

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 IPR2023-00739

U.S. Patent No. 10,888,601

**PETITIONER'S SECOND SET OF OBJECTIONS TO
PATENT OWNER'S EVIDENCE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Samsung Bioepis Co., Ltd. (“Petitioner”) submits the following second set of objections to Regeneron Pharmaceuticals, Inc. (“Patent Owner”)’s evidence. 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 five business days of Patent Owner’s service of the evidence. 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 2027, 2035, and 2043

Petitioner 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. Petitioner further objects to these exhibits under FRE 901 and 902 because these exhibits rely on improperly authenticated evidence. Moreover, Petitioner objects to these exhibits under FRE 106 because these exhibits rely on incomplete evidence or improper summary from a larger reference, which in fairness ought to be considered in its entirety at the same time.

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 these exhibits for the truth of the matter asserted, Petitioner further objects to these exhibits 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 objects to these exhibits under FRE 401, 402 and 403. These exhibits are not relevant, are facially incomplete, and their probative value is substantially outweighed by the danger of confusion of the issues.

Exhibits 2032-2034, 2037-2038, 2040, 2044-2046, 2048-2049, 2069-2070, 2075-2077, 2079-2081, 2090, 2092, 2096-2097, 2100-2101, 2103, 2106-2107, 2109-2119, 2123, and 2161

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. 10,888,601, are facially incomplete, 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 these exhibits for the truth of the matter asserted, Petitioner further objects

to these exhibits 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.

Exhibits 2030-31, 2041-2042, 2047 2050-2066, 2068, 2088-2089, 2091, 2093-2095, 2098-2099, 2102, 2104-2105, and 2108

To the extent Patent Owner relies on these exhibits for the truth of the matter asserted, 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.

Petitioner objects to these exhibits under FRE 401, 402 and 403. These exhibits are not relevant, are facially incomplete, and their probative value is substantially outweighed by the danger of confusion of the issues.

Exhibits 2071-2073, 2078, 2082-2087, 2120, 2124-2130, 2143-2160, and 2162-2168

Petitioner objects to these exhibits under FRE 701, 702, and 703 to the extent these exhibits include any analyses, results, and/or assessments that are not based on the application of reliable principles and methods and 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.

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 these exhibits for the truth of the matter asserted, 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.

Petitioner objects to these exhibits under FRE 401, 402 and 403. These exhibits are not relevant, are facially incomplete, and their probative value is substantially outweighed by the danger of confusion of the issues.

DATED: February 2, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. § 42.6(e), I hereby certify that on February 2, 2024, true and correct copies of the foregoing were served via electronic mail to Patent Owner at the following email addresses of record:

Brausa, Adam R. ABrausa@mofo.com
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DATED: February 2, 2024

Respectfully submitted,

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