

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD,
Petitioners,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

Case No. IPR2023-01103
U.S. Patent 10,961,307

**JOINT REQUEST TO FILE SETTLEMENT AGREEMENT AS
BUSINESS CONFIDENTIAL INFORMATION**

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,961,307 B2 issued to Johannis et al. (“307”)
1002	Declaration of Michael S. Epstein, M.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 10,961,307
1003	Janssen Research & Development, LLC published clinical overview summary for Phase 3 clinical trial for ustekinumab in UC (NCT02407236) on ClinicalTrials.gov (“NCT-236”)
1004	Stelara® Prescribing Information (Sept. 2016) (the “Stelara-PI(2017)”)
1005	Ochsenkühn et al., <i>P759 Ustekinumab as rescue treatment in therapy-refractory or -intolerant ulcerative colitis</i> , Journal of Crohn’s and Colitis, 12:S495 (Feb. 2018)
1006	Entyvio (vedolizumab) Prescribing Information (May 2014)
1007	Humira (adalimumab) Prescribing Information (July 2016)
1008	Remicade (infliximab) Prescribing Information (Jan. 2015)
1009	Danese & Fiocchi, <i>Ulcerative Colitis</i> , N Engl J Med., 365:1713-1725 (2011)
1010	Cote-Daigneault, <i>Biologics in inflammatory bowel disease: what are the data?</i> , UEG J., 3(5):419-428 (2015)
1011	Ahern et al., <i>Interleukin-23 Drives Intestinal Inflammation through Direct Activity on T Cells</i> , Immunity, 33:279-288 (Aug. 2010)
1012	Uhlig et al., <i>Differential Activity of IL-12 and IL-23 in Mucosal and Systemic Innate Immune Pathology</i> , Immunity, 25:309-318 (Aug. 2006)
1013	Yen et al., <i>IL-23 is essential for T cell-mediated colitis and promotes inflammation via IL-17 and IL-6</i> , J of Clinical Investigation, 116(6):1310-1316 (May 2006)
1014	Aggeletopoulou et al., <i>Interleukin 12/interleukin 23 pathway: Biological basis and therapeutic effect in patients with Crohn’s disease</i> , World J of Gastroenterol, 24(36):4093-4103 (Sept. 2018)
1015	Pedersen et al., <i>Inflammatory pathways of importance for management of inflammatory bowel disease</i> , World J Gastroenterol, 20(1):64-77 (Jan. 2014)

Exhibit No.	Description
1016	Coskun et al., <i>Novel Targeted Therapies for Inflammatory Bowel Disease</i> , Trends in Pharmacological Sciences, 38(2):127-142 (Feb. 2017)
1017	Sandborn et al., <i>A Randomized Trial of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Moderate-to-Severe Crohn's Disease</i> , Gastroenterology, 135(4):1130-1141 (2008)
1018	U.S. Patent No. 6,902,734 B2 issued to Giles-Komar et al. ("734 Patent")
1019	U.S. Patent No. 7,166,285 B2 issued to Giles-Komar et al. ("285 Patent")
1020	Application for Extension of Patent Term (37 C.F.R. § 1.740) for U.S. Patent No. 6,902,734
1021	Application for Extension of Patent Term (37 C.F.R. § 1.740) for U.S. Patent No. 7,166,285
1022	Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") had published the sequence for ustekinumab
1023	Webarchive screenshots of www.pmda.go.jp/english/index.html
1024	Stelara Prescribing Information (Sept. 2009) ("First Approved Label")
1025	U.S. Patent Publication No. US 2009/0181027 A1 ("027-Publication")
1026	Feagan et al., <i>Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease</i> , N Engl J Med 375(20):1946-60 (Nov. 17, 2016)
1027	Janssen Research & Development NCT02407236 Clinical Protocol (Apr. 20, 2016) ("Phase 3 Clinical Protocol")
1028	Affidavit of Nathaniel E Frank-White
1029	Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry (Aug. 2016)
1030	Field Trials of Health Interventions: A Toolbox, Smith (3rd ed. 2015)
1031	Sands et al., <i>Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis</i> , N Engl J Med 381(13):1201-1214 (Sept. 26, 2019)

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1032	Janssen Press Release: <i>Janssen Announces U.S. FDA Approval of STELARA (ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative</i> (Oct. 21, 2019)
1033	Tarr et al., <i>Superheroes in autoimmune warfare: Biologic therapies in current South African practice</i> , S Afr Med J 104(11):787-791 (2014)
1034	Kolios et al., <i>Paradoxical ulcerative colitis during adalimumab treatment of psoriasis resolved by switch to ustekinumab</i> , British Journal of Dermatology, 178:551-555 (2018)
1035	Afonso et al., <i>CP-202 Ustekinumab treatment in refractory inflammatory bowel disease</i> , European Journal of Hospital Pharmacy 24(Suppl. 1):A90 (2017)
1036	Excerpts from the file history for U.S. Patent No. 10,961,307
1037	Reserved
1038	Johnson and Johnson Press Release: <i>FDA Approves STELARA (Ustekinumab) for Treatment of Adults With Moderately to Severely Active Crohn's Disease</i> (Sept. 26, 2016)
1039	Reserved
1040	Reserved
1041	American of College of Rheumatology: Ustekinumab (Stelara) (2018)
1042	D'Haens et al., <i>A Review of Activity Indices and Efficacy End Points for Clinical Trials of Medical Therapy in Adults With Ulcerative Colitis</i> , Gastroenterology, 132:763-786 (2007)
1043	Dhanda et al., <i>Can Endoscopy Be Avoided in the Assessment of Ulcerative Colitis in Clinical Trials?</i> , Inflamm Bowel Dis 18:2056-2062 (Nov. 2012)
1044	Glossary of Common Site Terms, ClinicalTrials.gov (Oct. 2021)
1045	Outcome Measure Considerations for Clinical Trials Reporting on ClinicalTrials.gov, Harvard Catalyst (July 11, 2018)
1046	History of Changes for Study: NCT02407236, ClinicalTrials.gov archive
1047	History of Changes for Study: NCT02407236, ClinicalTrials.gov archive
1048	Kim et al., <i>Correlation between Histological Activity and Endoscopic, Clinical, and Serological Activities in Patients with</i>

Exhibit No.	Description
	<i>Ulcerative Colitis</i> , Gastroenterology Research & Practice (2016) (“Kim”)
1049	U.S. Patent Application Publication 2020/0262908 A1 issued to Jones et al. (“Jones”)
1050	Pithadia & Jain, <i>Treatment of inflammatory bowel disease (IBD)</i> , Pharmacological Reports, 63:629-642 (2011) (“Pithadia”)
1051	Higgins et al., <i>Is Endoscopy Necessary for the Measurement of Disease Activity in Ulcerative Colitis?</i> , Am J Gastroenterol, 100:355-361 (2005) (“Higgins”)
1052	International Publication Number WO 2017/049035 A1 issued to Georgantas et al. (“WO 2017/049035”)
1053	International Publication Number WO 2015/119841 A1 issued to Zuniga et al. (“WO 2015/119841”)
1054	History of Changes for Study: NCT02407236, ClinicalTrials.gov archive
1055	Stelara, European Medicines Agency https://www.ema.europa.eu/en/medicines/human/EPAR/stelara
1056	Nakov et al., <i>Correlation between Ulcerative Colitis Endoscopic Index of Severity, Lichtiger Index and Fecal Calprotectin in Ulcerative Colitis Patients</i> , Inter Med (2017)
1057	Reserved
1058	Reserved
1059	Reserved
1060	Webarchive of “A Safety and Efficacy Study for Infliximab (Remicade) in Patients With Ulcerative Colitis,” available at https://web.archive.org/web/20130703191943/http://www.clinicaltrials.gov/ct2/show/NCT00096655
1061	Webarchive of “Efficacy and Safety of Adalimumab in Subjects With Moderately to Severely Active Ulcerative Colitis” available at https://web.archive.org/web/20151007112912/https://clinicaltrials.gov/ct2/show/NCT00408629
1062	Webarchive of “Study of Vedolizumab (MLN0002) in Patients With Moderate to Severe Ulcerative Colitis (GEMINI I)” available at

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	https://web.archive.org/web/20170830060323/https://clinicaltrials.gov/ct2/show/NCT00783718
1063	Sequence published with International Publication Number WO 2015/119841 A1 issued to Zuniga et al. (WO 2015/119841) available at patentscope.wipo.int
1064	Webarchive of Janssen Research & Development, LLC published clinical overview summary for Phase 3 clinical trial for ustekinumab in UC (NCT02407236) available at https://web.archive.org/web/20161007165451/https://clinicaltrials.gov/ct2/show/NCT02407236
1065	Webarchive of Chemical Database for Ustekinumab available at https://web.archive.org/web/20160917081227/https://druginfo.nlm.nih.gov/drugportal/name/Ustekinumab
1066	Webarchive of Label: STELARA - ustekinumab injection, solution https://web.archive.org/web/20210527042114/https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c77a9664-e3bb-4023-b400-127aa53bca2b
1067	Webarchive of Label: STELARA - ustekinumab injection, solution, “View Labeling Archives for this Drug” https://web.archive.org/web/20210527042114/https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c77a9664-e3bb-4023-b400-127aa53bca2b
1068	Labeling Archives, search results for ustekinumab on 09/27/2016 STELARA- ustekinumab injection, solution https://dailymed.nlm.nih.gov/dailymed/archives/index.cfm?query=ustekinumab&date=09%2F27%2F2016
1069	STELARA- ustekinumab solution Archived Drug Label, https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=229160
1070	Ustekinumab (Stelara), <i>Ottawa (ON): Canadian Agency for Drugs and Technologies in Health</i> ; 2017 Apr., available at https://www.ncbi.nlm.nih.gov/books/NBK476200/?report=printable

Exhibit No.	Description
1071	Declaration of Noah S. Frank
1072	Listing of Challenged Claims of the '307
1073	Settlement Agreement [CONFIDENTIAL]

Pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c), Petitioner and Patent Owner (collectively, “the Parties”) jointly request to treat as business confidential information, and to keep separate from the file of the involved patent, the true and complete copy of the Settlement Agreement (Confidential Exhibit 1073) between the parties and their parents and affiliates, as referenced in the concurrently filed Joint Motion to Terminate Proceeding. The Settlement Agreement requires that the parties thereto keep the terms and conditions of the agreement confidential and generally prohibits disclosure to third parties.

In view of the terms of the Settlement Agreement, and the Parties’ joint request to file it confidentially, the Settlement Agreement has been filed for access by the “Board and Parties Only.” The present request, which is being filed contemporaneously with the Settlement Agreement, is timely and complies with the foregoing authority. Therefore, the Parties request that the Settlement Agreement (Confidential Exhibit 1073): (i) be treated as business confidential information; (ii) be maintained separate from the publicly available file of the involved patent; and (iii) be made available only to Federal Government agencies on written request, or to persons showing good cause on written request, pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c).

Date: August 3, 2023

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Respectfully submitted,

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CERTIFICATE OF SERVICE

In compliance with 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a copy of the foregoing Joint Request to File Settlement Agreement as Business Confidential Information was served on the 3rd day of August, 2023, via Federal Express® overnight delivery directed to Patent Owner at the correspondence address of record:

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This Joint Request to File Settlement Agreement as Business Confidential Information is also being served on the below litigation counsel for Patent Owner via electronic mail:

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