Discretionary denial is not warranted. The Director should assess the merits of the petition and institute trial.

Dated: May 18, 2026

Respectfully Submitted,

/Linnea P. Cipriano/

Linnea P. Cipriano

Reg. No. 67,729

GOODWIN PROCTER LLP

620 Eighth Avenue

New York, NY 10018

LCipriano@goodwinlaw.com

212-459-7258

Daryl L. Wiesen

Pro Hac Vice Forthcoming

Christie Larochelle

Reg No. 75,020

Thomas V. McTigue IV

Reg. No. 75,419

GOODWIN PROCTER LLP

100 Northern Avenue

Boston, MA 02210

*Counsel for Petitioner Bicara
Therapeutics, Inc.*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on May 18, 2026, a copy of the foregoing **Petitioner's Opposition to Patent Owner's Request for Discretionary Denial** and all supporting documents were served on counsel of record for Patent Owner by delivering a copy via electronic mail to the following addresses:

Jennifer Librach Nall
(Reg. No. 57053)
jennifer.nall.ptab@us.dlapiper.com
DLA Piper LLP (US)
303 Colorado Street
Suite 3000
Austin, TX 78701
Phone: (512) 457-7249
Facsimile: (512) 721-2249

Pamela E. Hwang
(Reg. No. 54984)
pamela.hwang@us.dlapiper.com
DLA Piper LLP (US)
4625 Executive Drive, Suite 1100
San Diego, CA 92121-2133
Telephone: (858) 677-1473
Facsimile: (858) 677-1401

Lisa A. Haile
(Reg. No. 38347)
Lisa.haile@us.dlapiper.com
DLA Piper LLP (US)
4625 Executive Drive, Suite 1100
San Diego, CA 92121-2133
Telephone: (858) 677-1456
Facsimile: (858) 677-1401

James M. Heintz
Reg. No. 41,828
jim.heintz@us.dlapiper.com
DLA Piper LLP (US)
One Fountain Square
11911 Freedom Drive, Suite 300
Reston, VA 20190-5602
Phone: (703) 773-4000
Facsimile: (703) 773-5000
jim.heintz@us.dlapiper.com

DLA-JHU-Bicara-PGR@us.dlapiper.com

Dated: May 18, 2026

/Linnea P. Cipriano/
Linnea P. Cipriano
Reg. No. 67,729
GOODWIN PROCTER LLP
620 Eighth Avenue

New York, NY 10018
LCipriano@goodwinlaw.com
212-459-7258

*Counsel for Petitioner Bicara
Therapeutics, Inc.*