

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). |

| Exhibit | Description |
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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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