

Filed on behalf of: Janssen Biotech, Inc.

Entered: May 27, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACCORD BIOPHARMA, INC., INTAS PHARMACEUTICALS LTD., AND
BIO-THERA SOLUTIONS, LTD.,
Petitioner,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

IPR2026-00258
Patent No. 12,122,824

PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	FACTUAL BACKGROUND.....	2
	A. Janssen's Simponi Aria Product.....	2
	B. The '824 Patent (Ex. 1003)	2
	C. Petitioners' Biosimilar Product	3
III.	INSTITUTION SHOULD BE DENIED TO PROTECT INVESTMENTS IN U.S. MANUFACTURING	3
	A. Simponi Aria Is Manufactured in Significant Part in the United States.....	4
	B. Petitioners Manufacture BAT2506 in China.....	6
	C. Petitioners Are Not Small Businesses.....	6
IV.	INSTITUTION SHOULD BE DENIED TO PROTECT U.S. INTERESTS	6
	A. Chinese Government Ties Warrant Denial of the Petition	6
	B. The Petition Improperly Promotes Petitioners' "Made in China" Agenda.....	8
V.	INSTITUTION SHOULD BE DENIED TO PROTECT JANSSEN'S STRONG SETTLED EXPECTATIONS	9
	A. Janssen Made Substantial Investments Based on Its Settled Expectations	9
	B. The Untimely Petition Undermines Janssen's Legitimate Settled Expectations	11
VI.	THE PETITION SHOULD BE DENIED UNDER § 325(d)	13
	A. <i>Advanced Bionics</i> Step 1 (<i>Becton</i> Factors (a), (b), and (d)): Substantially the Same Art and Arguments Were Previously Presented to the Patent Office	13

B.	<i>Advanced Bionics</i> Step 2 (<i>Becton</i> Factors (c), (e), and (f)): Petitioners Failed to Identify Any Material Error	17
VII.	THE PETITION'S WEAK MERITS WARRANT DENIAL	18
VIII.	CONCLUSION.....	20

TABLE OF AUTHORITIES**Page(s)****CASES**

<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential)	13, 17
<i>Allergan Sales, LLC v. Sandoz, Inc.,</i> 935 F.3d 1370 (Fed. Cir. 2019)	18
<i>Amgen Inc. v. Bristol-Myers Squibb Co.,</i> IPR2025-00603, Paper 8 (P.T.A.B. July 24, 2025) (informative).....	11
<i>Ascentcare Dental Prods., Inc. v. Solmetex, LLC,</i> IPR2025-01065, Paper 11 (P.T.A.B. Oct. 17, 2025).....	16
<i>Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.,</i> IPR2014-00440, Paper 68 (P.T.A.B. Aug. 18, 2015) (precedential)	7
<i>Dabico Airport Sols. Inc. v. AZA Power APS,</i> IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025) (informative).....	13
<i>Ecto World, LLC v. RAI Strategic Holdings, Inc.,</i> IPR2024-01280, Paper 13 (P.T.A.B. May 19, 2025) (precedential).....	14, 17
<i>Eli Lilly & Co. v. Teva Pharms. Int'l GmbH,</i> 8 F.4th 1331 (Fed. Cir. 2021)	19
<i>Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.,</i> IPR2025-01024, Paper 15 (P.T.A.B. Oct. 10, 2025).....	11, 16
<i>Magnolia Med. Techs., Inc. v. Kurin, Inc.,</i> IPR2026-00097, Paper 17 (P.T.A.B. May 14, 2026) (precedential).....	<i>passim</i>
<i>Microsoft Corp. v. SandPiper CDN, LLC,</i> IPR2026-00180, Paper 15 (P.T.A.B. May 6, 2026)	15
<i>Return Mail, Inc. v. United States Postal Service,</i> 587 U.S. 618 (2019).....	6

<i>Tanklogix, LLC v. SitePro, Inc.</i> , IPR2025-00761, Paper 10 (P.T.A.B. Sept. 3, 2025).....	16
<i>Tianma Microelectronics Co. v. LG Display Co.</i> , IPR2025-01579, Paper 12 (P.T.A.B. Mar. 18, 2026) (precedential).....	6, 7, 8
<i>Transclean Corp. v. Bridgewood Servs., Inc.</i> , 290 F.3d 1364 (Fed. Cir. 2002)	19
<i>Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.</i> , 97 F.4th 882 (Fed. Cir. 2024)	19

STATUTES

15 U.S.C. § 78m(d)(1)	7
35 U.S.C. § 316(b)	5
§ 325(d)	2, 13, 16
42 U.S.C. § 262(i)(3)	8
§ 262(l)(3)(B)(ii)(I)	12

REGULATIONS

37 C.F.R. § 42.4(a)	13
§ 42.104(b)(4)	19

EXHIBIT LIST

Exhibit	Description
2001	Prosecution History for U.S. Patent No. 11,041,020 B2 (“’020 Patent PH”) (EXCERPT)
2002	Prosecution History for U.S. Patent No. 12,122,824 B2 (“’824 Patent PH”) (EXCERPT)
2003	U.S. Patent Application Publication No. US 2021/0277104 A1 (“104 Publication”)
2004	RESERVED
2005	Proposed Protective Order
2006	Proposed Protective Order Redline
2007– 2011	RESERVED
2012	Press Release, Johnson & Johnson, Johnson & Johnson to Break Ground on New State-of-The-Art Biologics Facility in North Carolina to Deliver Market-Leading Portfolio of Transformational Therapies (Mar. 21, 2025), https://www.jnj.com/media-center/press-releases/johnson-johnson-to-break-ground-on-new-state-of-the-art-biologics-facility-in-north-carolina-to-deliver-market-leading-portfolio-of-transformational-therapies (“J&J 3/21/2025 Press Release”)
2013	Press Release, Johnson & Johnson, Johnson & Johnson Reaches Agreement with U.S. Government to Improve Access to Medicines and Lower Costs for Millions of Americans; Delivers on U.S. Manufacturing and Innovation Investments (Jan. 8, 2026), https://www.jnj.com/media-center/press-releases/johnson-johnson-reaches-agreement-with-u-s-government-to-improve-access-to-medicines-and-lower-costs-for-millions-of-americans-delivers-on-u-s-manufacturing-and-innovation-investments (“J&J 1/8/2026 Press Release”)

Exhibit	Description
2014	FDA, SIMPONI ARIA [®] (Golimumab) Prescribing Information (revised Apr. 2025), https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf (“SIMPONI ARIA [®] FDA Label”)
2015	Bio-Thera Solutions, Ltd., 2019 Annual Report (Chinese)
2016	English Translation and Certificate of Translation of an excerpt of Exhibit 2015 (Bio-Thera Solutions, Ltd., 2019 Annual Report) (“Bio-Thera 2019 Ann. Rep.”)
2017	Bio-Thera Solutions, Ltd., 2020 Annual Report (Chinese)
2018	English Translation and Certificate of Translation of an excerpt of Exhibit 2017 (Bio-Thera Solutions, Ltd., 2020 Annual Report) (“Bio-Thera 2020 Ann. Rep.”)
2019	Bio-Thera Solutions, Ltd., 2021 Annual Report (Chinese)
2020	English Translation and Certificate of Translation of an excerpt of Exhibit 2019 (Bio-Thera Solutions, Ltd., 2021 Annual Report) (“Bio-Thera 2021 Ann. Rep.”)
2021	Bio-Thera Solutions, Ltd., 2024 Annual Report (Chinese)
2022	English Translation and Certificate of Translation of an excerpt of Exhibit 2021 (Bio-Thera Solutions, Ltd., 2024 Annual Report) (“Bio-Thera 2024 Ann. Rep.”)
2023	Bio-Thera Solutions, Ltd., 2025 Semi-Annual Report (Chinese)
2024	English Translation and Certificate of Translation of an excerpt of Exhibit 2023 (Bio-Thera Solutions, Ltd., 2025 Semi-Annual Report) (“Bio-Thera 2025 Semi-Ann. Rep.”)
2025	RESERVED
2026	Factset Research Systems Inc., FactSet Entity Data Management: Accord BioPharma, Inc. (0TBGSZ-E) - Subsidiary (Apr. 2, 2026) (“Accord Entity Data”)

Exhibit	Description
2027	PitchBook Data, Inc., Intas Pharmaceuticals Private Company Profile (Mar. 16, 2026) (“Intas Pharms. Profile”)
2028	Company News, Bio-Thera Solutions, Ltd., Bio-Thera Solutions Announces Further Expansion of Partnership with Intas Pharmaceuticals for BAT2506, a Proposed Biosimilar Referencing Simponi® (Golimumab), Through Exclusive Commercialization and License Agreement in India (Mar. 23, 2026), https://www.bio-thera.com/col_62/1390.html (“Bio-Thera 3/23/2026 News”)
2029– 2030	RESERVED
2031	<i>The Chinese Government’s Evolving Control of The Nonstate Sector: Rep. to Cong. of the U.S.-China Econ. & Sec. Rev. Comm’n</i> , 117th Cong. 214–239 (Nov. 2021), https://www.uscc.gov/sites/default/files/2021-11/Chapter_2_Section_3--Chinese_Governments_Evolving_Control_of_the_Nonstate_Sector.pdf (“2021 Cong. Rep.”)
2032	RESERVED
2033	Memorandum from the Acting Under Sec’y of Com. for Intell. Prop. & Acting Dir. of the USPTO to Members of the P.T.A.B. (July 31, 2025), https://www.uspto.gov/sites/default/files/documents/aapa_memo_final__signed.pdf (“7/31/2025 Acting Dir. Mem.”)
2034	Memorandum from the Under Sec’y of Com. for Intell. Prop. & Dir. of the USPTO to All P.T.A.B. Users (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 (“3/11/2026 Dir. Mem.”)
2035	RESERVED

Exhibit	Description
2036	Tomas Gabriel Bas, <i>Innovative Formulation Strategies for Biosimilars: Trends Focused on Buffer-Free Systems, Safety, Regulatory Alignment, and Intellectual Property Challenges</i> , 18 PHARMS. 908 (2025) (“Bas (2025)”)
2037	Max Beauroyre, <i>Clinical-Trial Costing 101: Building a Phase-by-Phase Budget Your Board Will Trust</i> , ABACUM (June 25, 2025), https://www.abacum.ai/blog/clinical-trial-costing (“Beauroyre (2025)”)
2038	Marc D. Cohen & Edward C. Keystone, <i>Intravenous Golimumab in Rheumatoid Arthritis</i> , EXPERT REV. CLINICAL IMMUNOLOGY 1–8 (2014) (“Cohen (2014)”)
2039	RESERVED
2040	Hirotaka Nonaka, FTO (FREEDOM TO OPERATE) IN THE PHARMACEUTICAL INDUSTRY 16–33 (MIPLC Studies Vol. 34, 1st ed. 2018), https://www.jstor.org/content/oa_chapter_monograph/j.ctv941tn6.5?seq=1 (“Nonaka (2018)”) (EXCERPT)
2041– 2042	RESERVED
2043	Qichacha (QCC), Bio-Thera Solutions, Ltd. Enterprise Credit Report (Chinese)
2044	English Translation and Certificate of Translation of an excerpt of Exhibit 2043 (Qichacha (QCC) Report, Bio-Thera Solutions, Ltd. Enterprise Credit Report Professional Edition, Report No. 1775619203666287 Report Verification No.: sq0MJfAi (Apr. 8, 2026, 11:33:51 a.m.)) (“Bio-Thera Credit Rep.”)
2045	Qichacha (QCC), Bio-Thera Solutions, Ltd. Partnership Chart (Chinese)

Exhibit	Description
2046	English Translation and Certificate of Translation of an excerpt of Exhibit 2045 (Qichacha (QCC) Report, Bio-Thera Solutions Ltd. w-Guangzhou Zhongke Yuechuang No. 3 Venture Capital Partnership (Apr. 8, 2026)) (“Bio-Thera Partnership Rep.”)
2047	Press Release, N.C. Off. of Governor Josh Stein, Governor Stein Announces Johnson & Johnson Will Build Second Major Facility in Wilson County (Jan. 9, 2026), https://governor.nc.gov/news/press-releases/2026/01/09/governor-stein-announcesjohnson-johnson-will-build-second-major-facility-wilson-county (“N.C. Gov. Press Release”)
2048	RESERVED
2049	Nat’l Inst. of Health, Nat’l Lib. of Med., <i>History of Changes for Study: NCT02181673, A Study of Golimumab in Participants With Active Psoriatic Arthritis</i> , ClinicalTrials.gov archive (latest version submitted Dec. 20, 2017), https://clinicaltrials.gov/ct2/history/NCT02181673?V_30=View#StudyPageTop (last visited Feb. 12, 2020, 15:27) (“NCT02181673 Study History”)
2050	Press Release, Accord BioPharma, FDA Approves IMMGOLIS™ (golimumab-sldi) and IMMGOLIS INTRI™ (golimumab-sldi), First Biosimilars to Simponi® (golimumab) and Simponi Aria® (golimumab); Accord BioPharma to Lead U.S. Commercialization (5/18/2026, 12:05 ET), https://www.accordbiopharma.com/news/fda-approves-immgol-is-golimumab-sldi-and-immgol-is-intri-golimumab-sldi-first-biosimilars-to-simponi-golimumab-and-simponi-aria-golimumab-accord-biopharma-to-lead/ (“Accord 5/18/2026 Press Release”)
2051	Memorandum from the Under Sec’y of Com. for Intell. Prop. & Dir. of the USPTO to All P.T.A.B. Judges (Oct. 28, 2025), https://www.uspto.gov/sites/default/files/documents/Precedential_designation_of_Corning_Optical_Communications_RF_LLC_v._PPC_Broadband_Inc_Memo_-_Dated_10_28_25.pdf (“10/28/2025 Dir. Mem.”)

Exhibit	Description
2052– 2499	RESERVED
2500	Declaration of Ann Donlon (“Donlon Decl.”) (HC-AEO MATERIAL AND REDACTED VERSIONS)
2501	Declaration of Luke Brennan (“Brennan Decl.”) (HC-AEO MATERIAL AND REDACTED VERSIONS)
2502	Declaration of Thao Marzullo (“Marzullo Decl.”) (HC-AEO MATERIAL AND REDACTED VERSIONS)

I. INTRODUCTION

Patent Owner Janssen Biotech, Inc. (“Janssen”) respectfully requests that the Director deny the Petition filed by Accord BioPharma, Inc. (“Accord”), Intas Pharmaceuticals Ltd. (“Intas”), and Bio-Thera Solutions, Ltd. (“Bio-Thera”) (collectively, “Petitioners”) challenging U.S. Patent No. 12,122,824 (the “’824 Patent”). The Petition should be denied for at least five reasons.

First, Janssen has made and continues to make substantial investments in the United States to manufacture and supply innovative patented medicines, including SIMPONI ARIA[®]. Petitioners seek to produce a biosimilar version in China, in place of Janssen. Institution of the proceeding would conflict with the Office’s interest to protect American manufacturing.

Second, Bio-Thera has ties to the Chinese government and it will produce its product in China as part of a “Made in China” initiative. The Office should not invest resources to bolster China’s national interests at the expense of Janssen, an American company.

Third, Janssen has strong, settled expectations. Petitioners have known of the parent patent of the ’824 Patent for over five years, and then waited an additional year where they could have challenged the ’824 Patent by PGR or IPR. During that time, Janssen invested heavily in clinical studies, regulatory approval, and the

commercialization of Simponi Aria, which practices the claims of the '824 Patent. The Office should not expend resources on this belated challenge.

Fourth, denial is warranted under 35 U.S.C. § 325(d) because Petitioners recycle prior art and arguments already presented to the Office during prosecution. All grounds rely on NCT673-V23, which summarizes a clinical trial disclosed to and considered by the Examiner, who did not materially err in allowing the claims.

Finally, the Petition's merits are weak, as will be explained in Janssen's forthcoming Preliminary Response. Instituting review would be an unjustified use of the Office's resources. The Director should deny institution.

II. FACTUAL BACKGROUND

A. Janssen's Simponi Aria Product

Janssen, a subsidiary of Johnson & Johnson ("J&J"), is a research-based biopharmaceutical company based in Horsham, Pennsylvania. Janssen pioneered biologic therapies for immune-mediated diseases, including tumor necrosis factor-alpha (TNF- α) inhibitors such as Simponi Aria (golimumab).

Simponi Aria is an intravenous monoclonal antibody used to treat serious autoimmune diseases. Janssen has invested heavily to establish its safety and efficacy across multiple indications, and to bring this important medicine to patients.

B. The '824 Patent (Ex. 1003)

Psoriatic arthritis (PsA) is a debilitating, chronic, immune-mediated inflammatory disease associated with psoriasis. Without appropriate treatment, it

can result in progressive and permanent joint damage. Ex. 1003, 83:21-34. The '824 Patent claims intravenously administering golimumab to treat active PsA to improve key clinical outcome measures. *Id.* 139:13-55. The '824 Patent covers Simponi Aria for its labeled indication. Ex. 2014.

Janssen filed the original application leading to the '824 Patent in 2017, and it published on September 9, 2021, as US 2021/0277104 A1 (the "104 Publication"). Ex. 2003. The '824 Patent issued on October 22, 2024. Ex. 1003.

C. Petitioners' Biosimilar Product

Bio-Thera is a biosimilar manufacturer based in Guangzhou, China that is indirectly owned in part by the Chinese government. Compl. for Pat. Infringement [Redacted] ¶ 9, *Janssen Biotech, Inc. v. Accord BioPharma, Inc.*, No. 1:26-cv-00222 (D. Del. Mar. 11, 2026), Dkt. No. 10; *see infra* Section IV.A. Intas is an Indian pharmaceutical company based in Ahmedabad, India. Ex. 2027, -002. Intas wholly owns Accord. Ex. 2026.

Petitioners are developing BAT2506, a biosimilar version of Simponi Aria using the same active molecule (golimumab) and dosage regimens to treat the same diseases. Ex. 2028.

III. INSTITUTION SHOULD BE DENIED TO PROTECT INVESTMENTS IN U.S. MANUFACTURING

The Office should "appropriately weigh[] the interest of entities that invest in domestic production" when exercising its discretion on institution. Ex. 2034, -002.

Inter partes review “should not be used by foreign adversaries to harass American patentees.” Ex. 2051, -004. Here, Janssen has made extraordinary investments to develop and commercialize the patented technology. The Petition seeks to provide a commercial advantage to foreign companies—including one partially owned by the Chinese government—enabling them to offshore production of a medicine vital to American patients. That is not a proper use of inter partes review.

Director Squires’ Memorandum issued March 11, 2026, identifies three considerations for discretionary denial: (1) the extent to which the patent owner’s products are manufactured in the United States; (2) the extent to which the petitioner’s competing products are manufactured in the United States; and (3) whether the petitioner is a small business. Ex. 2034, -002; *see also Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 7-8 (P.T.A.B. May 14, 2026) (precedential). All three favor denial.

A. Simponi Aria Is Manufactured in Significant Part in the United States

Simponi Aria was developed by Janssen, a Pennsylvania-based biopharmaceutical company. Ex. 2014, -010. It is a complex biologic drug manufactured by culturing genetically modified cells specially programmed to produce the active ingredient in the medicine. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Janssen continues making substantial investments in U.S. manufacturing for Simponi Aria[®] and other drugs. In early 2026, J&J announced the third of its multi-billion-dollar investments, including a major drug product manufacturing facility in North Carolina (the “Wilson facility”). Ex. 2013; *see also* Ex. 2047. J&J made this investment to answer “President Trump’s call to lower drug prices for everyday Americans while maintaining our role in improving and saving lives and ensuring that the United States continues to lead the world in healthcare innovation.” Ex. 2013, -002. The Wilson facility represents an over \$2 billion investment in U.S. manufacturing. Ex. 2500 (Donlon Decl.) ¶ 4. The project is expected to create up to 500 new jobs at the facility. *Id.* The Wilson facility is part of J&J’s broader plan to invest more than \$55 billion in U.S. research and development, technology, and manufacturing over four years. *Id.* ¶ 5; Ex. 2012, -002.

Janssen’s substantial U.S. manufacturing investments depend on its ability to protect its intellectual property. The Petition seeks to undermine those investments in favor of foreign manufacturing. Discretionary denial best aligns the Office’s resources with its mission to protect the U.S. economy. *See* 35 U.S.C. § 316(b).

B. Petitioners Manufacture BAT2506 in China

Petitioners admit BAT2506 will be manufactured in China. Ex. 2024, -006. Bio-Thera touts its product as part of a “Made in China” initiative. Ex. 2022, -009; *see also infra* Section IV.B.

C. Petitioners Are Not Small Businesses

The final consideration in Director Squires’ March 11, 2026 Memorandum is whether Petitioners qualify as small businesses. Ex. 2034, -002; *see also Magnolia*, IPR2026-00097, Paper 17 at 4-6. They do not. They are large, well-funded Chinese and Indian corporations. Bio-Thera has over 1,000 employees. Ex. 2024, -006. Intas has over 22,000 employees. Ex. 2027, -001. Accord is a subsidiary of Intas. Ex. 2026. This consideration also favors discretionary denial.

IV. INSTITUTION SHOULD BE DENIED TO PROTECT U.S. INTERESTS**A. Chinese Government Ties Warrant Denial of the Petition**

The Petition should also be denied under *Return Mail, Inc. v. United States Postal Service*, 587 U.S. 618 (2019), because the Chinese government controls Petitioner Bio-Thera through its major shareholder. At minimum, the Chinese government’s influence over Bio-Thera warrants discretionary denial. *Tianma Microelectronics Co. v. LG Display Co.*, IPR2025-01579, Paper 12 at 7 (P.T.A.B. Mar. 18, 2026) (precedential); *see also Magnolia*, IPR2026-00097, Paper 17 at 5-6, 8.

Assets Supervision and Administration Commission of Guangzhou Municipal Government (“Assets Supervision”), an arm of the Chinese government, controls and owns 25% of Guangzhou Zhongke Yuechuang No.3 Venture Capital Partnership, which in turn is a major shareholder of Bio-Thera.¹ Ex. 2046; Ex. 2044, -008. As a government owner, Assets Supervision holds “privileged status in the governance of any corporation for which it is a shareholder, regardless of its ownership stake.” Ex. 2031, -014.

Assets Supervision’s “privileged status” as a government owner provides control over IPR proceedings, making it a real party-in-interest (“RPI”). *Corning Optical Commc’ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 at 14-15 (P.T.A.B. Aug. 18, 2015) (precedential). When a foreign government is an RPI, institution must be denied because it is not a “person” under the America Invents Act (“AIA”). *Tianma*, IPR2025-01579, Paper 12 at 4-5.

The Petition also should be denied as a matter of discretion in light of the Chinese government’s influence over Bio-Thera. Foreign government involvement in IPR proceedings is contrary to U.S. interests because “foreign state actors have

¹ Guangzhou Zhongke holds a 5.15% stake in Bio-Thera. Ex. 2044, -008. That exceeds the 5% threshold that would apply to a major shareholder in the U.S. for reporting purposes under 15 U.S.C. § 78m(d)(1).

sought to manipulate U.S. IP systems, including administrative challenges before the PTAB, to weaken or misappropriate U.S. technological leadership.” *Id.* at 6 (citation omitted). Denying institution here “would be comfortably within the Office’s settled broad discretion in deciding whether to use its limited resources to institute IPR in any given case.” *Id.* at 7 (citation omitted); *Magnolia*, IPR2026-00097, Paper 17 at 8.

B. The Petition Improperly Promotes Petitioners’ “Made in China” Agenda

Petitioners challenge Janssen’s patents to clear the way to supply golimumab from China. *See supra* Section III.B. Indeed, Petitioners obtained an “interchangeable” designation for their product (Ex. 2050, -002), permitting substitution for Janssen’s medication without a doctor’s approval. 42 U.S.C. § 262(i)(3).

Bio-Thera manufactures biologic drugs in China to advance the Chinese pharmaceutical industry, as Bio-Thera explained in its annual report:

“Made in China 2025” identifies the development of pharmaceutical manufacturing as one of the ten key areas for building a strong manufacturing nation.... [A]ctively fostering new growth engines such as biomanufacturing, and opening up new tracks like life sciences [is] part of the [Chinese] government’s tasks for 2024. This signifies that China will prioritize the strategic development of the biopharmaceutical, biomanufacturing, and life sciences industries.

Ex. 2022, -009; *see also id.* -012 (Bio-Thera's "goal is to enable China's independently developed and produced biological drugs to enter domestic and overseas markets[.]").

Petitioners seek to supplant Simponi Aria with a Chinese-sourced biosimilar in order to promote a "Made in China" agenda. The Director has recognized that such foreign manufacturing is counter to American interests and may undermine America's leadership in innovation. Ex. 2034, -001. Proceedings should not be used as a way to provide a "tactical advantage to companies that neither manufacture in the United States nor make American manufacturing investments." *Magnolia*, IPR2026-00097, Paper 17 at 7.

V. INSTITUTION SHOULD BE DENIED TO PROTECT JANSSEN'S STRONG SETTLED EXPECTATIONS

A. Janssen Made Substantial Investments Based on Its Settled Expectations

Nearly five years have passed since the application that led to the '824 Patent published on September 9, 2021, with claims covering the same products as those that ultimately issued. *Compare* Ex. 2003 (104 Publication), claims, *with* Ex. 1003 ('824 Patent), claims. Nearly five years have also passed since the parent of the '824 Patent, the '020 Patent, issued on June 22, 2021. Ex. 1001 ('020 Patent).

Janssen made substantial investments in reliance on its settled expectations. Before the '824 Patent issued, Janssen invested over [REDACTED] to design and

conduct the pivotal GO-VIBRANT clinical study, a Phase III randomized trial evaluating safety and efficacy of intravenous golimumab for PsA. Ex. 2501 (Brennan Decl.) ¶ 6. This trial was particularly resource-intensive, with per-patient costs exceeding [REDACTED]—substantially higher than typical clinical trials. *Id.*; Ex. 2037, -003. Janssen also invested approximately [REDACTED] to obtain regulatory approvals of the patented method. Ex. 2501 (Brennan Decl.) ¶ 8.

Janssen continued making significant investments in Simponi Aria after the '824 Patent issued. Janssen has spent approximately [REDACTED] between 2021 and 2025 to support marketing and sales of Simponi Aria. Ex. 2502 (Marzullo Decl.) ¶ 5. Janssen also funds patient support programs—including infusion center locator assistance, co-pay assistance, treatment and education services, and insurance and affordability support—to help patients access Simponi Aria for their autoimmune diseases, including PsA, as claimed. *Id.* ¶ 6. Janssen has invested approximately [REDACTED] between 2021 and 2025 in patient support programs. *Id.*

Janssen continues investing in clinical trials to further develop treatments with Simponi Aria. For example, it invested over [REDACTED] (over \$118,000 per patient), in a Phase III clinical study evaluating intravenous golimumab therapy in pediatric PsA patients. Ex. 2501 (Brennan Decl.) ¶ 7.

Finally, Janssen is investing aggressively in domestic manufacturing capacity for Simponi Aria. It has committed over \$2 billion to construct a state-of-the-art

manufacturing facility in North Carolina for [REDACTED] and other biologic medicines. *See supra* Section III.A.

Janssen's extensive investments, both before and after the '824 Patent, establish its settled expectations. Although no bright-line rule governs the required investment or passage of time, Janssen's extraordinary expenditures leave no doubt on that score. *See Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00603, Paper 8 at 2 (P.T.A.B. July 24, 2025) (informative) ("there may be good reasons why a patent owner has strong settled expectations in a patent that has only been in force for three years, for example an explanation of how an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations"); *Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, IPR2025-01024, Paper 15 at 2 (P.T.A.B. Oct. 10, 2025) ("Further, Patent Owner explains that it has made, and continues to make, substantial investments of time, money, and resources in the research, development, and commercialization of drugs which embody the claimed invention."). The Petition should be denied to protect Janssen's settled expectations.

B. The Untimely Petition Undermines Janssen's Legitimate Settled Expectations

Petitioners' role as biosimilar developers made them keenly aware of Janssen's long-standing patent rights. Innovative biologic medicines like Simponi Aria require substantial investment to develop and are protected by extensive patent

portfolios. Biosimilar developers must therefore thoroughly assess existing patents and published applications. “Conducting a comprehensive patent landscape analysis is integral to this process[.]” Ex. 2036, -036; *see also* Ex. 2040, -008 (“it is absolutely indispensable for a pharmaceutical company to carry out intensive research on the [freedom to operate] analysis from the very early stage of its R&D”). Bio-Thera recognized that third-party patent rights bear directly on its biosimilar development efforts. Ex. 2016, -012 (“Biosimilars are copies of originator drugs and can only be approved after the originator drug’s patent protection expires.”); Ex. 2020, -012 (“The company’s commercial success depends partly on ... operat[ing] its business without infringing, misappropriating, or otherwise violating the valid and enforceable intellectual property rights of third parties.”). Petitioners knew from the outset that the statutory framework governing biosimilar approval requires them to fully assess any potentially relevant patents. *See* 42 U.S.C. § 262(l)(3)(B)(ii)(I).

Petitioners had over six years to investigate Janssen’s patent rights on Simponi Aria for treating PsA. By 2019, Bio-Thera’s golimumab development program had reached the clinical trial stage. Ex. 2016, -015 (“BAT2506 started clinical trial application in January 2019 and received approval in April 2019.”). Shortly thereafter, Bio-Thera specifically identified the patent-protected indication (PsA) for its biosimilar product. Ex. 2018, -006 (“Specific Application Prospects ... PsA”);

Ex. 2020, -006 (“Specific Application Prospects RA, PsA, AS, UC, pJIA”). Petitioners were thus plainly on notice of Janssen’s patent rights. *See Dabico Airport Sols. Inc. v. AZA Power APS*, IPR2025-00408, Paper 21 at 3 (P.T.A.B. June 18, 2025) (informative). Petitioners’ delay in bringing this challenge is unjustified.

VI. THE PETITION SHOULD BE DENIED UNDER § 325(d)

Section 325(d) provides an additional basis for discretionary denial. The Director may decline to institute where the petition relies on the same or substantially the same prior art or arguments previously presented to the Office. 35 U.S.C. § 325(d); *see also* 37 C.F.R. § 42.4(a); *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (P.T.A.B. Feb. 13, 2020) (precedential). In such circumstances, institution is unwarranted absent a showing that the examiner materially erred. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8.

A. *Advanced Bionics* Step 1 (*Becton* Factors (a), (b), and (d)): Substantially the Same Art and Arguments Were Previously Presented to the Patent Office

The references and arguments in the Petition were considered and are cumulative of the art and arguments before the Examiner during prosecution. The Petition challenges the ’824 Patent on three grounds, all based on NCT673-V23 as the primary reference. NCT673-V23 discloses nothing new over the prior art the Examiner already considered.

NCT673-V23 is an online summary of a clinical trial investigating intravenous golimumab in patients with active PsA. Ex 1011. Aside from version information and study locations, its substantive disclosure spans just three pages and contains no data or results. *Id.*

The Examiner was fully aware of that clinical trial. During prosecution, Janssen disclosed “NCT02181673 History,” including a URL to Version 30 of NCT02181673, the same trial as NCT673-V23. Ex. 2002, -013. The submission to the Examiner lists all the previous versions, including Version 23—NCT673-V23. Ex. 2049, 1. Petitioners do not, and cannot, identify anything in NCT673-V23 that was not already available to the Examiner.

NCT02181673 History was identified in an Information Disclosure Statement (IDS), dated November 16, 2022 (Ex. 2002, -013), and the Examiner explicitly considered NCT02181673 History on April 17, 2023. *Id.* -103, -113. That disclosure establishes complete and unequivocal overlap under *Advanced Bionics* Step 1. *See Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 5 (P.T.A.B. May 19, 2025) (precedential) (“providing a document to the Office in an Information Disclosure Statement is sufficient to satisfy prong one of the *Advanced Bionics* analysis”) (citation omitted). This disclosure negates any argument Petitioners may make that Janssen failed to disclose its own prior art. *See*

Microsoft Corp. v. SandPiper CDN, LLC, IPR2026-00180, Paper 15 (P.T.A.B. May 6, 2026).²

Moreover, during prosecution, the Examiner rejected the pending claims as anticipated by Hoffman (Ex. 1036) and obvious in view of Doyle (Ex. 1035). Ex. 2002, -033, -036. Hoffman allegedly taught treating psoriatic arthritis using golimumab and administration by intravenous injection or infusion. *Id.* -035. Doyle allegedly taught subcutaneous as well as intravenous administration of golimumab, that intravenous is superior to subcutaneous in “reducing ant[i]-TNF α markers” and “administering 2 mg/kg golimumab iv infusion vs. subcutaneous for 4 weeks and 12 weeks.” *Id.* -038.

The Petition adds nothing over Hoffman and Doyle. Petitioners rely on NCT673-V23 for its disclosure of “IV administration of golimumab for the treatment of active PsA.” Pet. 24. But that is what the Examiner already took from Hoffman and Doyle. Ex. 2002, -038. NCT673-V23 adds nothing.

Petitioners' obviousness grounds fare no better. Petitioners rely on PI2013-Aria (prescribing information for Simponi Aria) in Ground 2, but only for disclosure

² In addition to NCT02181673 History, Janssen also disclosed the clinical trial protocol for NCT02181673, which the Examiner confirmed reviewing. Ex. 2002, -108, -113.

of a pharmaceutically acceptable carrier or diluent. Pet. 49. Petitioners fail to articulate how this disclosure constitutes a material difference from the prior art the Examiner considered. Petitioners' Ground 3 references—PI2015-Simponi, the four GO-REVEAL references, and WO213—are further removed from the claims, since they do not even disclose intravenous injection of golimumab, and their teachings are no closer to the claims than Hoffman and Doyle, which were applied by the Examiner. Ex. 1036, [0005], [0024]; Ex. 1035, 1214, 1216. The four GO-REVEAL references are also cumulative of Kavanagh 2014 (Ex. 1044 (disclosing results of GO-REVEAL study)), which the Examiner considered. Ex. 2002, -108, -113. PI2013-Aria and PI2015-Simponi are cumulative of Cohen Ex. 2038 (disclosing administration in accordance with labels)), which was also considered. Ex. 2002, -104, -113.

For these reasons, *Advanced Bionics* Step 1 is met. The Board consistently denies institution under § 325(d) when petitioners assert cumulative prior art to raise substantially similar arguments, and the Director should do so here. *See, e.g., Advanced Bionics*, IPR2019-01469, Paper 6 at 22; *Empower*, IPR2025-01024, Paper 15 at 3; *Ascentcare Dental Prods., Inc. v. Solmetex, LLC*, IPR2025-01065, Paper 11 at 2-3 (P.T.A.B. Oct. 17, 2025); *Tanklogix, LLC v. SitePro, Inc.*, IPR2025-00761, Paper 10 at 2-3 (P.T.A.B. Sept. 3, 2025).

**B. *Advanced Bionics* Step 2 (*Becton* Factors (c), (e), and (f)):
Petitioners Failed to Identify Any Material Error**

Petitioners fail to meet their burden to demonstrate Examiner error. To establish examiner error, a petition cannot “simply rely on its unpatentability contentions to imply that an error occurred.” *Ecto World*, IPR2024-01280, Paper 13 at 5 (citation omitted). Where, as here, “the Examiner applied the asserted prior art or substantially the same prior art during examination, then a petitioner must demonstrate that, for example, the previously presented art teaches the limitations of the challenged claims, and that no reasonable examiner could have found otherwise.” *Id.* at 6. “If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 9. Petitioners do little more than rely on their unpatentability arguments, and do not show any error occurred.

The Examiner carefully considered the prior art, but withdrew all rejections after finding Janssen's arguments persuasive. Ex. 2002, -153-154. The Examiner correctly concluded, on a record containing the same or cumulative prior art as discussed above (*supra* VI.A), that none of the prior art discloses the “surprising results in improving disease activity” and clinical endpoints. Ex. 2002, -153-154.

Petitioners fail to make a “substantial showing of apparent examiner error.” *Magnolia*, IPR2026-00097, Paper 17 at 8 (citation omitted). Petitioners argue that

the Examiner “erroneously concluded that the prior art did not teach administering golimumab to PsA patients intravenously.” Pet. 1. But the Examiner treated as “prima faci[a] obvious” that Hoffman and Doyle taught golimumab administered intravenously to psoriatic arthritis patients, and yet, Janssen was able to overcome these findings. Ex. 2002, -132. The Examiner did not err.

The Examiner also did not err in concluding the claims to be patentable based on surprising results achieved by the claims. *Id.* -153-154. Neither NCT673-V23, nor any other art relied upon by Petitioner, discloses such results. As Janssen will further explain in its Preliminary Response, Petitioners improperly attempt to ignore the express claim limitations directed to efficacy (Pet. 39-40), despite Federal Circuit precedent holding that, when recited in the claims, such limitations carry patentable weight. *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1375-79 (Fed. Cir. 2019) (efficacy and safety were correctly “relied on to define the claimed methods and distinguish them from the prior art”).

The Director should exercise discretion to deny institution.

VII. THE PETITION’S WEAK MERITS WARRANT DENIAL

The Petition’s failures on the merits independently support denial. Janssen will further address those deficiencies in its forthcoming Preliminary Response.

On Ground 1 (anticipation), Petitioners concede that the reference fails to disclose all claim limitations. Pet. 44. They instead rely on a POSA’s knowledge

and additional references to supply the missing limitation. *Id.* That approach is legally insufficient because anticipation requires all limitations to be found in a single reference. *See* Ex. 2033, -001 (other evidence may not be used to supply missing claim limitation); *see also* 37 C.F.R. § 42.104(b)(4). Nor can a theory of inherent anticipation cure such a shortcoming. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002).

On Grounds 2 and 3 (obviousness), Petitioners fail to show a POSA would have been motivated to combine the references in the manner claimed, particularly given the material differences between rheumatoid arthritis and psoriatic arthritis. *Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-87 (Fed. Cir. 2024). Indeed, the Examiner found the results in the '824 Patent to be unexpected. Ex. 2002, -153-154. Petitioners also fail to demonstrate a reasonable expectation of success in achieving the claimed endpoints. *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021).

These substantive deficiencies also support denial.

VIII. CONCLUSION

The Director should deny the Petition for Inter Partes Review.

Respectfully submitted,

Dated: May 27, 2026

By: / Inge A. Osman /

Inge A. Osman (Reg. No. 74,480)
inge.osman@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, DC 20004-1304
Tel.: 202.637.2200
Fax: 202.637.2201

*Counsel for Patent Owner
Janssen Biotech, Inc.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 27th day of May, 2026, a true and correct copy of the foregoing **Patent Owner's Brief on Discretionary Denial and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Lora M. Green (Reg. No. 43,541)
Robert Cerwinski (to be admitted *pro hac vice*)
Keith A. Zullo (Reg. No. 37,975)
Michael Cottler (Reg. No. 79,455)
Michael W. Johnson (Reg. No. 63,731)
Heather M. Schneider (Reg. No. 56,484)
Yahn-Lin (Franklin) Chu (Reg. No. 75,946)
lgreen@geminilaw.com
rcerwinski@geminilaw.com
kzullo@geminilaw.com
mcottler@geminilaw.com
mjohnson@geminilaw.com
hschneider@geminilaw.com
fchu@geminilaw.com
GEMINI LAW LLP
32 West 39th Street, 15th Floor
New York, NY, 10018
Tel.: 301-461-9580

By: / Inge A. Osman /

Inge A. Osman (Reg. No. 74,480)
inge.osman@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, DC 20004-1304
Tel.: 202.637.2200
Fax: 202.637.2201

*Counsel for Patent Owner
Janssen Biotech, Inc.*