

Filed on behalf of: Accord BioPharma, Inc.  
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JANSSEN BIOTECH, INC.,  
Patent Owner.

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Case No. IPR2026-00257  
Patent No. 11,041,020

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

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## I. INTRODUCTION

Respectfully, the Director should decline to exercise his discretion to deny institution. Although Janssen's Brief on Discretionary Denial (Br.) gives lip service to the Director's decision in *Magnolia Med. Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 (May 14, 2026) (precedential), it ignores many of the key considerations listed in *Magnolia* that weigh against discretionary denial. Chief among these is whether an IPR serves as a true "alternative" to district court litigation. Here, that is unquestionably the case. Janssen dropped the challenged claims from the parties' co-pending district court litigation when Accord carved out the claimed method of treatment from its FDA-approved label. With no allegation of infringement pending, the district court will not adjudicate validity of the challenged claims. Instead, Accord will adjudicate that solely in this forum.

Another key consideration is whether the Office committed material error in issuing the claims. Here, the Office committed clear error by allowing the challenged claims over Janssen's own prior-art clinical trial, which (as explained in the Petition) is the closest prior art and ***anticipates or renders obvious all of the challenged claims***. The fault for this error lies with Janssen, ***which did not explain the relevance of version 23 of its trial to the examiner***. Had Janssen been fully candid about its own prior art, the Office never would have allowed the claims. While Janssen weakly protests that the trial is "cumulative," the Petition shows that

it is the closest prior art and, unlike the art before the examiner, disclosed all of the elements of the claims arranged as in the claims.

A third key consideration is settled expectations. Here, Janssen could not have formed settled expectations regarding the validity of US11,041,020 (*US020*) by the filing date of the Petition. The patent is young, having issued less than 6 years ago. Further, owing to the lengthy, 12-year FDA regulatory exclusivity period for Simponi and Simponi Aria; patent protection for the golimumab molecule that did not expire until 2024; and publicly-announced biosimilar product development timelines that targeted 2026 for U.S. market entry, Janssen could not have expected that *US020* was safe from validity challenges.

Another key consideration, as explained by Accord's President, is the fact that primary Petitioner Accord is a U.S. company headquartered in North Carolina that is rapidly growing and continuing to make substantial investments in expanding its American workforce and infrastructure, including its U.S. manufacturing facilities. Janssen's discounting of Accord's American operations merely because Accord has a foreign parent does not square with the economic impact the improperly-granted *US020* patent will have on American households.

Similarly, Janssen's assertion that Bio-Thera is an "agent of the Chinese government" is belied by the very Bio-Thera annual reports that Janssen cited, which Janssen selectively translated. The sections of those reports Janssen left

untranslated establish that the sole investor Janssen alleges to be owned by the Chinese government *is not a government-owned entity*. In contrast, Janssen has significant investments in China, and *over 25% of Janssen's Chinese affiliate is owned by the Chinese government*.

Finally, Accord's biosimilar will further this Administration's critical goal of lowering U.S. healthcare costs. Should Accord prevail, it will be able to add an improperly-patented indication to its label and thus increase patient access to its lower-cost biosimilar. In contrast, Janssen charges more for its branded golimumab products in the U.S. than it does in other markets, and thus violates this Administration's desire to have most-favored nation pricing in the U.S.

When the totality of the relevant evidence and arguments are weighed, they do not support discretionary denial. Accordingly, Accord respectfully requests that the Petition be referred for review of the merits.

## **II. THE PETITION IS A TRUE "ALTERNATIVE" TO DISTRICT COURT LITIGATION**

Accord is not currently pursuing FDA approval for the treatment of psoriatic arthritis (PsA) or ankylosing spondylitis (AS) covered by the challenged method of treatment patents. As set forth in Accord's *Sotera* Stipulation, Janssen and Accord stipulated to dismissal of those patents in the district court, including *US020*, and the stipulation was so ordered. Paper 5, n.2. Thus, *US020* will not be before the district court and will be addressed only by the PTAB.

This fact weighs heavily against discretionary denial. As noted by the Director in *Magnolia*, the “purpose of AIA reviews was, and is, to provide a quick and cost-effective **alternative** to district court patent litigation.” *Magnolia*, 2 (emphasis original); see also *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601 Paper 9, 2 (Jul. 24, 2025) (informative); *Tesla, Inc. v. Bulletproof Property Management, LLC*, IPR2026-00204, Paper 14, 2-3 (Jun. 15, 2026) (informative). By choosing the PTAB as the sole forum to review the validity of the challenged claims, Accord has streamlined and simplified the issues before the district court. Notably, Janssen did not address this factor in its discretionary denial brief.

### **III. THE DIRECTOR SHOULD INSTITUTE TO CORRECT MATERIAL ERRORS DURING PROSECUTION**

“A substantial showing of apparent examiner error can overcome other factors that suggest discretionary denial.” *Magnolia*, 8. See also *Advanced Bionics LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8-9 (Feb. 13, 2020) (precedential). Discretionary denial under §325(d) is not appropriate here because the examiner erred in issuing the patent.

#### **A. The Strong Merits of the Grounds in the Petition Counsel Against Discretionary Denial**

The Petition challenges *US020* as anticipated by Janssen’s own clinical trial protocol, versions of which were published well over a year before the patent’s earliest possible filing date. The Petition relies on version 23 of the protocol, titled

“A Study of Golimumab in Participants With Active Psoriatic Arthritis” (*NCT673-V23*, EX1011), which was sponsored by Janssen Research & Development, LLC and was publicly available on ClinicalTrials.gov on January 8, 2016. EX1011. To gain allowance, Janssen argued that the combination of references the examiner relied on in rejecting the claims, *Inman* and *Doyle*, did not describe IV administration of golimumab at the claimed dose and using the claimed dosage regimen to achieve the claimed results. EX1007, 28. Janssen did ***not*** explicitly disclose or describe ***version 23 of its clinical trial, which disclosed precisely the subject matter Janssen argued was missing from the prior art.*** Had Janssen brought *NCT673-V23* to the examiner’s attention, no reasonable examiner would have allowed the challenged claims.

To rebut anticipation over its own clinical study, Janssen mischaracterizes Accord’s challenge as relying on “a POSA’s knowledge and additional references to supply the missing limitation.” Br., 19. The only limitation not explicitly described in *NCT673-V23* is the fact that the golimumab administered to the human patients in the trial was dispersed in a “pharmaceutically acceptable carrier.” But as the Petition explained, a POSA would have understood that the golimumab could not have been administered to patients via IV injection without being dissolved in a liquid pharmaceutical carrier. Janssen’s product insert for its Simponi Aria product (*PI2013-Aria*, EX1032) merely confirms that understanding.

*See Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Further, in the very unlikely event the Board concludes that a POSA would not have understood that the golimumab administered to the patients was disposed within a pharmaceutically acceptable carrier, Petitioners presented an obviousness challenge combining *NCT673-V23* with *PI2013-Aria*, which expressly disclosed this fact. Either challenge is sufficient to warrant cancellation.

Janssen also misstates the obviousness grounds in challenges two and three, asserting that the Petition failed “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.” Br., 19. Janssen ignores that *the prior art publication of its own study protocol taught all the active method steps of the claims, including the administration of IV golimumab to PsA patients at the claimed dose and using the claimed dosage regimen.*

**B. The Petition Presents New Art and Arguments Under *Advanced Bionics* Step One**

*Advanced Bionics* step one asks whether the same or substantially the same art or arguments previously were presented to the Office. *Becton* factors (a), (b), and (d) are particularly relevant here. *Becton, Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to §III.C.5, first paragraph). All of these factors counsel against discretionary denial.

As explained above in Section III.A., *NCT673-V23* (EX1011), the primary

reference relied on in the Petition, discloses what was missing in the art cited during prosecution, and is thus necessarily materially different from the art cited by the examiner. Citing *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, 5 (May 19, 2025) (precedential), Janssen contends that the clinical protocol was identified in an IDS. Br., 14. That assertion is misleading, however, because the protocol was cited as one of over 430 references, and as shown below, used a different date (Jun. 29, 2016, less than a year before the earliest possible filing date) than version 23 (Jan. 8, 2016, more than a year before the earliest possible filing date), and was listed in a combined entry after another, unrelated reference (EX2001, 228, 272):

|  |                                                                                                                                                                                                                                                       |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Khilji FA, Gonzalez M, Finlay AY. Clinical meaning of change in dermatology life quality index scores. Br J Dermatol. 2002;147(suppl 62): 25-54. SIMPONI IV (golimumab) Clinical Protocol CNTO148PSA3001 Amendment 2 98 Approved. 29 June 2016</p> |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

The clinical trial was reproduced the same way on the face of *US020* (EX1001, 6):

Khilji FA, Gonzalez M, Finlay AY. Clinical meaning of change in dermatology life quality index scores. Br J Dermatol. 2002;147(suppl 62): 25-54. SIMPONI IV (golimumab) Clinical Protocol CNTO148PSA3001 Amendment 2 98 Approved, Jun. 29, 2016.

It is thus, at best, unclear whether the examiner considered this single IDS entry as two separate references or even considered the second part of the entry. But as discussed below in Section III.C., even if *NCT673-V23* was disclosed to the Office, the examiner erred in allowing the claims.

Janssen asserts further that the art cited in the Petition is cumulative to the art relied upon by the examiner. Br., 13. According to Janssen, the examiner relied

on *Inman* (EX1016) for disclosing treatment of AS using subcutaneously (SC) administered golimumab and *Doyle* (EX1035) for disclosing that golimumab may be administered by the intravenous (IV) route. *Id.* Janssen then argues that *Demetri* (EX2035 ¶42) “disclosed the very same clinical trial Petitioners rely on” and was relied upon by the examiner to find that it was well known that golimumab could be administered IV or SC. Br., 15. But *Demetri* does not add anything to *Inman* and *Doyle*, as *Demetri* merely states that IV and SC golimumab are being studied for the treatment of PsA, RA, and AS, “administered as a 50mg-100mg injection every 2 or 4 weeks” (EX2035 ¶42), *i.e.*, a very different dose and dosing schedule than is claimed. In contrast, *NCT673-V23* taught precisely what Janssen argued was missing from the references relied upon by the examiner, including the claimed dose of IV golimumab and its claimed dosing schedule, for the treatment of PsA, the claimed patient population. *Cf. Microsoft Corp. v. SandPiper CDN, LLC*, IPR2026-00180, Paper 15, 3 (May 6, 2026). *NCT673-V23* therefore is not cumulative and there is no overlap in how the art may be argued.

Janssen’s arguments as grounds 2 and 3 of the Petition (Br., 16) fail for the same reason. None of those references were considered in conjunction with *NCT673-V23*. *Tesla*, Paper 14, 3-4. Janssen not only failed to explicitly disclose or describe its own prior art *NCT673-V23* to the examiner during prosecution, but it also doubled down on obfuscating the materiality of its omission with this Request.

Such behavior should not be rewarded with discretionary denial. *Cf. Microsoft*, Paper 15, 3.

**C. The Examiner Erred Under *Advanced Bionics* Step Two**

That the examiner did not evaluate *NCT673-V23* or use it in a rejection also weighs heavily against discretionary denial under step two of the *Advanced Bionics* framework. *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, 5 (May 19, 2025) (precedential as to §A). *Becton Dickinson* factors (c), (e), and (f) are relevant to whether an examiner materially erred under the second part of the *Advanced Bionics* framework. As explained, *NCT673-V23*—Janssen’s own clinical trial publication—discloses the claimed dose, dosing schedule, and patient population in one reference, without the need to combine multiple references as the examiner resorted to during prosecution. Had the examiner rejected the claims over *NCT673-V23*, Janssen could not have overcome it by arguing that neither *Inman*, *Doyle*, nor *Demetri* taught the claimed IV dose and dosing schedule of golimumab. This is precisely what *NCT673-V23* taught.

The examiner’s failure to analyze or cite *NCT673-V23* also compromised the required calculus concerning secondary evidence of unexpected results. To be unexpected, results must be compared to the closest prior art, i.e., *NCT673-V23*, which the examiner did not do. Thus, it was clear error for the examiner not to reject the challenged claims over Janssen’s own clinical study publication. This

error strongly weighs against discretionary denial. *Tesla*, Paper 14, 3-4. Because the second part of the *Advanced Bionics* two-part framework is satisfied, discretionary denial under § 325(d) is not appropriate.

#### **IV. JANSSEN DOES NOT HAVE SETTLED EXPECTATIONS IN *US020***

*US020* issued on June 22, 2021, less than 5 years before the March 20, 2026, filing of the instant Petition. Despite the young age of this patent, Janssen implausibly asserts that it has strong settled expectations because it remained “unchallenged for nearly five years after issuance and over six years after publication of the original application, until this Petition.” Br., 1. However, this is *not* one of those rare instances where a patent owner may have “strong settled expectations in a patent that has only been in force for [less than six] years” because of “an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval.” *Amgen*, Paper 9, 2.

Moreover, the vast majority of the investment supporting Janssen’s alleged settled expectations relates generally to “marketing and sales of Simponi Aria,” Br., 10, approved long ago for indications such as rheumatoid arthritis that are not covered by *US020*. Only Janssen’s investment in the clinical trial for administering IV golimumab to PsA patients bears any relation to alleged settled expectations in the challenged claims, and as shown by *NCT673-V23*, that investment was made over a year before the application that led to *US020* was filed. That relatively

modest, routine investment does not rise to the level of “extraordinary” and is dwarfed by Janssen’s profits from its sale of golimumab. Section V.A.

Janssen also argues that Accord “had over six years to investigate Janssen’s patent rights on Simponi Aria for treating PsA.” Br., 12. However, if the Petition had been filed before Accord was able to file its aBLA, Accord may not have had standing to appeal any adverse decision on the petition, while still being bound to the estoppel provision of 35 U.S.C. § 315(e)(2). *See, e.g., Momenta Pharms., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 769 (Fed. Cir. 2019). A reference product sponsor like Janssen simply cannot have any settled expectations about a patent that may apply to a Simponi Aria biosimilar until after Simponi Aria biosimilars near FDA approval and their manufacturers have accrued sufficient economic interest to have standing to challenge the patent in an Article III court.

Moreover, most biosimilar manufacturers wait to enter the market until the primary patents covering the molecule expire. Janssen first started selling golimumab for SC administration in 2009 and IV administration in 2013. EX1018; EX1019. Janssen told investors and the public that its golimumab composition of matter patent would expire in 2024. EX1081, 2; EX1082, 19. Far from having settled expectations, Janssen should have anticipated that biosimilars would wait to bring challenges until they could enter the market after this patent expired.

Most biosimilar manufacturers also wait to bring PTAB challenges until

they are nearing the FDA application stage, for the practical reason that they do not (1) know which of the multitude of secondary patents typically erected to stave off biosimilar competition will be asserted against them in eventual biosimilar litigation, or (2) have the resources to challenge all of the patents that could be asserted. Most reference product sponsors like Janssen accrue thickets of new secondary patents and applications in the run-up to the date they project a biosimilar may first try to enter the U.S. market, to prevent or delay that entry for as long as possible. EX1064, 7-9. No biosimilar can afford to challenge all of them, especially early in development when it is unclear whether clinical testing and the competitive landscape will justify fully developing the product for marketing. Unlike a small-molecule generic drug, it takes 6 to 9 years to develop a biosimilar product. EX1114, 3-4. Indeed, one chief goal of a patent thicket strategy is to make the thicket so large it cannot be challenged in its entirety. To keep the costs of litigation low enough to be practical, a biosimilar must wait to bring PTAB challenges until its product, manufacturing process, and label are all fully developed and the patent dance has revealed which patents the reference product sponsor will assert.<sup>1</sup> Biosimilar manufacturers should not be forced to decide

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<sup>1</sup> No BPCIA equivalent to the Orange Book exists. Rather, within 60 days of receiving notice of an aBLA, the product sponsor will identify a list of unexpired

between (a) challenging a large number of patents so far in advance that they may lack standing to appeal and do not yet know whether they will advance the product through FDA approval and launch, or (b) forfeiting the opportunity to challenge the patents before the PTAB.

**V. JANSSEN’S INVESTMENTS IN U.S. MANUFACTURING DO NOT SUPPORT DISCRETIONARY DENIAL**

**A. Janssen’s Commercial Success Dwarfs Its Domestic Investments and Fails to Demonstrate “Extraordinary” Investment**

Janssen’s domestic-investment narrative and assertion that it “has made extraordinary investments to develop and commercialize the patented technology” are entirely decoupled from the commercial reality of the Simponi franchise. Br.,

4. Janssen’s claimed extraordinary investment is not meaningfully tied to the challenged patent in a way that should outweigh the public interest in testing patent validity through the statutory IPR process.

Janssen has reaped a staggering **\$26 billion** in cumulative global sales for Simponi/Simponi Aria since they launched (EX1083, 6 (2023-2025); EX1084-88 (providing same for 2010-2022)) and sold **\$269 million** of Simponi/Simponi Aria in the U.S. in the first quarter of 2026 alone. EX1080, 24. Janssen’s self-reported 2021-2025 investment in marketing and sales support represents a negligible

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patents for which a claim of infringement may reasonably be made.

fraction of its multi-billion-dollar sales. As noted above, that investment is not specific to the claimed indication. Furthermore, a generalized, macro-level \$2 billion investment by its parent company should not override the public interest in ensuring patent validity. Br., 5.

In fact, Janssen’s historical supply chain undercuts its domestic manufacturing narrative: *every* product label for Simponi Aria prior to the most recent Supplement 36 (issued April 18, 2025) explicitly states that the drug was “Manufactured by: Janssen Biotech, Inc. Horsham, PA 19044 US License No. 1864 *at Cilag AG Schaffhausen, Switzerland.*” EX1066, 33; EX1067-EX1079 (providing same) (emphasis added); EX2014, 10. Janssen’s *Swiss* manufacture of Simponi Aria in the last 13 years has done little to support the U.S. economy.

**B. Accord Is Seeking Legitimate Administrative Review, Not Harassing Patent Owners**

Far from a harassment campaign, this IPR is an alternative to and streamlines the district court litigation to commercialize a more affordable therapeutic alternative in the U.S. Using the IPR mechanism to challenge a patent that blocks competition is precisely what the America Invents Act intended.

**C. The Specific Discretionary Manufacturing Factors Are Soundly Outweighed by Other Core Policy Considerations**

While Janssen relies on the domestic production framework articulated in Director Squires’ March 11, 2026 Memorandum, its rigid application of that

framework ignores other factors and the broader context of this case. As shown above, Janssen's Simponi Aria has not been manufactured domestically for most of its time on the market. Even if it is manufactured domestically now, the considerations of Janssen's domestic manufacturing and Accord's competing manufacturing are equitable guidelines to be weighed with other factors. Here, any preference for domestic operations is fully satisfied by the fact that Accord is an American enterprise that will drive the U.S. commercial distribution and manage the domestic supply chain. To the extent that public policy favors small businesses or domestic manufacturers, here it favors Accord over Janssen. Also, such policy should not be used to insulate an invalid patent from review, especially when a domestic Petitioner is introducing cost savings to the U.S. healthcare system.

**D. Janssen and Its Parent Company Maintain Massive Operational and Financial Investments Tied to the Chinese Government**

Janssen's attempt to position itself as a purely domestic champion fighting foreign influence is profoundly hypocritical when contrasted with the deep, state-partnered footprint that Janssen and Johnson & Johnson maintain inside China.

Johnson & Johnson operates a prominent Chinese domestic division, Xi'an Janssen Pharmaceutical Ltd., which has actively operated as a joint venture with Chinese state entities since 1985. EX1058, 1. Public corporate registries confirm that at least 27.00% of Xi'an Janssen's equity is directly held by Chinese state-owned entities: Shaanxi Pharmaceutical Holding Group Co., Ltd. holds 21.00% (a

provincial state-owned enterprise); China National Pharmaceutical Investment Co., Ltd. holds 5.76% (a central enterprise subsidiary); and Sinopharm Group Asset Management Co., Ltd. holds 0.24% (a state-owned enterprise). EX1105, 3. Xi'an Janssen openly celebrated its "rich heritage in China" and formally "reaffirmed its commitment to partner with the Chinese Government" during its 30th-anniversary ceremony. EX1058, 1.

Last year, J&J MedTech China's president, Edward Zhou, publicly lauded China as a "critical frontier for shaping the future of healthcare" and noted that J&J Medtech has "deeply woven itself into the fabric of China's healthcare ecosystem and continues to actively contribute to its modernization and resilience." EX1063, 2. J&J's global board chairman and CEO, Alex Gorsky, similarly stated that one focus of J&J's global strategy is continued investment in China, backed by a massive \$500 million investment by Janssen Pharmaceuticals Inc. to develop pulmonary drugs in the Chinese market. EX1060, 1-2. In 2017, J&J Innovation partnered with the Shanghai Municipal Government and Pudong New Area Government to launch JLABS @ Shanghai—the first JLABS facility established outside North America—which has incubated 70 companies and helped raise \$3.1 billion. EX1059, 5, 8. Meanwhile, in the past two years J&J closed half of its U.S. JLABS locations: Houston, Washington, D.C., and New York City. EX1062, 1.

Janssen cannot in good faith demand discretionary denial based on Bio-

Thera's Chinese connections while its own corporate parent actively integrates its manufacturing and R&D operations into the state-owned infrastructure of the Chinese government. And unlike Xi'an Janssen, as discussed below, Bio-Thera is not a state-owned enterprise. Section VI.

**E. Accord Is a U.S. Company Driving Significant Investment in Domestic Manufacturing and Infrastructure**

Janssen's brief systematically ignores the foundational role of Accord BioPharma, Inc., painting this case exclusively as an offshore challenge. As explained in the attached Declaration of Accord's President Mr. Chrys Kokino, Accord is an American company focused on expanding domestic access to biosimilar therapies. EX1053 ¶2. Accord has operated in the U.S. since 2009 with hundreds of millions in U.S. annual sales. *Id.*, ¶3. Its U.S. sales force met in Las Vegas this June and will be selling the golimumab biosimilar when it launches. *Id.*, ¶8; EX1054 (Photograph of Accord U.S. Team, June 2026).

Accord's parent, Intas, has made massive direct investments to expand its U.S. footprint, acquiring the Udenyca franchise from Coherus Biosciences (another American company) in 2025, processing and manufacturing Udenyca in the U.S., and acquiring an active pharmaceutical manufacturing facility in New Jersey—including retaining all of the acquired company's employees—in early 2026. EX1053 ¶4. Moreover, Accord has secured seven U.S. biosimilar approvals over the past two years, including three U.S. biosimilar approvals in the first half of

2026. *Id.*, ¶9. Accord’s golimumab biosimilar will be introduced at a discount to branded pricing, saving money for American healthcare patients, plans, and providers. *Id.*, ¶10. Discretionarily denying institution would directly harm an American company’s concrete investments in domestic infrastructure and deprive American patients of a highly competitive, lower-cost medicine.

## **VI. JANSSEN IS WRONG IN ASSERTING THAT BIO-THERA IS A CHINESE GOVERNMENT AGENT**

Janssen’s allegations of foreign sovereign influence in this discretionary-denial dispute are false and unsupported by the record. Janssen asserts that the Assets Supervision and Administration Commission of Guangzhou Municipal Government (“Assets Supervision”) controls Bio-Thera via a 25% ownership stake in Guangzhou Zhongke Yuechuang No. 3 Venture Capital Partnership. Br., 7. Janssen’s ownership narrative rests on an attenuated and heavily diluted chain of indirect interests that, even under its own framing, does not establish any control.

Even according to the document Janssen cites, which Bio-Thera disputes, Assets Supervision has at most a 1.1588% shareholding. EX2046, 1. That is a far cry from a “major shareholder” under any legal standard and much less than the 5% threshold used in the United States for mandatory beneficial ownership reporting under 15 U.S.C. §78m(d)(1). Janssen left out the 1.1588% of Assets Supervision’s indirect holding and instead alleged Chinese government control using the 5.15% holdings of No. 3 Venture Capital Partnership. EX2046, 1.

Moreover, Bio-Thera’s verified corporate annual reports explicitly state that the No. 3 Venture Capital Partnership is a “Domestic, ***non-state-owned*** legal person.” EX1093, 4; EX1095, EX1097, EX1099, EX1101 (providing same) (emphasis added). These are the same Annual Reports that Janssen attached to its Brief (EX2015, EX2017, EX2019, EX2021, EX2023), but ***Janssen did not translate those pages***. In contrast, Accord has translated the pages that show Bio-Thera’s ownership, which clearly demonstrate that Bio-Thera is not owned in any part by a Chinese state actor.

In addition, Bio-Thera has attached a confirmation letter from the No. 3 Venture Capital Partnership, which officially states that it “does not fall under any of the following circumstances that would cause it to be recognized as a ‘state-owned shareholder.’” EX1103, 2. It includes an Equity Structure Chart that does not include Assets Supervision. EX1103, 4. Thus, *Return Mail, Inc. v. United States Postal Service*, 587 U.S. 618 (2019) simply does not apply here because Bio-Thera is ***not*** owned or controlled by the Chinese government.

## **VII. INSTITUTION WOULD FURTHER THE ADMINISTRATION’S GOAL OF LOWERING DRUG PRICES**

Challenging *US020* also serves the public interest of increasing biosimilar market entry and reducing the cost of biologics and healthcare. *E.g.*, *Magnolia*, 6-7. Biosimilars reduce healthcare costs, and the current administration and legislature have strongly favored bringing biosimilars onto the market for that

purpose. In 2024, generics and biosimilars saved over \$467 billion. EX1065, 11.

On April 15, 2025, the White House issued Executive Order 14273, titled “Lowering Drug Prices by Once Again Putting Americans First.” EX1106. A Fact Sheet announcing it states that the Order “increases the availability of generics and biosimilars, which can be as much as 80% cheaper than brand alternatives.”

EX1107, 2; *see also* EX1110 (May 12, 2025, Executive Order discussing importance of reducing drug prices). Members of Congress from both sides of the aisle have also introduced bills to increase the availability of biosimilars. EX1108; EX1109. The White House’s Executive Order and the legislative efforts all support a public and economic policy of encouraging biosimilar products to enter the market. This is particularly important here, where Janssen charges more for Simponi in the U.S. than it does abroad (Simponi Aria is not available in many of those countries). For example, the price of Simponi in Germany is around \$1,000 USD, while the WAC in the U.S. is \$6,663.50 and Janssen’s net price is \$2,998.59. EX1112, 2-3; EX1111. The same is true for the United Kingdom and China. EX1113; EX1116, 2.

## **VIII. CONCLUSION**

The totality of the evidence and arguments presented support that the Director should decline to exercise his discretion to deny institution and allow the PTAB panel to evaluate the Petition on the merits.

Respectfully submitted,

Dated: June 29, 2026

/ Lora M. Green /

Lora M. Green, Lead Counsel

Reg. No. 43,541

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§42.6(e), this is to certify that I caused to be served a true and correct copy of the foregoing Petitioners' Opposition to Patent Owner's Request for Discretionary Denial (and accompanying Exhibits) by electronic mail on Patent Owner's lead and backup counsel at the following email addresses:

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