

**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. IPR2021-01025  
U.S. Patent No. 10,744,201

---

**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).

Exhibit	Description
2009	European Medicines Agency, <i>ICH Topic E 5 (R1) Ethnic Factors in the Acceptability of Foreign Clinical Data</i> , Sept. 1998, <a href="https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-5-r1-ethnic-factors-acceptability-foreign-clinical-data-step-5_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-5-r1-ethnic-factors-acceptability-foreign-clinical-data-step-5_en.pdf</a> .
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, <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/08085slr052,scm055_rheumatrex_lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/08085slr052,scm055_rheumatrex_lbl.pdf</a> .
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, <a href="https://www.fresenius-kabi.com/news/fresenius-kabi-tocilizumab-shows-positive-results-in-two-clinical-trials">https://www.fresenius-kabi.com/news/fresenius-kabi-tocilizumab-shows-positive-results-in-two-clinical-trials</a> .
2029	<i>Pharmacokinetics/Pharmacodynamics (PK/PD) Equivalence Study of MSB11456 (NCT03282851)</i> , ClinicalTrials.gov, <a href="https://clinicaltrials.gov/ct2/show/NCT03282851">https://clinicaltrials.gov/ct2/show/NCT03282851</a> (last updated Feb. 12, 2020).
2030	<i>MSB11456 in Participants with Moderately to Severely Active Rheumatoid Arthritis (NCT04512001)</i> , ClinicalTrials.gov, <a href="https://clinicaltrials.gov/ct2/show/NCT04512001">https://clinicaltrials.gov/ct2/show/NCT04512001</a> (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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.