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.

IPR2026-00259
Patent No. 12,291,566

PATENT OWNER'S BRIEF ON DISCRETIONARY DENIAL

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EXHIBIT LIST

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2001	Prosecution History for U.S. Patent No. 11,014,982 B2 ("'982 Patent PH") (EXCERPT)
2002	Prosecution History for U.S. Patent No. 12,291,566 B2 ("'566 Patent PH") (EXCERPT)
2003	U.S. Patent Application Publication No. US 2021/0238271 A1 ("271 Publication")
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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.")
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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)

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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")
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")
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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.")

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2037	Max Beauroyre, *Clinical-Trial Costing 101: Building a Phase-by-Phase Budget Your Board Will Trust*, ABACUM (June 25, 2025), https://www.abacum.ai/blog/clinical-trial-costing ("Beauroyre (2025)")
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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.")

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2045	Qichacha (QCC), Bio-Thera Solutions, Ltd. Partnership Chart (Chinese)
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")
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2049	RESERVED
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-immgolis-golimumab-sldi-and-immgolis-intri-golimumab-sldi-first-biosimilars-to-simponi-golimumab-and-simponi-aria-golimumab-accord-biopharma-to-lea/ ("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. 12,291,566 (the "'566 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 '566 Patent for over five years, and then waited an additional year where they could have challenged the '566 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 '566 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 NCT873-V24, which Petitioners argue provides the alleged missing limitation during prosecution, intravenous ("IV") administration to ankylosing spondylitis ("AS") patients, but that argument was considered and rejected 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 '566 Patent (Ex. 1004)

AS is a chronic inflammatory disease of unknown etiology that affects the joints, including the spine, entheses (where connective tissue attaches to bone), and peripheral joints. Ex. 1004, 84:47-50. Without treatment, AS may lead to substantial loss of range of motion and disability, significantly impairing patients' quality of life and functional capacity. *Id.* 84:52-56. The '566 Patent claims intravenously administering golimumab to treat AS to improve key clinical outcome measures. *Id.* 131:34-67. The '566 Patent covers Simponi Aria for its labeled indication. Ex. 2014.

Janssen filed the original application leading to the '566 Patent in 2017, and it published on August 5, 2021, as US 2021/0238271 (the "271 Publication"). Ex. 2003. The '566 Patent issued on May 6, 2025. Ex. 1004.

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]

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 ("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.

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[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).

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 sought to manipulate U.S. IP systems, including administrative challenges before the PTAB, to weaken or misappropriate U.S. technological leadership." *Tianma*, IPR2025-01579, Paper 12 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 its 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 '566 Patent published on August 5, 2021, with claims covering the same products as the claims that ultimately issued. *Compare* Ex. 2003 (271 Publication), claims, *with* Ex. 1004 ('566 Patent), claims. Five years have passed since the parent of the '566 Patent, the '982 Patent, issued on May 25, 2021. Ex. 1002.

Janssen made substantial investments in reliance on its settled expectations. Before the '566 Patent issued, Janssen invested over [redacted] to design and conduct the pivotal GO-ALIVE clinical study, a Phase III randomized trial evaluating safety and efficacy of intravenous golimumab for AS. Ex. 2501 (Brennan Decl.) ¶ 5. This trial was particularly resource-intensive, with per-patient costs exceeding [redacted]—higher than typical clinical trials. *Id.*; Ex. 2037, -003.

Janssen continued making significant investments in Simponi Aria after the '566 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 AS, as claimed. *Id.* ¶ 6. Janssen has invested approximately [redacted] between 2021 and 2025 in patient support programs. *Id.*

Janssen is also 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 '566 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 AS. 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 (AS) for its biosimilar product. Ex. 2020, -006 ("Specific Application Prospects RA, PsA, AS, UC, and 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 '566 Patent on three grounds, all based on NCT873-V24 as the primary reference. NCT873-V24 discloses nothing new over the prior art the Examiner already considered.

NCT873-V24 is an online summary of a clinical trial investigating intravenous golimumab in patients with active AS. Ex. 1014. Aside from version information and study locations, its substantive disclosure spans just five pages. *Id.* It contains no data or results. *Id.*

During prosecution, the Examiner thoroughly reviewed the claims and the prior art, making several § 102 and § 103 rejections, and finally rejected the pending claims as obvious via Wong (Ex. 1024) in view of Zhuang (Ex. 1038). Wong allegedly taught treating ankylosing spondylitis with golimumab by infusion. Ex. 2002, -311-12. The Examiner relied on Zhuang for teaching administering golimumab (in RA) at 2 mg/kg at 0 and every 12 weeks, and administering for a period of 30 minutes. *Id.* -312; *see also* Ex. 2007 (cited to Examiner at Ex. 2002, -012, disclosing golimumab for infusion at 2 mg/kg at weeks 0 and 4, then every 8 weeks thereafter, over a 30-minute period).

The Petition adds nothing over Wong and Zhuang. Petitioners rely on NCT873-V24 for its disclosure of "IV administration of golimumab for the treatment of active AS." Pet. 24-26. But that is what the Examiner already took from Wong and Zhuang: "it would have been obvious to one [of] ordinary skill in

the art (e.g., a physician) to treat ankylosing spondylitis using 2mg/kg golimumab by intravenous administration for a period of 30 min." Ex. 2002, -313. While NCT873-V24 does allegedly teach golimumab by intravenous administration in AS, it is still *missing* the key combination of limitations the Examiner relied upon to allow the claims—administering golimumab at the claimed dosage and infusion time for the treatment of AS. Pet. 42 ("NCT873-V24 does not expressly state that the golimumab was administered over 30±10 minutes").

Petitioners' obviousness grounds fare no better. Petitioners rely on PI2013-Aria (prescribing information for Simponi Aria) in Ground 2, but only for disclosure of a pharmaceutically acceptable carrier or diluent. Pet. 46-47. Petitioners fail to articulate how this disclosure constitutes a material difference from the prior art the Examiner considered. Petitioners' Ground 3 references—van der Heijde and Inman—were disclosed to the Examiner by Janssen and are cited on the face of the '566 Patent. Ex. 2002, -017, -022. And Petitioners' final reference, PI2015-Simponi, is further removed from the claims, since it does not even disclose intravenous injection of golimumab, and in any event is cumulative of Shealy 2010 (Ex. 2048), disclosed to the Examiner in an IDS. Ex. 2002, -049.

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, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 5 (P.T.A.B. May 19, 2025) (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, -383-84. The Examiner

correctly concluded, on a record containing the same or cumulative prior art as discussed above (*supra* Section VI.A), that none of the prior art discloses "the instantly recited anti-TNF antibody dosage and infusion time for the treatment of ankylosing spondylitis." Ex. 2002, -383-84.

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 conclude[d] that the prior art did not teach administering golimumab to AS patients intravenously." Pet. 1. But the Examiner found it was the combination of the claimed dosage and infusion time of golimumab for the treatment of AS that was missing from the prior art, a combination that is not present in Petitioners' grounds. Ex. 2002, -383-84. The Examiner did not err.

Janssen also argued to the Examiner that the claims are patentable based on surprising results achieved by the claims. *Id.* -368-70. Neither NCT873-V24, 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. 37-38) 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. 42. They instead rely on a POSA's knowledge and additional references to supply the missing limitation. *Id.* That approach is legally insufficient because all limitations must come from a single document for inherent anticipation. *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). 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

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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:

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