

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner

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

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**PATENT OWNER'S 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 objections to Petitioner Mylan Pharmaceuticals Inc.’s (“Petitioner”) Exhibits 1001–1094, and any reference to and/or reliance on the foregoing. Patent Owner’s objections below apply the Federal Rules of Evidence (“FRE”) as required by 37 C.F.R. § 42.62.

**Exhibit 1002** - Paragraphs 43, 44, 58, 60, 71, 72, 78, 79, 128, 149, 172, 173, 176, 187, 199, 202, 221, 245, 269, 293, 318, 342, 367, 369, 390, and 409 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 44, 50, 51, 52, 127, 128, 405, and 407 are also objected to under FRE 401, 402, and 403 to the extent they discuss or rely on information that was not publicly available before the priority date of the challenged claims of the ’338 patent (January 13, 2011), because such information is irrelevant and its probative value is substantially outweighed by the danger of confusing the issues and misleading the fact finder. Paragraphs 44, 127, 149, 176, 199, 219, 221, 225, 245, 269, 293, 318, 342, 369, and 390 are further objected to under FRE 901 and FRE 802 as relying on unauthenticated and hearsay evidence. Paragraphs 44, 58, 60, 61, 77, 90 (footnote 13), 99, 127, 128 (footnote 18),

175, 180, 184, 187, 202, 221, 245, 269, 293, 318, 342, 366, 368, 369, 390, 407, 410, 411, 412, and 413 are also objected to as improper expert testimony under FRE 702, 703, and 705 because the opinions offered therein are not based on sufficient facts or data.

**Exhibit 1003** - Paragraphs 16, 17, 30, 31, 32, 34, 35, 36, 38, 68, 69, 70, 76, 78, 79, 80, 81, 88, 91, and 92 of Exhibit 1003 are objected to under FRE 401, 402 and 403 to the extent they discuss or rely on information that was not publicly available before the priority date of the challenged claims of the '338 patent (January 13, 2011), because such information is irrelevant and its probative value is substantially outweighed by the danger of confusing the issues and misleading the fact finder. Paragraphs 78, 79, and 91 of Exhibit 1003 is also objected to under FRE 901 and FRE 802 as relying on unauthenticated and hearsay evidence to the extent it relies on Exhibit 1078.

**Exhibit 1005** - Exhibit 1005 is objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1005. It is not clear where the exhibit came from or how it was compiled

**Exhibit 1006** - Exhibit 1005 is objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1005. It is not clear where the exhibit came from or how it was compiled.

**Exhibit 1011** - Exhibit 1011 is objected to under FRE 401, 402 and 403. Exhibit 1011 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 1014** - Exhibit 1014 is objected to under FRE 401, 402 and 403. Exhibit 1014 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 1014 is also objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1014. It is not clear where the exhibit came from, how it was compiled, or what methods or metrics were used to arrive at the information in the document.

**Exhibit 1015** - Exhibit 1015 is objected to under FRE 401, 402 and 403. Exhibit 1015 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 1015 is also objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1015. It is not clear where

the exhibit came from, how it was compiled, or what methods or metrics were used to arrive at the information in the document.

**Exhibit 1017** - Exhibit 1017 is objected to under FRE 401, 402 and 403. Exhibit 1017 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 1017 is also objected to under FRE 106. Petitioner has filed what appears to be an portion from the file history of patent application no. 13/940,370. The remainder of the file history 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 1017 is also objected to under FRE 901 because Petitioner has not demonstrated the authenticity of Exhibit 1017. It is not clear how it was compiled.

**Exhibit 1018** - Exhibit 1018 is objected to under FRE 401, 402 and 403. Exhibit 1018 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 1019** - Exhibit 1019 is objected to under FRE 401, 402 and 403. Exhibit 1019 is not relevant, and its probative value is substantially outweighed by

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