**UNITED STATES PATENT AND TRADEMARK OFFICE**

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS INC.,

Petitioner,

v.

JANSSEN BIOTECH, INC.,

Patent Owner.

Patent No. 10,961,307
Filing Date: September 24, 2019
Issue Date: March 30, 2021

Inventors: Jewel Johanns, Katherine Li, Colleen Marano, Richard Strauss, Hongyan Zhang, Christopher O'Brien, Omoniyi Adedokun, and Kimberly Shields-Tuttle

Title: METHODS OF TREATING MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS BY ADMINISTERING AN ANTI-IL12/IL23 ANTIBODY

# JOINT MOTION TO TERMINATE PROCEEDING

Case No. IPR2023-01444

# LIST OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 1001 | U.S. Patent No. 10,961,307 B2 issued to Johanns et al. ("'307") |
| 1002 | Declaration of Alan V. Safdi, 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., *P759 Ustekinumab as rescue treatment in therapy-refractory or -intolerant ulcerative colitis*, 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, *Ulcerative Colitis*, N Engl J Med., 365:1713-1725 (2011) |
| 1010 | Cote-Daigneault, *Biologics in inflammatory bowel disease: what are the data?*, UEG J., 3(5):419-428 (2015) |
| 1011 | Ahern et al., *Interleukin-23 Drives Intestinal Inflammation through Direct Activity on T Cells*, Immunity, 33:279-288 (Aug. 2010) |
| 1012 | Uhlig et al., *Differential Activity of IL-12 and IL-23 in Mucosal and Systemic Innate Immune Pathology*, Immunity, 25:309-318 (Aug. 2006) |
| 1013 | Yen et al., *IL-23 is essential for T cell-mediated colitis and promotes inflammation via IL-17 and IL-6*, J of Clinical Investigation, 116(6):1310-1316 (May 2006) |
| 1014 | Aggeletopoulou et al., *Interleukin 12/interleukin 23 pathway: Biological basis and therapeutic effect in patients with Crohn's disease*, World J of Gastrenterol, 24(36):4093-4103 (Sept. 2018) |
| 1015 | Pedersen et al., *Inflammatory pathways of importance for management of inflammatory bowel disease*, World J Gastroenterol, 20(1):64-77 (Jan. 2014) |
| 1016 | Coskun et al., *Novel Targeted Therapies for Inflammatory Bowel Disease*, Trends in Pharmacological Sciences, 38(2):127-142 (Feb. 2017) |

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|---|---|
| 1017 | Sandborn et al., *A Randomized Trial of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Moderate-to-Severe Crohn's Disease*, 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 ofwww.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., *Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease*, 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., *Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis*, N Engl J Med 381(13):1201- 1214 (Sept. 26, 2019) |
| 1032 | Janssen Press Release: *Janssen Announces U.S. FDA Approval of STELARA (ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative* (Oct. 21, 2019) |
| 1033 | Tarr et al., *Superheroes in autoimmune warfare: Biologic therapies in current South African practice*, S Afr Med J 104(11):787-791 (2014) |

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|---|---|
| 1034 | Kolios et al., *Paradoxical ulcerative colitis during adalimumab treatment of psoriasis resolved by switch to ustekinumab*, British Journal of Dermatology, 178:551-555 (2018) |
| 1035 | Afonso et al., *CP-202 Ustekinumab treatment in refractory inflammatory bowel disease*, 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: *FDA Approves STELARA (Ustekinumab) for Treatment of Adults With Moderately to Severely Active Crohn's Disease* (Sept. 26, 2016) |
| 1039 | Reserved |
| 1040 | Reserved |
| 1041 | American of College of Rheumatology: Ustekinumab (Stelara) (2018) |
| 1042 | D'Haens et al., *A Review of Activity Indices and Efficacy End Points for Clinical Trials of Medical Therapy in Adults With Ulcerative Colitis*, Gastroenterology, 132:763-786 (2007) |
| 1043 | Dhanda et al., *Can Endoscopy Be Avoided in the Assessment of Ulcerative Colitis in Clinical Trials?*, 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., *Correlation between Histological Activity and Endoscopic, Clinical, and Serological Activities in Patients with Ulcerative Colitis*, Gastroenterology Research & Practice (2016) ("Kim") |
| 1049 | U.S. Patent Application Publication 2020/0262908 A1 issued to Jones et al. ("Jones") |
| 1050 | Pithadia & Jain, *Treatment of inflammatory bowel disease (IBD)*, Pharmacological Reports, 63:629-642 (2011) ("Pithadia") |
| 1051 | Higgins et al., *Is Endoscopy Necessary for the Measurement of Disease Activity in Ulcerative Colitis?*, Am J Gastroenterol, 100:355-361 (2005) ("Higgins") |

| Exhibit No. | Description |
|---|---|
| 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., *Correlation between Ulcerative Colitis Endoscopic Index of Severity, Lichtiger Index and Fecal Calprotectin in Ulcerative Colitis Patients*, 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 UlcerativeColitis (GEMINI I)" available at 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 |

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| 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), *Ottawa (ON): Canadian Agency for Drugs and Technologies in Health*; 2017 Apr., available athttps://www.ncbi.nlm.nih.gov/books/NBK476200/?report=printable |
| 1071 | Declaration of Noah S. Frank |
| 1072 | Listing of Challenged Claims of the '307 |
| 1073 | Confidential Settlement Agreement |

Pursuant to 35 U.S.C. § 317(a), 37 C.F.R. § 42.74, and the Board's email of February 28, 2024, Petitioner Biocon Biologics Inc. ("Biocon" or "Petitioner") and Patent Owner, Janssen Biotech, Inc. ("Janssen" or "PO") (collectively, the "Parties") have reached a resolution and jointly move to terminate the above-captioned proceeding.

## I. STATEMENT OF FACTS

The Parties have reached an agreement to resolve their disputes in the above-captioned *inter partes* review relating to U.S. Patent No. 10,961,307.

Pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(b), Petitioner and Patent Owner submit a true copy of the confidential settlement agreement in its entirety, filed herewith as Exhibit 1073. A "Joint Request That Settlement Agreement be Treated as Business Confidential Information and Kept Separate Under 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c)" is being filed concurrently with this Joint Motion to Terminate, to treat Exhibit 1073 as business confidential information and to keep them separate from the files of the involved patent pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c).

There are no other collateral agreements between the Parties made in connection with, or in contemplation of, the termination sought.

Both Petitioner and Patent Owner support termination of the proceeding. This proceeding is still in its preliminary stages. Patent Owner has not filed a Preliminary

Response to the Petition, and the Board has not rendered an Institution Decision.

There is currently no pending related litigation nor any related proceedings currently pending before the Office. The '307 Patent was previously asserted by Patent Owner in *Janssen Biotech, Inc. v. Amgen Inc.*, Case No. 1:22-cv-01549-MN (D. Del. Nov. 29, 2022), but the case is no longer pending. The '307 Patent was previously challenged in IPR2023-001103, but that proceeding is no longer pending.

## II. RELIEF REQUESTED

Termination of this *inter partes* review is requested, and the Parties respectfully submit that such termination is justified. "There are strong public policy reasons to favor settlement between the parties to a proceeding." Consolidated Trial Practice Guide 86 (Nov. 2019). "The Board expects that a proceeding will terminate after the filing of a settlement agreement, unless the Board has already decided the merits of the proceeding." *Id.* (citing 35 U.S.C. §§ 317(a)).

The Board should terminate this proceeding, as the Parties jointly request, for the following reasons.

***First***, Biocon and Janssen have met the statutory requirement that they file a "joint request" to terminate before the Office "has decided the merits of the proceeding." 35 U.S.C. § 317(a). Under section 317(a), an *inter partes* review shall be terminated upon such joint request "unless the Office has decided the merits of the proceeding before the request for termination is filed." There are no other preconditions recited in 35 U.S.C. § 317(a).

***Second***, Biocon and Janssen have reached a resolution as to all the disputes in this proceeding and as to the '307 Patent. Pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(b), the agreement made in connection with, or in contemplation of, the termination of the proceeding is in writing, and a true and correct copy is being filed concurrently herewith as Exhibit 1073.[1] The Parties are also filing concurrently herewith a joint request under 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c) to treat these agreements as business confidential information and keep them separate from the files of the '307 Patent. The Parties certify that there are no other agreements, oral or written, between the Parties made in connection with, or in contemplation of, the termination of this proceeding.

***Third***, termination would save significant further expenditure of resources by the Board and the Parties. Termination upon settlement, as requested, would also further the purpose of *inter partes* review proceedings, which seek to provide an efficient and less costly alternative forum for patent disputes. Further, maintaining the proceeding would discourage further resolutions, as patent owners in similar situations would have a strong disincentive to resolve the dispute if they perceived that an *inter partes* review would continue regardless of a resolution.

[1] The agreement is being filed via the Patent Trial and Appeal Board Case Tracking System (PTACTS) system with access to the "Board only."

## III. CONCLUSION

For the foregoing reasons, Biocon and Janssen respectfully request termination of this *inter partes* review.

Date: March 1, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

A copy of the JOINT MOTION TO TERMINATE PROCEEDING and Exhibit 1073 has been served on counsel of record.

March 1, 2024

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