

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00884

U.S. Patent No. 11,253,572

**PETITIONER'S OBJECTIONS TO
PATENT OWNER'S EXHIBITS**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Samsung Bioepis Co., Ltd. (“Petitioner”) submits the following objections to evidence submitted by Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”). Petitioner’s objections apply equally to Patent Owner’s reliance on this evidence in any subsequently filed documents or further proceedings in this matter. These objections are timely, having been filed and served within ten business days of the institution of the trial. Notwithstanding these objections, Petitioner expressly reserves the right to rely on any evidence submitted by Patent Owner, including on the ground that such evidence constitutes a party admission.

Objections

Exhibits 2001, 2003, 2026, 2028, 2031-2032, and 2034

Petitioner objects to these exhibits under FRE 401, 402 and 403. These exhibits are not relevant, and their probative value is substantially outweighed by the danger of confusion of the issues. Petitioner further objects to these exhibits for lack of foundation and lack of personal knowledge under FRE 602.

Petitioner additionally objects to these exhibits under FRE 701, 702, and 703 to the extent these exhibits include improper lay and/or expert testimony that fails to properly provide the requisite underlying facts, data, and other required disclosures.

Moreover, Petitioner objects to these exhibits as inadmissible hearsay and/or double-hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807, to the extent Patent Owner relies on these exhibits for the truth of the matter asserted. Petitioner further objects to the extent Patent Owner seeks to rely on declaration and trial testimony in a manner that circumvents Board rules regarding making the declarant available for cross-examination. Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, 51 (“a party has the opportunity to cross-examine a witness providing declaration testimony submitted by another party, after institution, unless the Board orders otherwise. 37 C.F.R. § 42.51(b)(1)(ii).”)

Exhibits 2004-2011, 2013, 2015, 2017-2025, 2035-2045, 2047-2048, and 2050-2054

Petitioner objects to these exhibits as not properly authenticated under FRE 901 because Patent Owner has not presented sufficient evidence to show that they are authentic or self-authenticating under FRE 902. Petitioner further objects to these exhibits for lack of foundation and lack of personal knowledge under FRE 602. To the extent Patent Owner relies on Exhibits 2005-2011, 2013, 2015, 2017-2019, 2021-2025, 2035-2045, 2047-2048, and 2050-2054 for the truth of the matter asserted, Petitioner further objects to Exhibits 2005-2011, 2013, 2015, 2017-2019, 2021-2025, 2035-2045, 2047-2048, and 2050-2054 as inadmissible hearsay and/or

inadmissible double hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

Petitioner additionally objects to Exhibits 2005-2011, 2015, 2017-2019, 2024, 2035, and 2039-2045 under FRE 401-403 because Exhibits 2005-2011, 2015, 2017-2019, 2024, 2035, and 2039-2045 are not relevant, are facially incomplete, and their probative value is substantially outweighed by the danger of confusion of the issues.

Exhibits 2002, 2012, 2014, 2016, 2046, 2049, and 2055-2058

Petitioner objects to these exhibits under FRE 401, 402 and 403. These exhibits are not relevant, including because these exhibits postdate the alleged priority date of U.S. Patent No. 11,253,572, and their probative value is substantially outweighed by the danger of confusion of the issues. Petitioner further objects to these exhibits as not properly authenticated under FRE 901 because Patent Owner has not presented sufficient evidence to show that they are authentic or self-authenticating under FRE 902. To the extent Patent Owner relies on Exhibits 2012, 2014, 2016, 2046, 2049, and 2055-2058 for the truth of the matter asserted, Petitioner objects to Exhibits 2012, 2014, 2016, 2046, 2049, and 2055-2058 as inadmissible hearsay under FRE 801 and 802 that does not fall under any exceptions, including those of FRE 803, 804, 805, or 807.

DATED: December 4, 2023

Respectfully submitted,

By /Raymond N. Nimrod/

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