

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**BICARA THERAPEUTICS, INC.,**  
Petitioner

v.

**THE JOHNS HOPKINS UNIVERSITY,**  
Patent Owner

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CASE: PGR2026-00025

Patent No. 12,295,968

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**PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL**

Mail Stop **Patent Board**  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**PATENT OWNER'S EXHIBIT LIST**

| <b>Exhibit #</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
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## **I. INTRODUCTION**

Patent Owner respectfully requests that the Director discretionarily deny this PGR because the Petition is not eligible for PGR, the Petition fails to name all RPIs, JHU's settled expectations strongly favor denial, and US investment in healthcare therapies should take priority over an India-based company's conflicting allegations of inventorship and invalidity presented in two different forums.

## **II. BACKGROUND**

In 2009 and 2010, Drs. Atul Bedi and Rajani Ravi invented several revolutionary cancer immunotherapies, including the use of certain novel fusion proteins—i.e., proteins with multiple parts, or moieties, fused together—and their use in cancer immunotherapy (the “’789 Bedi IP”) in the course of their NIH-sponsored research as faculty members of JHU. Drs. Bedi and Ravi, then full-time faculty, assigned their rights in these inventions to their employer, JHU. JHU exclusively licensed the ’789 Bedi IP to Y-Trap, a US start-up biotechnology company founded in 2015 by Drs. Bedi and Ravi, to further develop and commercialize the technology. The ’789 Bedi IP includes PCT/US2011/027317, filed on March 4, 2011 claiming the benefit of provisional applications filed on March 5, 2010 and January 24, 2011, as well as related US patents and foreign counterparts, including the challenged ’968 patent.

Though the Petition only challenges the recently issued ’968 patent, the

dispute underlying Petitioner's challenge spans the life of the '789 Bedi IP patent family and dates back more than 15 years. In about June 2010, after filing the first provisional patent application, Dr. Bedi initially disclosed his and Dr. Ravi's inventions to select employees of Biocon (an Indian pharmaceutical company), including its founder and chairperson Ms. Kiran Mazumdar-Shaw. *Y-Trap, Inc. v. Biocon Ltd.*, No. 24-12678-GAO, 2025 WL 2807694, at \*1 (D. Mass. Sep. 30, 2025). Biocon and Ms. Mazumdar-Shaw had requested this information after learning of the first provisional patent application. At the time, Ms. Mazumdar-Shaw wanted to review the information to potentially license the '789 Bedi IP inventions from JHU, thus acknowledging the importance of those inventions and Drs. Bedi and Ravi's role as the inventors. *See Y-Trap*, 2025 WL 2807694, at \*1. Biocon's attempt to obtain a license to the '789 Bedi IP was unsuccessful. *Id.*

After its failed attempts to license the '789 Bedi IP, Biocon filed its own patent applications covering the '789 Bedi IP and launched an inventorship challenge to JHU's Indian patents for the '789 Bedi IP through the Indian Patent Office, arguing that its own scientists had invented the '789 Bedi IP. The Indian Patent Office rejected that challenge. *Id.* at \*2.

Biocon publicly launched Petitioner Bicara around 2019, first as a wholly owned-subsidiary of Biocon, (*see* EX2001 at 8), then Biocon "spun off" Bicara "to raise capital" (*see* EX2005 at 16-17 (21:12-22:30)). As discussed below, Biocon is

still “able to exert significant control” over Petitioner Bicara. EX2008 at 89. Bicara has just one product under development—a fusion protein, ficerafusp alfa (aka BCA101), the rights to which Biocon licensed to Bicara. *Y-Trap*, 2025 WL 2807694, at \*1; EX2019 at 104; EX2008 at 59. Bicara claims that this protein stems from inventions made by Biocon’s scientists. However, the BCA101 protein implements the identical structures described and disclosed in the ’789 Bedi IP that Dr. Bedi disclosed to Biocon years ago, which Biocon unsuccessfully attempted to license from JHU. *Y-Trap*, 2025 WL 2807694, at \*1-2.

JHU’s exclusive licensee (for all therapeutic uses) of the ’789 Bedi IP, Y-Trap, filed suit in federal court to correct the inventorship of Biocon patents, which cover BCA101 and which were licensed to Petitioner Bicara, and to recover relief under “a host of state law claims,” including unfair competition. *Id.* at \*1.

### **III. MULTIPLE INDEPENDENT REASONS WARRANT DENIAL**

#### **A. Petitioner fails to show that the ’968 Patent is subject to PGR.**

As a threshold matter, the Petition should be denied because the ’968 patent is not eligible for post-grant review. The ’968 patent on its face claims priority through an unbroken chain of continuation and divisional applications tracing back to at least the PCT application filed on March 4, 2011. The Office examined it under pre-AIA first-to-invent rules. As will be explained further in the Patent Owner Preliminary Response, and contrary to the Petition, the specification

provides written description support for the claims. EX1001, p.102 (Sequence Listing, SEQ ID NO:2), p.117-118 (Sequence listing, SEQ ID NO:71), p.120 (Sequence listing, SEQ ID NO:87), p.123 (Sequence listing, SEQ ID NO:104), Figs. 1B, 1C, and 3; EX1016 (showing same). Briefly, Figures 1B, 1C, and 3 and the sequence listing disclose the sequence for the fusion protein claimed in the '968 patent. *Id.* The specific sequence for the claimed fusion protein is shown below, noting that the extracellular domain of TGF $\beta$ -RII is disclosed as part of SEQ ID NO:2 in Figure 3 and separate as SEQ ID NO:87 in Figure 1B; the linker is disclosed as part of SEQ ID NO:2 and separate as SEQ ID NO:104 in Figure 1C:

FIG. 3 of application



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9. An isolated molecule comprising:
- (a) a targeting moiety comprising an antibody fragment which specifically binds Epidermal Growth Factor Receptor (EGFR) comprising a light chain domain comprising the amino acid sequence of SEQ ID NO: 71 and a variable heavy chain domain comprising amino acids 1-119 of SEQ ID NO: 2;
- (b) an immunomodulatory moiety comprising an amino acid sequence of the extracellular domain of Transforming growth factor-beta receptor II (TGF $\beta$ -RII) comprising the amino acid sequence of SEQ ID NO: 87; and
- (c) a polypeptide linker comprising the amino acid sequence of SEQ ID NO: 104;
- wherein the light chain domain comprising the amino acid sequence of SEQ ID NO: 71 is fused to an N-terminus of the polypeptide linker comprising the amino acid of SEQ ID NO: 104; and
- wherein the immunomodulatory moiety comprising the amino acid sequence of SEQ ID NO: 87 is fused to a C-terminus of the polypeptide linker comprising the amino acid sequence of SEQ ID NO: 104.

FIG. 1B of application

(iv) TGF $\beta$ -RII containing the extracellular domain that binds TGF $\beta$  (SEQ ID NO: 87):

TIPPHVQR SYNNDMIVTD NRGAVFPQL CKFCDFRFS CDNQKSCMSN CSTTSICEKP  
QEVCAVNRK NDNITLETV CHDPKLPYND FILEDAASP CIMKEKKKPG ETFFMCSGSS  
DECDNIIIPS EYNTSNPD

FIG. 1B

FIG. 1C of application

Linker sequence used in fusion proteins (SEQ ID NO: 104):

GGGGSGGGSGGGG

FIG. 1C

EX1001 (emphases added). The 2011 PCT expressly contemplates fusion of the

TGF $\beta$ -RII to the light chain. See PCT/US2011/027317, ¶ [0182] ("In another

aspect, the immunomodulatory moiety is a polypeptide that is fused to the C-terminus of the light chain of a targeting antibody.”). Thus, the ’968 patent has an effective filing date of at least 2011. Since PGR is available only for patents having claims with an effective filing date on or after March 16, 2013, the ’968 patent is ineligible and the Petition fails at the outset.

**B. The Petition fails to name all real parties-in-interest.**

**1. Biocon and Ms. Mazumdar-Shaw are RPIs.**

The Office should also deny institution because the Petition fails to name all real parties-in-interest. As discussed below, Biocon and Ms. Kiran Mazumdar-Shaw are RPIs: they are each a “clear beneficiary that has a preexisting, established relationship with” Petitioner Bicara and will benefit from this PGR proceeding. *See Entegris, Inc. v. Inpria Corp.*, IPR2025-00267, Paper 33 at 8 (P.T.A.B. Jan. 27, 2026) (quoting *RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01750, Paper 128 at 2 (P.T.A.B. Oct. 2, 2020) (precedential)).

Both Biocon and Ms. Mazumdar-Shaw have a substantial preexisting, established relationship with Bicara. Bicara was formed by Biocon and Ms. Mazumdar-Shaw is the founder, Executive Chairperson, and principal shareholder of Biocon and the aunt of Bicara’s Chief Executive Officer, Dr. Claire Mazumdar. *See* EX2001 at 8; EX2002 at 3 (Table II); EX2003 at 2. Bicara started as a wholly-owned subsidiary of Biocon (*see* EX2001 at 8), before Ms. Mazumdar-Shaw “spun

off” Bicara “to raise capital.” See EX2005 at 16-17 (21:12-22:30). Biocon then “parked” its assets and IP in Bicara (*see id.*); provided \$40 million in seed money to Bicara (EX2006 at 2); and provided an unsecured loan of \$9 million to Bicara (*see* EX2004 at F-16). In August 2024, it was reported that “Biocon and . . . [Ms.] Mazumdar-Shaw hold a combined 35% stake in Bicara.” EX2021 at 2. It appears that Biocon and Ms. Mazumdar-Shaw still collectively own the largest block of Bicara stock:

| Name of Beneficial Owner                                                     | Shares Beneficially Owned | Percentage of Shares Beneficially Owned |
|------------------------------------------------------------------------------|---------------------------|-----------------------------------------|
| <b>Greater-than-five Percent Stockholders:</b>                               |                           |                                         |
| Entities affiliated with Biocon <sup>(1)</sup>                               | 5,523,897                 | 10.1 %                                  |
| Entities affiliated with RA Capital Management, L.P. <sup>(2)</sup>          | 6,955,993                 | 12.8 %                                  |
| Entities affiliated with Red Tree Venture Fund, L.P. <sup>(3)</sup>          | 3,170,509                 | 5.8 %                                   |
| Invus Public Equities, L.P. <sup>(4)</sup>                                   | 3,041,286                 | 5.6 %                                   |
| TPG GP A, LLC <sup>(5)</sup>                                                 | 3,010,425                 | 5.5 %                                   |
| FMR LLC <sup>(6)</sup>                                                       | 2,803,807                 | 5.1 %                                   |
| <b>Named Executive Officers and Directors:</b>                               |                           |                                         |
| Claire Mazumdar, Ph.D., M.B.A. <sup>(7)</sup>                                | 999,045                   | 1.8 %                                   |
| Ryan Cohlhepp, Pharm.D. <sup>(8)</sup>                                       | 580,757                   | 1.1 %                                   |
| Ivan Hyep, M.B.A. <sup>(9)</sup>                                             | 422,803                   | *                                       |
| Nils Lonberg, Ph.D. <sup>(10)</sup>                                          | 63,933                    | **                                      |
| Patrolyn Ng, Ph.D. <sup>(11)</sup>                                           | —                         | *                                       |
| Kiran Mazumdar-Shaw <sup>(12)</sup>                                          | 6,328,894                 | 11.6 %                                  |
| Jake Simson, Ph.D. <sup>(12)</sup>                                           | 23,746                    | **                                      |
| Kate Haviland, M.B.A. <sup>(13)</sup>                                        | 46,059                    | **                                      |
| Scott Robertson, M.B.A. <sup>(14)</sup>                                      | 46,060                    | **                                      |
| Michael Powell <sup>(15)</sup>                                               | 11,157                    | **                                      |
| Christopher Bowden <sup>(16)</sup>                                           | 11,157                    | **                                      |
| All executive officers and directors as a group (13 persons) <sup>(17)</sup> | 8,735,981                 | 15.5 %                                  |

EX2007 at 47 (emphases added). Bicara also has publicly recognized the strong overlap in interest between Bicara, Biocon, and Ms. Mazumdar-Shaw. In its SEC filings, Bicara stated that Ms. Mazumdar-Shaw, “a member of our board of directors, is the managing member of Biocon Ltd and Biocon Pharma Inc. and *may be deemed to have voting and dispositive power with respect to the shares held by Biocon Ltd and Biocon Pharma*, and Ms. Mazumdar-Shaw may be deemed to beneficially own the shares held by Biocon Ltd.” See *id.* at 48 (emphasis added). In addition to their direct ownership in Bicara, Biocon and Ms. Mazumdar-Shaw

engage in business dealings with Bicara that give them significant control over Bicara. Ms. Mazumdar-Shaw is a Director of Bicara's board, and Biocon and its affiliates have entered into agreements with Bicara that were or are crucial to Bicara's business. *See id.* at 13, 45. For example, Bicara has entered into agreements with "Entities affiliated with Biocon" that provide for: (1) "contract development and manufacturing for drug products"; (2) "contract research and project management services for drug products"; (3) "dedicated research laboratories and personnel"; (4) "certain research and development services"; and (5) "specified quantities of products to" Bicara "to be utilized in research and development and manufacturing pursuant to purchase orders." *Id.* at 45. In a recent SEC filing, Bicara represented that some of its agreements with Biocon are "Significant Agreements." EX2008 at 20-21. That is not surprising, as Biocon licensed the very IP to Bicara that purportedly allows Bicara to make ficerafusp alfa. *Id.* at 59 ("[C]ollaborations involving our product candidates may pose various risks to us, including .... the mutual termination of the Contract Transfer and License Agreement with Biocon could delay the commercialization of ficerafusp alfa."); EX2004 at 130 ("We have an exclusive license from Biocon Limited to one patent family directed to ficerafusp alfa and other fusion proteins."). Thus, Biocon and Ms. Mazumdar-Shaw are "a clear beneficiary" of the Petition. *RPX*, IPR2015-01750, Paper 128 at 2.

**2. Biocon and Ms. Mazumdar-Shaw exercised or could have exercised control over the Petition.**

“One factor relevant to whether a third party is a real party in interest . . . is whether it ‘exercised or could have exercised control over a party’s participation in a proceeding.’” *VirnetX Inc. v. Mangrove Partners Master Fund, Ltd.*, 778 F. App’x 897, 902 (Fed. Cir. 2019) (quoting Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012)). “Complete . . . control is not required for a non-party to be considered a real party in interest.” *Toshiba Memory Corp. v. Anza Tech., Inc.*, No. IPR2018-01597, Paper 56 at 11 (P.T.A.B. Mar. 12, 2020). The Board has recognized that “actual proof of some control would weigh in favor of a finding that the non-party is an RPI,” but “the lack of evidence of control is not a dispositive indication that the non-party is not an RPI.” *Bungie, Inc. v. Worlds Inc.*, No. IPR2015-01264, Paper 64 at 38 (P.T.A.B. Jan. 14, 2020).

Bicara has admitted that Biocon has control over Bicara and therefore exercised or could have exercised control over Bicara’s participation in this PGR—especially given Biocon’s direct interest in the outcome. As shown below, in an SEC filing, Bicara represented that Biocon is “able to exert significant control” over Bicara:

*Our executive officers, directors, principal stockholders and their respective affiliates own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

Based on the beneficial ownership of our common stock as of September 30, 2025, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our common stock. These stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. In addition, certain of our principal stockholders, including Biocon Ltd., RA Capital and TPG LSA, are affiliated with members of our board of directors. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

EX2008 at 89 (emphases added); EX2019 at 92 (2025 Form 10-K with same

representation); *see also* *Sirius XM Radio, Inc. v. Fraunhofer-Gesellschaft*, No.

IPR2018-00681, Paper 12 at 4-6 (P.T.A.B. Sept. 6, 2018) (relying in part on filed

Form 10-K in RPI analysis), *vacated on other grounds*, Paper 24 at 7 (P.T.A.B.

June 25, 2019).

Moreover, Biocon and Ms. Mazumdar-Shaw are interested shareholders of Bicara and therefore exercised or could have exercised control over Bicara's participation in this proceeding. An interested shareholder is "[s]omeone who owns enough of a corporation's stock to affect corporate decision-making, usu. at least 15–20% of the corporation's outstanding stock." EX2009. Collectively, 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. *See Robbins & Co. v. A. C. Israel Enters., Inc.*, No. 7919, 1985 WL 149627, at \*5 (Del. Ch. Oct. 2, 1985) ("This Court and others have recognized that substantial minority interests ranging from 20% to 40% often provide the holder with working control.") (collecting cases).

Also, Biocon and Ms. Mazumdar-Shaw are a “control group” and readily satisfy the Delaware common law definition of “a controlling stockholder.” *See In re Hansen Med., Inc. S’holders Litig.*, C.A. No. 12316-VCMR, 2018 WL 3025525, at \*5 (Del. Ch. June 18, 2018) (“A group of stockholders may be deemed a ‘control group’ and considered a controlling stockholder.”). A controlling shareholder is “[a] shareholder who can influence the corporation’s activities because the shareholder either owns a majority of outstanding shares or owns a smaller percentage but a significant number of the remaining shares are widely distributed among many others.” EX2009. Under Delaware common law, “Delaware courts will deem a stockholder a controlling stockholder when the stockholder . . . owns less than 50% of the voting power of the corporation but ‘*exercises control* over the business affairs of the corporation’” and “there is no absolute percentage of voting power that is required in order for there to be a finding that a controlling stockholder exists.” *In re Tesla Motors, Inc. S’holder Litig.*, C.A. No. 12711-VCS, 2018 WL 1560293, at \*12-14 (Del. Ch. Mar. 28, 2018) (quoting *Kahn v. Lynch Commc’n Sys., Inc.*, 638 A.2d 1110, 1113-14 (Del. 1994) and *In re PNB Holding Co. S’holders Litig.*, C.A. No. 28-N, 2006 WL 2403999, at \*9 (Del. Ch. Aug. 18, 2006)). “Indeed, ‘[a]ctual control over business affairs may stem from sources extraneous to stock ownership.’” *Id.* (alteration in original) (quoting *In re Zhongpin Inc. S’holders Litig.*, C.A. No. 7393-VCN, 2014 WL 6735457, at \*6-7 (Del. Ch.

Nov. 26, 2014)). As discussed *supra* Part III.B.1, Biocon and its founder Ms. Mazumdar-Shaw have already exercised and continue to exercise significant control over the business affairs of Bicara, including through: (1) “relationships with particular directors [(such as Ms. Mazumdar-Shaw)] that compromise their disinterestedness or independence”; (2) “relationships with key managers or advisors [(such as Ms. Mazumdar-Shaw and Dr. Mazumdar)] who play a critical role in presenting options, providing information, and making recommendations”; (3) “commercial relationships that provide [Biocon] with leverage over the corporation, such as status as a key customer or supplier”; (4) “ownership of a significant equity stake (albeit less than a majority)”; and (5) “the ability to exercise outsized influence in the board room, such as through high-status roles like CEO, Chairman, or founder.” *Basho Techs. Holdco B, LLC v. Georgetown Basho Invs., LLC*, C.A. No. 11802-VCL, 2018 WL 3326693, at \*26-27 (Del. Ch. July 6, 2018) (providing examples indicative of actual or effective control).

The failure to identify all RPIs warrants denial of the Petition.

**C. JHU’s strong settled expectations favor denial.**

Generally, “the Office is disinclined to disturb the settled expectations of [a] Patent Owner.” *Dabico Airport Sols. Inc. v. Axa Power Aps*, No. IPR2025-00408, Paper 21 at 3 (Director June 18, 2025) (informative). “[T]here is no bright-line rule on when expectations become settled.” *Id.* “[T]he determination of whether to

exercise discretion to deny institution in each case is based on a holistic assessment of all the facts and circumstances.” *Dabico Airport Sols. Inc. v. Axa Power Aps*, No. IPR2025-00408, Paper 24 at 4 (Director Aug. 21, 2025). As discussed below, assessment of all relevant facts and circumstances weighs against disturbing JHU’s strong settled expectations.

**1. JHU’s settled expectations attach to the continuity chain of the ’968 patent’s family and weigh against institution.**

Although the ’968 patent was granted in 2025, in view of its ancestors, JHU has strong settled expectations concerning the ’968 patent. The relevant inquiry under § 324(a) is whether the public had a meaningful opportunity to evaluate, rely upon, and design around the claimed technology, not whether the challenged continuation issued recently. Allowing a late-stage challenge years into a continuity chain—a chain that Petitioner, Biocon, and Ms. Mazumdar-Shaw knew about for many years—would upset settled expectations and would not comport with the equity and resource-allocation rationale for instituting a post-grant challenge.

Strong evidence that settled expectations attached early in the continuity chain of the ’968 patent comes from the Office itself. During prosecution of the ’968 patent, the Office issued a double patenting rejection based on claims in U.S. Patent No. 9,441,044 (“’044 patent”), which issued in 2016. EX2010 at 9. Specifically, the examiner stated that “[a]lthough the claims at issue are not

identical, they are not patentably distinct from each other.” *Id.* JHU filed a terminal disclaimer to overcome the examiner’s rejection. EX2011 at 1. Neither Biocon nor Bicara has ever challenged the claims of the ’044 patent.

The examiner’s double patenting rejection has a direct and significant consequence for the settled expectations analysis. Because the Office determined the ’968 patent’s claims are not patentably distinct from earlier-issued claims, the ’968 patent does not represent a late-stage deviation in claim scope. On the contrary, the public-facing scope of the family’s claims (i.e., what competitors would assess, attempt to design around, and litigate) was established no later than the 2016 issuance of the ’044 patent—about a decade before the Petition was filed.

The ’968 patent follows routine and predictable continuation practice: refining claims based on the original disclosure. Moreover, Biocon knew about the ’968 patent’s family as early as 2010, understood the scope of the ’789 Bedi IP, crafted Bicara’s business and product to be within the scope of the ’968 family, and proceeded for over a decade before challenging the patent family in the US. See *infra* Section III.C.3 (explaining Biocon’s efforts to first license the ’789 Bedi IP and then subsequent efforts to claim inventorship over those same inventions when its licensing efforts failed). This confirms the settled expectations that attached to this stable, publicly available patent family. Bicara fails to justify expending Office resources to upend such expectations.

**2. Significant investments in the '789 Bedi IP establish settled expectations.**

Settled expectations due to significant investments in the '789 Bedi IP should also foreclose review. *Amgen, Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 at 2 (Director July 24, 2025) (informative). JHU and its exclusive licensee, Y-Trap, have collectively invested years and millions of dollars, including federal funding, into the research and development of the robust platform and products relating to the '789 Bedi IP. *See, e.g.*, EX2023 at 1 (estimating that Y-Trap has raised over \$27 million); EX2024 at 2 (listing NIH funding, including grants for “Using Targeted Immunotherapy to Enhance Chemotherapy of Colorectal Cancer”). These investments have led to preclinical and in vivo studies of certain molecules within the '789 Bedi IP and clinical trials beginning this year for related molecules.

**3. Biocon’s prior conduct should foreclose review.**

Biocon’s conduct in attempting to license and then claim inventorship of the '968 patent should also foreclose review. *See L’Oreal USA, Inc. v. Brightex Bio-Photonics, LLC*, IPR2025-00971, Paper 13 at 2 (Director Sept. 26, 2025) (that the Petitioner was informed of the provisional application leading to the challenged patent and therefore had notice of the patent for a significant period of time favored denial); *Microsoft Corp. v. TS-Optics Corp.*, IPR2025-00767, Paper 13

(Director Aug. 14, 2025) (“Absent exceptional circumstances, it is not an efficient use of Board resources where a party licensed the challenged patent, and then . . . advocates for the unpatentability of that same patent.”).

**Biocon attempted to license the ’789 Bedi IP:** As early as June 2010, after filing the first provisional application for the ’789 Bedi IP, Dr. Bedi disclosed his and Dr. Ravi’s inventions to Biocon employees so Biocon could evaluate a potential license to those inventions. *Y-Trap*, 2025 WL 2807694, at \*1. Dr. Bedi made these disclosures at the behest of Biocon and Ms. Mazumdar-Shaw, both of whom made every effort to secure a license. For example, between January and April 2012, Ms. Mazumdar-Shaw “repeatedly pressured Dr. Bedi to obtain a license” to the inventions for Biocon. EX2020, ¶ 31. Biocon’s attempts to obtain a license were unsuccessful, 2025 WL 2807694, at \*1, and Biocon (and its spin-off, Bicara) should not be heard now to argue that those inventions are invalid. On April 30, 2012, “Biocon filed a provisional patent application...of its own, claiming the same subject matter” as the ’789 Bedi IP. EX2020, ¶ 32.

Biocon attempted to interfere with JHU’s efforts to obtain patent protection for the ’789 Bedi IP, first in India and then in the US in 2025. Specifically, Biocon filed a pre-grant opposition in the Indian Patent Office to Patent Application 8417/CHENP/2012 on the basis of incorrect inventorship. *See Y-Trap*, 2025 WL 2807694, at \*2; EX2020, ¶ 48. JHU was not informed of the challenge by Biocon

or the Indian Patent Office until February 2022, when Biocon filed a Representation for Opposition at the Indian Patent Office and renewed its inventorship claims by urging the Indian Patent Office to act on its 2014 filing. EX2020, ¶¶ 49-50. Ultimately, in August 2024, the Indian Patent Office ruled that Biocon scientists had no inventive contribution to the '789 Bedi IP, rejected Biocon's opposition, and granted JHU's Indian patent application with Drs. Bedi and Ravi as sole inventors. *Y-Trap*, 2025 WL 2807694, at \*2; EX2020, ¶ 53.

In addition, after Y-Trap filed suit against Biocon and Bicara in October 2024, Biocon filed a counterclaim for Correction of Inventorship for the '789 Bedi IP Pursuant to 35 U.S.C. § 256, under which Biocon once again alleges that “employees of Biocon conceived of a portion of the significant features of the inventions claimed by the '789 Bedi IP and all related patents and patent applications” and “were under an obligation to assign any IP developed through the course of their employment to Biocon.” EX2018, ¶¶ 19, 21.

#### **4. Y-Trap's license enhances JHU's settled expectations.**

That Y-Trap took a license to the '968 patent's family enhances JHU's settled expectations in the '968 patent. *Alliance Laundry Sys., LLC v. PayRange LLC*, IPR2025-00950, Paper 11 at 3 (Director Sept. 19, 2025) (informative) (“[A]lthough the challenged patent has not been in force for a significant period of

time (issued in 2021), Patent Owner presents evidence that it has licensed the challenged patent, which creates some settled expectations favoring [it].”).

**D. Domestic economic, public health, and national security interests weigh in favor of discretionary denial.**

Considerations of “[c]ompelling economic, public health, or national security interests” are relevant to the discretionary denial analysis. Interim Processes Memo, dated March 26, 2025 at 2. Here, compelling economic public health, and national security interests favor denying institution.

As noted earlier, Bicara was formed as a wholly-owned subsidiary of an India corporation and was incorporated in the US for the purpose of obtaining funding from American investors. *See supra* Part III.B.1; EX2005 at 16 (21:22). While Bicara may be funded by American investors (EX2005 at 16 (21:22)), Bicara outsources its manufacturing to India (*id.* at 17 (21:57); EX2022 at 2 (“The company’s manufacturing and research operations are concentrated in India.”)).

On the other hand, JHU has strong ties to the US. JHU is a premier academic and research institution located in Baltimore, Maryland, and was America’s first research university. EX2012 at 3, 5. According to an independent analysis for the 2024 fiscal year, The Johns Hopkins University and The Johns Hopkins Health System (collectively, “Johns Hopkins”) is Maryland’s largest private employer and, “[a]cross Maryland, its annual operations support approximately 149,000 jobs and

contribute over \$40 billion in total economic activity.” EX2013 at 5. As of 2026, there are over 600 “leading researchers” affiliated with Johns Hopkins, including “154 featured in the ranking of top researchers,” according to “a leading educational platform.” EX2014 at 10; EX2015 at 1. Twenty-nine Nobel Prize winners have been associated with Johns Hopkins over the years, along with MacArthur fellows, Presidential honorees, National Academies members, and Academy of Arts and Sciences members. EX2012 at 7; EX2013 at 9. To further its mission, JHU “strives to support its faculty and employees in securing commercial development of intellectual and other property resulting from their research.” EX2016 at 1. In fiscal year 2024, Johns Hopkins had 5,392 active patents. EX2013 at 67. “The[se] active patents held by Johns Hopkins today could become lifesaving medical devices and therapeutic treatments tomorrow.” EX2012 at 13.

Indeed, the challenged patent is one such patent. As explained earlier, the challenged patent has been exclusively licensed to Y-Trap, who has developed multiple fusion proteins of the ’789 Bedi IP, including but not limited to EGFR/TGF $\beta$ -binding fusion proteins, PDL1/TGF $\beta$ -binding fusion proteins, and PD1/VEGF-binding fusion proteins. *See generally* EX2017 at 3 (noting that Y-Trap “is developing the Y-trap technology platform”).

Not discretionarily denying the Petition would allow foreign interests—in the vehicle of a weak petition that harasses JHU and would tax the Board’s limited

resources—to trump domestic economic, public health, and national security interests served by JHU’s research and development activities, which benefit patients and communities through partnerships with other businesses based on the university’s patented innovations. Indeed, the patents JHU duly obtains allow JHU to collaborate with businesses and are important to JHU’s ongoing innovation.

**E. The Petition should be denied because of unexplained and inconsistent positions in the parallel litigation.**

“[W]hen a petitioner advances different positions before the Board and a district court, that petitioner is *required* to explain why those different positions are warranted.” *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper 18 at 3 (Director Nov. 5, 2025) (informative). Petitioner Bicara and RPI Biocon have taken different positions before the Board and the district court in the Y-Trap litigation.

In this PGR, the Petition asserts that all claims of the ’968 patent are unpatentable (i.e., invalid) because the subject matter of those claims lacks written description support and enablement in the specification of the ’968 patent. *E.g.*, Pet. at 1. In contrast, Bicara’s position concerning inventorship before the district court, which is not disclosed in the Petition,<sup>1</sup> is different. There, Bicara asserts that

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<sup>1</sup> The Petition at 92 notes Biocon’s counterclaim regarding correction of inventorship, but fails to inform the Board of Bicara’s position.

Biocon has inventorship of the '968 patent. Specifically, in its Amended Answer, Bicara claims that: (1) the '789 Bedi IP do not accurately list their inventors, and (2) Biocon and its employees in fact invented the subject matter of the '789 Bedi IP claimed in the '789 Bedi IP, including the '968 patent. *See, e.g.*, EX2018, ¶ 28 (denying “no Biocon scientist could have made any inventive contributions to the[] [Bedi-Ravi] patent applications”), ¶ 36 (denying “sole inventor of the '247 patent is Dr. Bedi, and more generally, Dr. Bedi or Drs. Ravi and Bedi are the inventors of all other patents in the Copycat Biocon IP”), ¶ 47 (denying “Bicara was undoubtedly aware that Biocon had copied BCA101 from the '789 Bedi IP”).

These positions are inconsistent because seeking correction of inventorship for the '968 patent is futile if the allegations in the Petition are true, as there would be no valid claims for which Biocon personnel could be named as an inventor.

Alternatively, if the claim for inventorship succeeds in the district court, there is no doubt that Biocon as the patent owner and Bicara as the Petitioner would quickly move to terminate this PGR, resulting in a waste of the Board's limited resources. Petitioner fails to explain these inconsistent positions. The Director should exercise his discretion to deny this Petition in light of Bicara's inconsistent positions and gamesmanship.

#### **IV. CONCLUSION**

Respectfully, the Director should grant this request for discretionary denial.

PGR2026-00025  
U.S. Patent No. 12,295,968

Date: April 17, 2026

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies pursuant to 37 C.F.R. §§ 42.6(e) and 42.105 that on April 17, 2026, a true and correct copy of Patent Owner's Request for Discretionary Denial was served by emailing a copy of same by agreement to the following attorneys for the Petitioner:

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