Filed on behalf of: Accord BioPharma, Inc.
By: Lora M. Green (lgreen@geminilaw.com)

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.

Case No. IPR2026-00256
Patent No. 11,014,982

PETITIONERS' SUR-REPLY SUPPORTING ITS OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL[1]

[1] Authorized by the Board via e-mail on July 7, 2026. *See* EX3101.

Patent Owner's ("PO") Reply brief doubles down on the unsupported narrative that Bio-Thera is an agent of the Chinese government and that the Chinese government is thus a real party in interest ("RPI") with the ability to control this IPR. But the evidence, including PO's, shows that the Chinese government is ***not*** an RPI. PO also takes inconsistent positions regarding U.S. investment, crediting years of ***Swiss*** manufacturing and generalized investments by its parent company, while simultaneously arguing that Petitioner cannot rely on Accord's significant and growing investments in generalized U.S. manufacturing and infrastructure. Discretionary factors and public policy support Accord, an American company, investing in the U.S. and introducing savings to the U.S. healthcare system.

I. THE CHINESE GOVERNMENT IS NOT AN RPI

PO's own evidence disproves its claims. Bio-Thera is not a state actor and the Chinese government is not an RPI with control over Bio-Thera or this IPR. Bio-Thera is legally independent of the Chinese government. PO alleges that the Chinese government can control Bio-Thera through Assets Supervision and Administration Commission of Guangzhou Municipal Government's ("Assets Supervision") alleged 25% stake in Guangzhou CAS Yuechuang No. 3 Venture Capital Partnership ("No. 3"), which holds shares in Bio-Thera. Reply, 3-4. However, PO's own exhibit demonstrates that Assets Supervision has, at most, an indirect 1.1588% interest in Bio-Thera which is far below the 5% threshold utilized in 15 U.S.C. §78m(d)(1) to

track influential corporate holdings. EX2046, 1. Furthermore, PO does not dispute that Bio-Thera's corporate annual reports explicitly state that No. 3 is a "Domestic non-state-owned legal person," or that the confirmation letter from No. 3 confirms it is not a "state-owned shareholder." EX1093, EX1095, EX1097, EX1099, EX1101; EX1103. PO argues that the confirmation letter is at best a deficient declaration (Reply, 3), but that document was not created by Petitioner for this IPR—it was a preexisting business record prepared in the ordinary course.

PO's reliance on *Tianma* (IPR2025-01579, Paper 12) and *Sun Pharma* (PGR2026-00021, Paper 12) is misplaced. Under *Tianma*, PO bears the threshold burden to produce evidence sufficient to put into dispute whether a petition identified all RPIs, specifically identifying any foreign sovereign entities. Critically, *Tianma* demands probative, case-specific evidence of state ownership; it does not authorize discretionary denial based on rank speculation or attenuated ownership percentages. Only once a genuine dispute is raised does the burden shift to the petitioner to demonstrate that all RPIs were properly named. Similarly, under *Sun Pharma*, the petitioner, a wholly owned subsidiary of a foreign company, failed to establish that all RPIs were identified because it did not address or dispute whether its foreign parent had the ability to control the proceeding.

Tianma is inapposite because Petitioner has provided robust documentary evidence that the Chinese government is ***not*** an RPI. Unlike in *Tianma*, where

petitioner failed to provide any documentary evidence regarding share structures or governance rights, Petitioner here has submitted a comprehensive, undisputed, record comprising: (a) audited annual reports filed with the Shanghai Stock Exchange (EX1093, EX1095, EX1097, EX1099, EX1101); (b) No. 3's equity chart (EX1103); and (c) the sworn declaration of a U.S. corporate officer (EX1053). Petitioner's clear evidence of the lack of a state owned or controlled entity is the opposite of *Tianma*, which involved a direct subsidiary of a wholly Chinese government owned defense conglomerate. For the same reason, the "ability to control" issue for which PO cites *Sun Pharma* (Reply, 3) is inapplicable here.

PO claims that Bio-Thera's equity structure demonstrates "opacity in [the] chain of control." Reply, 4. Not so. Janssen manufactured opacity by selectively translating excerpts of Bio-Thera's annual reports (EX2015, EX2017, EX2019, EX2021, and EX2023) while omitting pages that explicitly designate No. 3 as a "Domestic non-state-owned legal person" (EX1093, EX1095, EX1097, EX1099, and EX1101), demonstrating that the Chinese government does not control the investment vehicle and is not an RPI. PO cannot dispute their accuracy.

PO's procedural objection to the No. 3 confirmation letter under 37 C.F.R. §42.63(a) (Reply, 3) merits little weight. Corporate confirmation sheets accompanied by authenticated equity diagrams are useful, ordinary course evidence of corporate structure. Apart from the letter, the audited annual reports

independently defeat PO's state-control narrative. Moreover, this is not a case where a nominal petitioner acts as a passive front for an offshore government entity. Mr. Kokino's sworn testimony explicitly establishes that "Accord controls this IPR and related district court litigation for Petitioners." EX1053 ¶5.

PO relies on a generic congressional report (EX2031) to argue that even a miniscule government ownership fraction affords the Chinese state absolute structural "ability to control" any firm. Reply, 3. This is not the case. Exhibit 2031 discusses broad corporate governance trends across mainland China and does not establish a binding legal rule that an indirect, passive interest of 1.1588% strips a corporation of its separate legal identity or subverts its corporate structure. If the Board adopted PO's reasoning, large swathes of international companies would be banned from filing IPR petitions because they utilized public capital markets. Such an interpretation would force more litigation to district courts, where identifying RPIs does not control jurisdiction, contravening the purpose of AIA reviews, *i.e.*, "to provide a quick and cost-effective ***alternative*** to district court patent litigation." *Magnolia*, IPR2026-00097, Paper 17, 2.

II. ACCORD'S DOMESTIC INVESTMENTS AND CORE POLICY CONSIDERATIONS SUPPORT INSTITUTION

Accord is a substantial domestic enterprise incorporated in Delaware and headquartered in North Carolina, with hundreds of millions of dollars in U.S. annual sales, hundreds of American employees, and seven U.S. biosimilar approvals over

the past two years. EX1053 ¶¶2-4, 9. Accord owns the FDA approved application for BAT2506, handles its U.S. supply chain, and will direct all U.S. marketing, commercial sales, and distribution. *Id.* ¶¶6, 8; EX1054. Discretionary denial would directly harm an American company's concrete investments in domestic infrastructure, deprive American patients of a highly competitive, lower-cost medicine, and contravene the purpose of AIA reviews by driving patent litigation to the district court.

Tianma aims to ensure transparency and prevent foreign sovereign entities from surreptitiously manipulating administrative channels to weaken U.S. technological infrastructure. These concerns are absent here. In 2024 alone, generic and biosimilar competition introduced over $467 billion in U.S. healthcare infrastructure savings. EX1065, 11. Denying institution would not protect domestic innovation; it would insulate PO's monopoly pricing on a drug that costs American patients significantly more than in Germany, the United Kingdom, and China. Opp. Br., 19-20.

The Director has observed that the integrity of PTAB proceedings depends on knowing who funds, directs, and stands to benefit from a petition. Here, there is no opacity and no undisclosed state adversary. Petitioner has fully demonstrated that the Chinese government is neither an RPI nor in control of this IPR. Thus, discretionary denial is not warranted.

Respectfully submitted,

Dated: July 15, 2026

/ Lora M. Green /
Lora M. Green, Lead Counsel
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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 Petitioner's Sur-Reply Supporting Its Opposition To Patent Owner's Request For Discretionary Denial by electronic mail on Patent Owner's lead and backup counsel at the following email addresses:

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