

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC and FRESENIUS KABI SWISSBIOSIM GmbH
Petitioners,

v.

CHUGAI SEIYAKU KABUSHIKI KAISHA,
Patent Owner.

Case No. IPR2021-01024
U.S. Patent No. 7,521,052

PATENT OWNER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Chugai Seiyaku Kabushiki

Kaisha hereby submits a current listing of Patent Owner's exhibits in this proceeding.

Exhibit	Description
2001	Aletaha, D. & Smolen, J.S., <i>The rheumatoid arthritis patient in the clinic: comparing more than 1300 consecutive DMARD courses</i> , RHEUMATOL., 41:1367-74 (2002).
2002	Bulpitt, K., <i>Biologic Therapies in Rheumatoid Arthritis</i> , CURR. RHEUMATOL. REP., 1:157-63 (1999).
2003	Calabrese, L.H., <i>Molecular differences in anitcytokine therapies</i> , CLIN. EXPER. RHEUMATOL., 21:241-48 (2003).
2004	Carmichael, S.J., et al., <i>Combination therapy with methotrexate and hydroxychloroquine for rheumatoid arthritis increases exposure to methotrexate</i> , J. RHEUMATOL., 29(10):2077-83 (2002).
2005	Combe, B., et al., <i>EULAR recommendations for the management of early arthritis: report of a task force of the European Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT)</i> , ANN. RHEUMATOL. DIS., 66:34-45 (2007).
2006	Conaghan, P.G. & Brooks, P., <i>Disease-modifying antirheumatic drugs, including methotrexate, gold, antimalarials, and D-penicillamine</i> , CURR. OP. RHEUMATOL., 7:167-73 (1995).
2007	Cutolo, M., et al., <i>Anti-inflammatory mechanisms of methotrexate in rheumatoid arthritis</i> , ANN. RHEUMATOL. DIS., 60:729-35 (2001).
2008	Deon, D., et al., <i>Cross-talk between IL-1 and IL-6 signaling pathways in rheumatoid arthritis synovial fibroblasts</i> , J. IMMUNOL., 167(9):5395-5403 (2001).

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2009	European Medicines Agency, <i>ICH Topic E 5 (R1) Ethnic Factors in the Acceptability of Foreign Clinical Data</i> , Sept. 1998, https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-5-r1-ethnic-factors-acceptability-foreign-clinical-data-step-5_en.pdf .
2010	Felson, D.T., et al., <i>The efficacy and toxicity of combination therapy in rheumatoid arthritis</i> , <i>ARTHRITIS RHEUMATOL.</i> , 37(10):1487-91 (1994).
2011	Fleischmann, R.M., <i>Examining the efficacy of biologic therapy: are there real differences?</i> , <i>J. RHEUMATOL.</i> , Suppl. 65:27-32 (2002).
2012	Frei, E., et al., <i>Seminars in Medicine of the Beth Israel Hospital, Boston: New Approaches to Cancer Chemotherapy with Methotrexate</i> , <i>NEW ENG. J. MED.</i> , 292(16):846-51 (1975).
2013	Keyston, E.C., <i>Abandoned therapies and unpublished trials in rheumatoid arthritis</i> , <i>CURR. OP. RHEUMATOL.</i> , 15:253-58 (2003).
2014	Kremer, J.M., <i>The mechanism of action of methotrexate in rheumatoid arthritis: the search continues</i> , <i>J. RHEUMATOL.</i> , 21:1-5 (1994).
2015	Kremer, J.M., <i>Methotrexate and Emerging Therapies</i> , <i>RHEUMATOL. DIS. CLIN. N. AM.</i> , 24(3):651-58 (1998).
2016	Kremer, J.M., <i>Not yet time to change the guidelines for monitoring methotrexate liver toxicity: they have served us well</i> , <i>J. RHEUMATOL.</i> , 29(8):1590-92 (2002).
2017	Elliott, M.J. & Maini, R.N., <i>Anti-cytokine therapy in rheumatoid arthritis</i> , <i>BAILLIERES CLIN. RHEUMATOL.</i> , 9(4):633-52 (1995).

Exhibit	Description
2018	Moreland, L.W., <i>Initial experience combining methotrexate with biologic agents for treating rheumatoid arthritis</i> , J. RHEUMATOL., Suppl. 44:78-83 (1996).
2019	Okuda, O., <i>Anti-IL-6 receptor antibody MRA</i> , Chugai Pharm. Co., Ltd., Project Promotion Dep't (Jan. 21, 2003) (A301).
2020	Okuda, O., <i>Anti-IL-6 receptor antibody MRA</i> , Chugai Pharm. Co., Ltd., Project Promotion Dep't (Jan. 21, 2003) (A302).
2021	Rheumatrex®, Methotrexate Sodium Tablets, Oct. 2003, https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/08085slr052,scm055_rheumatrex_lbl.pdf .
2022	Verhoeven, A.C., et al., <i>Combination therapy in rheumatoid arthritis: updated systematic review</i> , BRIT. J. RHEUMATOL., 37:612-19 (1998).
2023	Weinblatt, M.E., et al., <i>A trial of etanercept, a recombinant tumor necrosis factor receptor:fc fusion protein, in patients with rheumatoid arthritis receiving methotrexate</i> , NEW ENG. J. MED., 340:253-59 (1999).
2024	Williams, H.J., et al., <i>Comparison of auranofin, methotrexate, and the combination of both in the treatment of rheumatoid arthritis</i> , ARTHRITIS RHEUMATOL., 35(3):259-69 (1992).
2025	Xing, Z., et al., <i>IL-6 is an antiinflammatory cytokine required for controlling local or systemic acute inflammatory responses</i> , J. CLIN. INVEST., 311-20 (1998).
2026	1 Shaun Ruddy et al., KELLEY'S TEXTBOOK OF RHEUMATOLOGY Chs. 20, 62, 64, & 65 (6th ed. 2001).
2027	Uchida, K., <i>Acceptability of Foreign Clinical Trial Data in Japan</i> , DRUG INF. J., 22:103-08 (1988).
2028	<i>Fresenius Kabi's tocilizumab biosimilar candidate MSB11456</i>

Exhibit	Description
	<i>shows positive results in two clinical trials</i> , Fresenius Kabi, Sept. 7, 2021, https://www.fresenius-kabi.com/news/fresenius-kabi-tocilizumab-shows-positive-results-in-two-clinical-trials .
2029	<i>Pharmacokinetics/Pharmacodynamics (PK/PD) Equivalence Study of MSB11456 (NCT03282851)</i> , ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/NCT03282851 (last updated Feb. 12, 2020).
2030	<i>MSB11456 in Participants with Moderately to Severely Active Rheumatoid Arthritis (NCT04512001)</i> , ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/NCT04512001 (last updated Mar. 11, 2021).
2031	2021.09.27 Email from K. DeJong to T. Fletcher.
2032	Declaration of Paul B. Gaffney in support of <i>pro hac vice</i> admission.
2033	Declaration of Ana C. Reyes in support of <i>pro hac vice</i> admission.
2034	Declaration of Charles L. McCloud in support of <i>pro hac vice</i> admission.
2035	Declaration of Kristin L. Froehle in support of <i>pro hac vice</i> admission.

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