Filed: June 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.,
Petitioners,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

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

PETITIONERS' UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioners Accord BioPharma, Inc., Intas Pharmaceuticals Ltd., and Bio-Thera Solutions, Ltd. hereby submit a current listing of petitioners' exhibits. Exhibits 1053–1116 are being filed today.

Exhibit	Description
1001	U.S. Patent No. 11,041,020 to Harrison et al. (June 22, 2021) ("*US020*")
1002	U.S. Patent No. 11,014,982 to Harrison et al. (May 25, 2021) ("*US982*")
1003	U.S. Patent No. 12,122,824 to Harrison et al. (Oct. 22, 2024) ("*US824*")
1004	U.S. Patent No. 12,291,566 to Harrison et al. (May 6, 2025) ("*US566*")
1005	Declaration of Dr. Roy M. Fleischmann in Support of IPR Petition
1006	Dr. Roy M. Fleischmann *curriculum vitae*
1007	Excerpts from prosecution history of U.S. Application No. 16/517,594, now U.S. Patent No. 11,041,020
1008	Excerpts from prosecution history of U.S. Application No. 16/517,592, now U.S. Patent No. 11,014,982
1009	Excerpts from prosecution history of U.S. Application No. 17/320,490, now U.S. Patent No. 12,12 02,824
1010	Excerpts from prosecution history of U.S. Application No. 17/237,650, now U.S. Patent No. 12,291,566
1011	U.S. National Library of Medicine, ClinicalTrials.gov, NCT02181673, "*A Study of Golimumab in Participants with Active Psoriatic Arthritis*" (Version 23, January 8, 2016), available at https://clinicaltrials.gov/study/NCT02181673? ("*NCT673-V23*")
1012	M. E. Weinblatt, et al., *Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial*, 72 ANN RHEUM DIS 381-389 (2013) ("*Weinblatt*")
1013	M. Rossini, et al., *Why golimumab in the treatment of psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis*?, 66 REUMATISMO 4:285-303 (Apr. 2014) ("*Rossini*")

Exhibit	Description
1014	U.S. National Library of Medicine, ClinicalTrials.gov, NCT02186873, "*A Study of Golimumab in Participants with Active Ankylosing Spondylitis*" (Version 24, October 27, 2015), available at https://clinicaltrials.gov/study/NCT02186873? ("*NCT873-V24*")
1015	*SIMPONI (golimumab) injection, for subcutaneous use*, FOOD AND DRUG ADMINISTRATION (June 2015), https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125289s024lbl.pdf ("*PI2015-Simponi*")
1016	R. D. Inman, et al., *Efficacy and Safety of Golimumab in Patients With Ankylosing Spondylitis,* 58 ARTHRITIS & RHEUMATISM 11:3402-3412 (Nov. 2008) ("*Inman*")
1017	*Understanding the Difference: Standard Error vs. Standard Deviations*, SIXSIGMA (September 25, 2024), *available at* https://www.6sigma.us/six-sigma-in-focus/standard-error-vs-standard-deviation/ ("*SixSigma*")
1018	*BLA Approved re BLA 125289*, FOOD AND DRUG ADMINISTRATION (Apr. 24, 2009) ("*2009 Approval*")
1019	*BLA Approved re BLA 125433*, FOOD AND DRUG ADMINISTRATION (July 18, 2013) ("*2013 Approval*")
1020	-- Intentionally Left Blank --
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1022	S. D'Angelo, *Psoriatic arthritis: treatment strategies using biologic agents*, 64 REUMATISMO (2):113-121 (Feb. 2012) ("*D'Angelo*")
1023	-- Intentionally Left Blank --
1024	U.S. Patent Publication 2009/0123378 to Wong et al. (May 14, 2009) ("*Wong*")
1025	International Publication WO 2008/063213 A2 to Medich et al. (May 29, 2008) ("*WO213*")
1026	J. Kay & M. U. Rahman, *Golimumab: A novel human anti-TNF-α monoclonal antibody for the treatment of rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis*, Core Evidence 4:159-170 (2009) ("*Kay*")
1027	E. C. Keystone & C. F. Ware, *Tumor Necrosis Factor and Anti-Tumor Necrosis Factor Therapies*, J RHEUMATOL SUPPL. 85:27-39 (May 2010) ("*Keystone*")

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1028	H. Shim, *One target, different effects: a comparison of distinct therapeutic antibodies against the same targets*, 43 EXP MOL MED. 10:539-549 (Oct. 2011) ("*Shim*")
1029	J. Kalden, *Anti-TNF therapy: what have we learned in 12 years?*, ARTHRITIS RES THER. 13(Suppl 1):S1 (May 25, 2011) ("*Kalden*")
1030	L. C. Coates, et al., *Anti-TNF therapy in ankylosing spondylitis: insights for the clinician*, 2 THER ADV MUSCULOSKELET DIS. 1:37-43 (2010) ("*Coates*")
1031	-- Intentionally Left Blank --
1032	*SIMPONI ARIA (golimumab) injection, for intravenous use*, FOOD AND DRUG ADMINISTRATION (July 2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125433s000lbledt.pdf ("*PI2013-Aria*")
1033	D. van der Heijde, et al., *The Effect of Golimumab Therapy on Disease Activity and Health-related Quality of Life in Patients with Ankylosing Spondylitis: 2-year Results of the GO-RAISE Trial*, 41 THE JOURNAL OF RHEUMATOLOGY 6:1095-1103 (2014) ("*Van der Heijde*")
1034	*Administrative and Correspondence Documents, Application Number: 125433Orig1s000,* CENTER FOR DRUG EVALUATION AND RESEARCH, (September 30, 2013) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/125433review.pdf ("*CDER Review*")
1035	M. K. Doyle et al., *Effects of subcutaneous and intravenous golimumab on inflammatory biomarkers in patients with rheumatoid arthritis: results of a phase 1, randomized, open-label trial*, 52 RHEUMATOLOGY 7:1214-9 (2013) ("*Doyle*")
1036	U.S. Publication No. 2008/0311043 to Hoffman et al. ("*Hoffman*")
1037	U.S. Patent No. 5,656,272 to Le et al. ("*Le*")
1038	Y. Zhuang, et al., *Golimumab Pharmacokinetics After Repeated Subcutaneous and Intravenous Administrations in Patients with Rheumatoid Arthritis and the Effect of Concomitant Methotrexate: An Open-Label, Randomized Study*, 34 CLINICAL THERAPEUTICS 1:77-90 (Jan. 2012) ("*Zhuang*")
1039	*New Phase 3 Data Show Simponi Aria® (Golimumab) Significantly Improved Signs and Symptoms in Patients with Active Ankylosing Spondylitis*, JOHNSON & JOHNSON (Nov. 14, 2016) ("*J&J 2016*")

Exhibit	Description
1040	*New Phase 3 Data Show SIMPONI ARIA® (golimumab) Significantly Improved Signs and Symptoms in Patients with Active Ankylosing Spondylitis*, JANSSEN RESEARCH & DEVELOPMENT, LLC (Nov. 14, 2016) ("*Janssen 2016*")
1041	A. Kavanaugh, et al., *Golimumab, a New Human Tumor Necrosis Factor α Antibody, Administered Every Four Weeks as a Subcutaneous Injection in Psoriatic Arthritis,* 60 ARTHRITIS & RHEUMATISM 4, 976-986 (Apr. 2009) ("*Kavanaugh 2009*")
1042	A. Kavanaugh, et al., *Golimumab in Psoriatic Arthritis, One-Year Clinical Efficacy, Radiographic, and Safety Results From a Phase III, Randomized, Placebo-Controlled Trial*, 64 ARTHRITIS & RHEUMATISM 8, 2504-2517 (2012) ("*Kavanaugh 2012*")
1043	A. Kavanaugh, et al., *Patient-Reported Outcomes and the Association With Clinical Response in Patients With Active Psoriatic Arthritis Treated With Golimumab: Findings Through 2 Years of a Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial*, 65 ARTHRITIS CARE & RESEARCH 10, 1666-73 (OCT. 2013) ("*Kavanaugh 2013*")
1044	A. Kavanaugh, et al., *Clinical efficacy, radiographic and safety findings through 5 years of subcutaneous golimumab treatment in patients with active psoriatic arthritis: results from a long-term extension of a randomised, placebo-controlled trial (the GO-REVEAL study),* 73 ANN. RHEUM. DIS. 1689-1694 (Apr. 19, 2014) ("*Kavanaugh 2014*")
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1050	*Appendix 6 Summary of Comparators* in *Golimumab (Simponi) IV: In Combination with Methotrexate (MTX) for the Treatment of Adult Patients with Moderately to Severely Active Rheumatoid Arthritis*, CANADIAN AGENCY FOR DRUGS AND TECHNOLOGIES IN HEALTH (Jul. 2015) ("*CADTH*")
1051	*Guidance for Industry – Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products*, U.S. DEPARTMENT OF HEALTH

Exhibit	Description
	AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH & CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (May 1998) ("*Industry Guidance*")
1052	*National Institutes of Health, Press Release: National Institutes of Health Launches "ClinicalTrials.gov"*, U.S. NATIONAL LIBRARY OF MEDICINE (February 29, 2000), https://www.nlm.nih.gov/ archive/20040831/news/ press_releases/clntrlpr00.html ("*NLM Press Release*")
1053	Declaration of Mr. Chrys Kokino
1054	Accord, Photograph of Accord U.S. Team (June 2026)
1055	Compl. for Pat. Infringement [Redacted], *Janssen Biotech, Inc. v. Accord BioPharma, Inc.*, No. 1:26-cv-00222 (D. Del. Mar. 11, 2026), Dkt. No. 10
1056	Accord BioPharma, Inc., *Accord BioPharma, Inc. Announces Completion of UDENYCA (pegfilgrastim-cbqv) Franchise Acquisition from Coherus BioSciences, Inc., Expanding U.S. Biosimilar Portfolio*, PR NEWSWIRE (Apr. 14, 2025), https://www.prnewswire.com/news-releases/accord-biopharma-inc-announces-completion-of-udenyca-pegfilgrastim-cbqv-franchise-acquisition-from-coherus-biosciences-inc-expanding-us-biosimilar-portfolio-302427584.html/
1057	Accord BioPharma, Inc., *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*, PR NEWSWIRE (May 18, 2026), https://www.prnewswire.com/news-releases/fda-approves-immgolis-golimumab-sldi-and-immgolis-intri-golimumab-sldi-first-biosimilars-to-simponi-golimumab-and-simponi-aria-golimumab-accord-biopharma-to-lead-us-commercialization-302774328.html/
1058	*Xian Janssen Celebrates 30 Years of Commitment to China*, XIAN JANSSEN PHARM. LTD. (Oct. 13, 2015), https://www.xian-janssen.com.cn/en/news/473/
1059	*A Spotlight on Our Collaborations in Asia Pacific*, JOHNSON & JOHNSON INNOVATION (2022), https://jnjinnovation.com/pages/a-spotlight-on-our-collaborations-in-asia-pacific-2022/

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1060	*Janssen Pharmaceuticals to Invest USD500 Million in China to Develop Pulmonary Disease Drugs*, YICAI GLOBAL (May 19, 2017), https://www.yicaiglobal.com/news/janssen-pharmaceuticals-to-invest-usd500-million-in-china-to-develop-pulmonary-disease-drugs/
1061	Eric Palmer, *Xian Janssen Announces Plans to Build State-of-the-Art Manufacturing Site in China*, FIERCE PHARMA (Nov. 18, 2013), https://www.fiercepharma.com/manufacturing/xian-janssen-announces-plans-to-build-state-of-art-manufacturing-site-china/
1062	Will Maddox, *J&J changes New York state of mind, closing JLABS site after 8 years*, FIERCE BIOTECH (Mar. 17, 2026), https://www.fiercebiotech.com/biotech/jlabs-cant-make-it-anywhere-exit-new-york-location/
1063	Zheng Yiran, *China a 'Critical Frontier' for the Future of Healthcare, J&J MedTech China President Says*, CHINA DAILY (Nov. 5, 2025), https://www.chinadaily.com.cn/a/202511/05/WS690aee95a310bfcd27fc4f8e.html/
1064	AAM, *Anatomy of a Biosimilar Patent Litigation: Problems and Solutions* at 8–10 (July 2025), https://accessiblemeds.org/wp-content/uploads/2025/07/White-Paper-Anatomoy-of-Biosimilar-Patent-Legislation-July-2025.pdf/
1065	AAM, *The U.S. Generic & Biosimilar Medicines Saving Report* (September 2025), https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf/
1066	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-032 (Feb. 1, 2021)
1067	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-031 (Sep. 29, 2020)
1068	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-028 (Sep. 24, 2019)
1069	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-024 (Feb. 9, 2018)
1070	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-021 (Oct. 20, 2017)
1071	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-020 (Oct. 20, 2017)

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1072	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-019 (Jan. 30, 2017)
1073	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-018 (Aug. 19, 2016)
1074	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-017 (Feb. 22, 2016)
1075	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-015 (Jan. 8, 2016)
1076	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-014 (Aug. 5, 2015)
1077	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-005 (Feb. 12, 2014)
1078	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433/S-002 (Feb. 4, 2014)
1079	Janssen Biotech, Inc., Simponi Aria Labeling, BLA No. 125433 (July 18, 2013)
1080	Johnson & Johnson, Quarterly Report (Form 10-Q) (Apr. 22, 2026)
1081	Johnson & Johnson, Information about our Innovative Medicine patent portfolio (Updated February 16, 2024)
1082	Johnson & Johnson 2019 Annual Report
1083	Excerpt of Johnson & Johnson, 2025 Annual Report (Form 10-K) (Feb. 11, 2026)
1084	Excerpt of Johnson & Johnson, 2024 Annual Report (Form 10-K) (Feb. 13, 2025)
1085	Excerpt of Johnson & Johnson, 2021 Annual Report (Form 10-K) (Feb. 17, 2022)
1086	Excerpt of Johnson & Johnson, 2018 Annual Report (Form 10-K) (Feb. 20, 2019)
1087	Excerpt of Johnson & Johnson, 2015 Annual Report (Form 10-K) (Feb. 24, 2016)
1088	Excerpt of Johnson & Johnson, 2012 Annual Report (Form 10-K) (Feb. 22, 2013)
1089	Johnson & Johnson 2015 Q4 Results, https://www.investor.jnj.com/financials/quarterly-results/ (choose "2015" from dropdown; then follow "Johnson & Johnson Reports 2015 Fourth-Quarter Results" hyperlink)

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1090	Johnson & Johnson 2013 Q4 Results, https://www.investor.jnj.com/financials/quarterly-results/ (choose "2013" from dropdown; then follow "Johnson & Johnson Reports 2013 Fourth-Quarter and Full-Year Results" hyperlink)
1091	Johnson & Johnson 2011 Q4 Year End Press Release Charts, https://www.jnj.com/document/2011-q4-year-end-press-release-charts
1092	Excerpt of Janssen Exhibit 2015 (Bio-Thera Solutions, Ltd., 2019 Annual Report)
1093	English Translation and Certificate of Translation of excerpt of Janssen Exhibit 2015 (Bio-Thera Solutions, Ltd., 2019 Annual Report)
1094	Excerpt of Janssen Exhibit 2017 (Bio-Thera Solutions, Ltd., 2020 Annual Report)
1095	English Translation and Certificate of Translation of excerpt of Janssen Exhibit 2017 (Bio-Thera Solutions, Ltd., 2020 Annual Report)
1096	Excerpt of Janssen Exhibit 2019 (Bio-Thera Solutions, Ltd., 2021 Annual Report)
1097	English Translation and Certificate of Translation of excerpt of Janssen Exhibit 2019 (Bio-Thera Solutions, Ltd., 2021 Annual Report)
1098	Excerpt of Janssen Exhibit 2021 (Bio-Thera Solutions, Ltd., 2024 Annual Report)
1099	English Translation and Certificate of Translation of excerpt of Janssen Exhibit 2021 (Bio-Thera Solutions, Ltd., 2024 Annual Report)
1100	Excerpt of Janssen Exhibit 2023 (Bio-Thera Solutions, Ltd., 2025 Annual Report)
1101	English Translation and Certificate of Translation of excerpt of Janssen Exhibit 2023 (Bio-Thera Solutions, Ltd., 2025 Annual Report)
1102	"机构股东确认函-粤创三号" (Confirmation Letter for Guangzhou CAS Yuechuang No. 3 Venture Capital Partnership (Limited Partnership)) (Original)
1103	English Translation and Certificate of Translation of "机构股东确认函-粤创三号" (Confirmation Letter for Guangzhou CAS Yuechuang No. 3 Venture Capital Partnership (Limited Partnership))
1104	"西安杨森制药有限公司 - 企查查" (QiChaCha webpage for Xi'an Janssen Pharmaceutical Co., Ltd.)

Exhibit	Description
1105	English Translation and Certificate of Translation of "西安杨森制药有限公司 - 企查查" (QiChaCha webpage for Xi'an Janssen Pharmaceutical Co., Ltd.)
1106	Executive Order No. 14273, Lowering Drug Prices by Once Again Putting Americans First, 90 Fed. Reg. 16441 (April 15, 2025)
1107	*Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices*, THE WHITE HOUSE (Apr. 15, 2025), https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/
1108	*Dr. Rand Paul Introduces Legislation to Modernize FDA Prescription Drug Approvals and Lower Drug Prices*, Sen. Rand Paul (Apr. 8, 2025), https://www.paul.senate.gov/dr-rand-paul-introduces-legislation-to-modernize-fda-prescription-drug-approvals-and-lower-drug-prices/
1109	*Klobuchar, Grassley Introduce Bipartisan Bills to Reduce Drug Prices by Promoting Competitionand Taking on Big Pharma*, Sen. Amy Klobuchar (Mar. 26, 2025), https://www.klobuchar.senate.gov/public/index.cfm/2025/3/klobuchar-grassley-introduce-bipartisan-bills-to-reduce-drug-prices-by-promoting-competition-and-taking-on-big-pharma/
1110	*Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*, THE WHITE HOUSE (May 12, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/
1111	Golimumab U.S. Pricing Data
1112	Excerpt of "festbetraege-20260615" German Pricing for Simponi, https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Festbetraege-und-Zuzahlungen/Festbetraege/_node.html)
1113	Excerpt of British Formulary and NICE Reimbursement Listing for Simponi, https://bnf.nice.org.uk/drugs/golimumab/medicinal-forms/
1114	Miriam Fontanillo, Boris Körs & Alex Monnard, *Three Imperatives for R&D in Biosimilars*, MCKINSEY & CO. (Aug. 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars/

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1115	Excerpt of China Healthcare Security Bureau Price Listing for Simponi, JIANGSU PROVINCIAL HEALTHCARE SECURITY BUREAU, https://ybj.jszwfw.gov.cn/hsa-local/web/hallPersonal/#/ggcxDrugsSJ (search in search bar for "戈利木单抗")
1116	English Translation and Certificate of Translation of excerpt of China Healthcare Security Bureau Price Listing for Simponi, JIANGSU PROVINCIAL HEALTHCARE SECURITY BUREAU, https://ybj.jszwfw.gov.cn/hsa-local/web/hallPersonal/#/ggcxDrugsSJ (search in search bar for "戈利木单抗")

Respectfully submitted,

Dated: June 29, 2026

/ Lora M. Green /
Lora M. Green, Lead Counsel
Reg. No. 43,351

Filed: June 29, 2026

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing Petitioners' Updated Exhibit List and Exhibit 1053–1116 were served electronically via email on June 29, 2026, in their entirety on the following:

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