

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2021-00881
Patent No. 9,254,338 B2

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”), submits the following supplemental objections to Petitioner Mylan Pharmaceuticals Inc.’s (“Petitioner”) Exhibits 1102–1176, and any reference to and/or reliance on the foregoing including, without limitation, citations thereto in Petitioner’s Reply. Patent Owner’s objections below apply the Federal Rules of Evidence (“FRE”) as required by 37 C.F.R. § 42.62.

These objections supplement Patent Owner’s Objections to Petitioner’s Exhibits, served November 24, 2021, which Patent Owner maintains.

Exhibit 1102 - Exhibit 1102 is objected to under FRE 401, 402 and 403. Exhibit 1102 is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of United States Patent No. 9,254,338 (“the ’338 patent”) (January 13, 2011).

Exhibit 1103 - Exhibit 1103 is objected to under FRE 401, 402 and 403. Exhibit 1103 is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Exhibit 1104 - Exhibit 1104 is objected to under FRE 901 and FRE 802 as unauthenticated and hearsay evidence. It is not clear where the exhibit came from or how it was compiled. Exhibit 1104 is also objected to under FRE 106. Petitioner has filed what appears to be an excerpt of correspondence from Volume 29 of Eye. The

remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided. Exhibit 1104 is also objected to under FRE 401, 402 and 403. Exhibit 1104 is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '338 patent (January 13, 2011).

Exhibit 1105 - Exhibit 1105 is objected to under FRE 901 and FRE 802 as unauthenticated and hearsay evidence. It is not clear where the exhibit came from or how it was compiled.

Exhibit 1106 - Exhibit 1106 is objected to under FRE 901 and FRE 802 as unauthenticated and hearsay evidence. It is not clear where the exhibit came from or how it was compiled. Exhibit 1106 is also objected to under FRE 401, 402 and 403. Exhibit 1106 is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder because it was not published before the priority date of the challenged claims of the '338 patent (January 13, 2011).

Exhibit 1107 - Exhibit 1107 is objected to under FRE 901 and FRE 802 as unauthenticated and hearsay evidence. It is not clear where the exhibit came from or how it was compiled. Exhibit 1107 is also objected to under FRE 106. Petitioner has

filed what appears to be an excerpt of the Volume 20 of the WHO Drug Information. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided. Exhibit 1107 is also objected to under FRE 401, 402 and 403. Exhibit 1107 is not relevant, and its probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder.

Exhibit 1112 - Exhibit 1112 is objected to under FRE 901 and FRE 802 as unauthenticated and hearsay evidence. Exhibit 1112 is not cited, discussed or authenticated by any of Petitioner's experts. Exhibit 1112 is also objected to under FRE 106 as incomplete, to the extent that it is relied upon in purported support Petitioner's statement that "VEGF Trap-Eye/aflibercept was publicly distributed long before 2011." Exhibit 1112 does not provide any information about the terms and restrictions surrounding transfer of the "VEGF Trap" discussed therein, and Petitioner has not introduced or filed any information concerning such terms and restrictions. Such information in fairness ought to be considered at the same time as Exhibit 1112. Exhibit 1112 is also objected to under FRE 401, 402, and 403, to the extent it is relied upon in purported support of Petitioner's statement that "VEGF Trap-Eye/aflibercept was publicly distributed long before 2011." As noted, Exhibit 1112 does not provide any information about the terms and restrictions surrounding transfer of the "VEGF Trap" discussed therein. Absent such information, Exhibit

1112 is irrelevant and its probative value is substantially outweighed by the danger of confusing the issues and misleading the fact finder.

Exhibit 1113 - Exhibit 1113 is objected to under FRE 106. Petitioner has filed what appears to be a chapter excerpted from a larger volume. The remainder of this document has not been introduced or filed by Petitioner, but in fairness ought to be considered at the same time as those pages that were provided.

Exhibit 1114 - Patent Owner incorporates its prior objections to Exhibits 1002 and 1038 to the extent that Paragraphs 2 and 5 of Exhibit 1114 purport to incorporate Exhibits 1002 and 1038. Paragraphs¹ 9, 11-25, 27-29, 31-40, 42, 43, 48-54, 56, 59, 63, 67-74, 76, 78, 80-82, 84, 85, 88-93, 97-101, 105-116, and 118 and Appendices A and B are objected to under FRE 106 and/or FRE 1006 as relying on incomplete evidence or improper summary and/or improperly cherry-picking selective passages of a reference, while ignoring other passages in the same reference. Paragraphs 18-24, 26, 40, 56, 59, 74, 80, 81, 86, 88-90, 92, 95, and 97-118 are also objected to under FRE 401, 402, and 403 because they discuss or rely on information that is irrelevant and for which probative value is substantially outweighed by the danger of confusing the issues and misleading the fact finder, including, with respect to paragraphs 56, 59, 74, 80, 81, 86, 90, 92, 105-110, 112, and 116, information that

¹ For avoidance of doubt, as used herein, an objection to a numbered paragraph of an Exhibit applies equally to all footnotes to that paragraph.

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