Filed on behalf of: Janssen Biotech, Inc.

Entered: September 29, 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 UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner respectfully submits the following updated 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")

Exhibit	Description
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")
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.")

Exhibit	Description
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")
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	*The Chinese Government's Evolving Control of The Nonstate Sector: Rep. to Cong. of the U.S.-China Econ. & Sec. Rev. Comm'n*, 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

Exhibit	Description
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
2036	Tomas Gabriel Bas, *Innovative Formulation Strategies for Biosimilars: Trends Focused on Buffer-Free Systems, Safety, Regulatory Alignment, and Intellectual Property Challenges*, 18 PHARMS. 908 (2025) ("Bas (2025)")
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)")
2038	Marc D. Cohen & Edward C. Keystone, *Intravenous Golimumab in Rheumatoid Arthritis*, 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

Exhibit	Description
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)
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., *History of Changes for Study: NCT02181673, A Study of Golimumab in Participants With Active Psoriatic Arthritis*, 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")

Exhibit	Description
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.")
2052	Eur. Meds. Agency (EMA), Sci. Meds. Health, Comm. for Med. Prods. for Hum. Use (Day 120 Assessment Report, EMA/416184/2014), *Withdrawal Assessment Report: Simponi (golimumab)*, EMEA/H/C/000992/X/0047 (Janssen Biologics B.V., Applicant) (Oct. 24, 2013)
2053	Ctr. for Drug Evaluation & Rsch., Clinical Pharm. & Biopharmaceutics Rev., Simponi (Golimumab), BLA Appl. No. 125289 (submitted June 24, 2008) (EXCERPTS)
2054	Declaration of Dr. Nigil Haroon, M.D., Ph.D., M.B.A. in Support of Patent Owner's Preliminary Response ("Haroon")
2055	*Curriculum Vitae* of Dr. Nigil Haroon
2056	Press Release, Johnson & Johnson, Janssen Receives Two U.S. FDA Approvals for Simponi Aria® (Golimumab) for the Treatment of Adults With Active Psoriatic Arthritis or Active Ankylosing Spondylitis (Oct. 20, 2017), https://www.jnj.com/media-center/press-releases/janssen-receives-two-us-fda-approvals-for-simponi-aria-golimumab-for-the-treatment-of-adults-with-active-psoriatic-arthritis-or-active-ankylosing-spondylitis

Exhibit	Description
2057	NIH, Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., ClinicalTrials.gov: Search operation, https://clinicaltrials.gov/ (last visited May 3, 2026)
2058	NIH, Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., ClinicalTrials.gov, *An Efficacy and Safety Study of Golimumab in Participants With Ulcerative Colitis* (Janssen Rsch. & Dev., LLC, ClinicalTrials.gov ID NCT00488774) (updated June 14, 2013), https://clinicaltrials.gov/study/NCT00488774
2059	Internet Archive Wayback Machine, Calendar of https:/clinicaltrials.gov/study/NCT02181673, https://web.archive.org/web/20230815000000*/https:/clinicaltrials.gov/study/NCT02181673 (last visited May 21, 2026)
2060	Internet Archive Wayback Machine, Search of ClinicalTrials.gov studies, https://web.archive.org/web/20151118232332/https://clinicaltrials.gov/ (last visited May 3, 2026)
2061	FDA, Actemra Prescribing Information (revised Oct. 2013) ("ACTEMRA® (tocilizumab) Label")
2062	FDA, Remicade Prescribing Information (revised Oct. 2015) ("REMICADE® (infliximab) Label")
2063	Anthony D. Bai et al., *Intention-To-Treat Analysis May Be More Conservative Than Per Protocol Analysis in Antibiotic Non-Inferiority Trials: A Systematic Review*, 21 BMC MED. RSCH. METHODOLOGY 1–10 (2021)
2064	B. Bruce & J.F. Fries, *The Health Assessment Questionnaire (HAQ)*, 23 CLINICAL EXPERIMENTAL RHEUMATOLOGY S14 (2005)
2065	L. Congi & E. Roussou, *Clinical Application of the CASPAR Criteria for Psoriatic Arthritis Compared to Other Existing Criteria*, 28 CLINICAL EXPERIMENTAL RHEUMATOLOGY 304 (2010)

Exhibit	Description
2066	A. Farid et al., *Narrow Band Ultraviolet B Therapy Deactivates Th1/Th17 Pathway and Activates Th2 Cytokines Secretion in Egyptian Psoriatic Arthritis Patients*, 13 J. RADIATION RSCH. APPLIED SCIS. 356 (2020)
2067	David T. Felson et al., *American College of Rheumatology Preliminary Definition of Improvement in Rheumatoid Arthritis*, 38 ARTHRITIS RHEUMATISM 727 (1995)
2068	Oliver FitzGerald et al., *Concepts of Pathogenesis in Psoriatic Arthritis: Genotype Determines Clinical Phenotype*, 17 ARTHRITIS RSCH. THERAPY 1–11 (2015)
2069	FITZPATRICK'S DERMATOLOGY IN GENERAL MEDICINE 427 (Irwin M. Freedberg eds., 6th ed. 2003)
2070	Mathurin Flamant et al., *Golimumab for the Treatment of Ulcerative Colitis*, 17 EXPERT OP. BIOLOGICAL THERAPY 879 (2017)
2071	Lars Fugger & Arne Svejgaard, *Association of MHC and Rheumatoid Arthritis HLA-DR4 and Rheumatoid Arthritis: Studies in Mice and Men*, 2 ARTHRITIS RSCH. 208 (2000)
2072	Dafna D. Gladman, *Effectiveness of Psoriatic Arthritis Therapies*, 33 SEMINARS ARTHRITIS RHEUMATISM 29 (2003)
2073	D.D. Gladman et al., *Psoriatic Arthritis: Epidemiology, Clinical Features, Course, and Outcome*, 64 ANNALS RHEUMATIC DISEASES ii14 (2005)
2074	Deepak R. Jadon et al., *Psoriatic Arthritis Mutilans: Characteristics and Natural Radiographic History*, 42 J. RHEUMATOLOGY 1–8 (2015)
2075	CHARLES A. JANEWAY, JR., ET AL., IMMUNOBIOLOGY-THE IMMUNE SYSTEM IN HEALTH & DISEASE ch. 3-6 (5th ed. 2001), https://www.ncbi.nlm.nih.gov/books/NBK27160/ (EXCERPT)

Exhibit	Description
2076	Arthur Kavanaugh et al., *Treatment of Psoriatic Arthritis in a Phase 3 Randomised, Placebo-Controlled Trial with Apremilast, An Oral Phosphodiesterase 4 Inhibitor*, 73 ANNALS RHEUMATIC DISEASES 1020 (2014)
2077	Gabrielle H. Kingsley et al., *A Randomized Placebo-Controlled Trial of Methotrexate in Psoriatic Arthritis*, 51 RHEUMATOLOGY 1368 (2012)
2078	Mayke B.G. Koek et al., *Home Versus Outpatient Ultraviolet B Phototherapy for Mild to Severe Psoriasis: Pragmatic Multicentre Randomised Controlled Non-Inferiority Trial (PLUTO Study)*, 338 BRIT. MED. J. 1–11 (2009)
2079	Monalyn Labitigan et al., *Higher Rates and Clustering of Abnormal Lipids, Obesity, and Diabetes in Psoriatic Arthritis Compared with Rheumatoid Arthritis*, 66 ARTHRITIS CARE RSCH. 600 [1–16] (2014)
2080	R.J. Lories & D.L.P. Baeten, *Differences in Pathophysiology Between Rheumatoid Arthritis and Ankylosing Spondylitis*, 27 CLINICAL EXPERIMENTAL RHEUMATOLOGY S10 (2009)
2081	Iain B. McInnes et al., *Secukinumab, a Human Anti-Interleukin-17A Monoclonal Antibody, in Patients with Psoriatic Arthritis (FUTURE 2): A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Trial*, S0140-6736(15)61134-5 LANCET 1–10 (2015)
2082	Philip J. Mease et al., *Etanercept Treatment of Psoriatic Arthritis – Safety, Efficacy, and Effect on Disease Progression*, 50 ARTHRITIS RHEUMATISM 2264 (2004)
2083	Philip J. Mease, *Is There a Role for Rituximab in the Treatment of Spondyloarthritis and Psoriatic Arthritis?*, 39 J. RHEUMATOLOGY 2235 (2012)
2084	D.R. Mould & R.N. Upton, *Basic Concepts in Population Modeling, Simulation, and Model-Based Drug Development—Part 2: Introduction to Pharmacokinetic Modeling Methods*, 2 CPT: PHARMACOMETRICS SYS. PHARMACOLOGY 1–14 (2013)

Exhibit	Description
2085	Philip Ian Murray & Saaeha Rauz, *The Eye and Inflammatory Rheumatic Diseases: The Eye and Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis*, 30 BEST PRAC. RSCH. CLINICAL RHEUMATOLOGY 802 (2016)
2086	Makoto Naganuma et al., *Recent Trends and Future Directions for the Medical Treatment of Ulcerative Colitis*, 9 CLINICAL J. GASTROENTEROLOGY 329 (2016)
2087	Masatsugu Ono et al., *Structural Basis for Tumor Necrosis Factor Blockade with the Therapeutic Antibody Golimumab*, 27 PROTEIN SCI. 1038 (2018)
2088	Eric M. Ruderman, *The Role of Concomitant Methotrexate in Biologic Therapy for Rheumatoid Arthritis*, 71 BULL. HOSP. JOINT DISEASES S29 (2013)
2089	P. Rutgeerts et al., *Randomised Clinical Trial: A Placebo-Controlled Study of Intravenous Golimumab Induction Therapy for Ulcerative Colitis*, 42 ALIMENTARY PHARMACOLOGY THERAPEUTICS 504 (2015) ("Rutgeerts 2015")
2090	P. Rutgeerts et al., *Supplemental Appendix* (2015) ("Rutgeerts App'x")
2091	Georg Schett et al., *Structural Damage in Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis: Traditional Views, Novel Insights Gained From TNF Blockade, and Concepts for the Future*, 13 ARTHRITIS RSCH. THERAPY S4 (2011)
2092	Georg Schett et al., *Oral Apremilast in the Treatment of Active Psoriatic Arthritis – Results of a Multicenter, Randomized, Double-Blind, Placebo-Controlled Study*, 64 ARTHRITIS RHEUMATISM 3156 (2012)
2093	Calen A. Steiner et al., *Anti-TNF Biologic Therapies Other Than Infliximab* in PEDIATRIC INFLAMMATORY BOWEL DISEASE 401 (P. Mamula et al. eds., 2017)

Exhibit	Description
2094	William Taylor et al., *Classification Criteria for Psoriatic Arthritis – Development of New Criteria From a Large International Study*, 54 ARTHRITIS RHEUMATISM 2665 (2006)
2095	Bella Ungar & Uri Kopylov, *Advances in the Development of New Biologics in Inflammatory Bowel Disease*, 29 ANNALS GASTROENTEROLOGY 243 (2016)
2096	R.N. Upton & D.R. Mould, *Basic Concepts in Population Modeling, Simulation, and Model-Based Drug Development: Part 3—Introduction to Pharmacodynamic Modeling Methods*, 3 CPT: PHARMACOMETRICS SYS. PHARMACOLOGY 1–16 (2014)
2097	Désirée van der Heijde et al., *Psoriatic Arthritis Imaging: A Review of Scoring Methods*, 64 ANNALS RHEUMATIC DISEASES ii61 (2005)
2098	Karin A. van Schie et al., *Therapeutic TNF Inhibitors Can Differentially Stabilize Trimeric TNF by Inhibiting Monomer Exchange*, 6 NATURE SCI. REPS. 1–10 (2016)
2099	Ronald F. van Vollenhoven, *Sex Differences in Rheumatoid Arthritis: More Than Meets the Eye...*, 7 BIOMED CENT. MED. 1–4 (2009)
2100	J.E. WARE & M. KOSINSKI, SF-36 PHYSICAL & MENTAL HEALTH SUMMARY SCALES: A MANUAL FOR USERS OF VERSION 1 (2d ed. 1994) (EXCERPTS)
2101	Michael E. Weinblatt, *Methotrexate in Rheumatoid Arthritis: A Quarter Century of Development*, 124 TRANSACTIONS AM. CLINICAL CLIMATOLOGICAL ASS'N 16 (2013)
2102-2123	RESERVED
2124	Declaration of Roger J. Chin Pursuant to 37 C.F.R. § 42.10(c)(2)
2125	Declaration of Kevin N. Zhang in Support of Patent Owner's Unopposed Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)(1)

Exhibit	Description
2126–2499	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)

Respectfully submitted,

Dated: September 29, 2026

By: / Raghav Bajaj /

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 29th day of September, 2026, a true and correct copy of the foregoing **Patent Owner's Updated Exhibit List and Exhibit 2124** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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