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 9,254,338 B2

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**PETITIONER'S SECOND OBJECTIONS TO ADMISSIBILITY OF EVIDENCE SUBMITTED BY PATENT OWNER**

Pursuant to 37 C.F.R. § 42.64(b), Petitioner Mylan Pharmaceuticals Inc. ("Petitioner"), hereby objects as follows to the admissibility of evidence filed by Patent Owner Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Patent Owner"), in conjunction with the Patent Owner Response, filed February 11, 2022.

In this paper, a reference to "FRE" means the Federal Rules of Evidence, a reference to "CFR" means the Code of Federal Regulations, and "'338 patent" means U.S. Patent No. 9,254,338. All objections under FRE 802 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are Patent Owner's exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Objection Key:

A: FRE 802 (hearsay)
B: FRE 901 (lacking authentication)
C: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '338 patent or the prior art status is not clear
D: FRE 402 (relevance) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods
E: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '338 patent or the prior art status is not clear
F: FRE 403 (confusing, waste of time) to the extent the document is relied

upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods

G: FRE 702 (improper expert testimony) expert testimony that relies on the document is not based on sufficient facts or data and/or is not the product of reliable principles and methods

H: FRE 703 (bases of expert opinion) expert testimony that relies on the document is unreliable because the document is not of a type reasonably relied upon by experts in the field

I: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document

J: FRE 701/702 (improper expert testimony) improper expert testimony by a lay witness

K: FRE 1001-1003 (best evidence)

L: FRE 403, 901 (improper compilation)

M: FRE 403 (cumulative)

N: FRE 402 (relevance) the document is not relevant to any issue in the IPR proceeding

O: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding

P: No exhibit filed

Q: Expert testimony fails to identify with particularity the underlying facts or data on which the opinion is based violating 37 C.F.R. § 42.65(a)

R: FRE 602 (lack of personal knowledge)

S: FRE 702/703 to the extent that the expert declarant relies on an exhibit objected to under grounds G and H, the testimony is (i) not based on sufficient facts or data and/or is not the product of reliable principles and methods and/or is (ii) is unreliable because the exhibit is not of a type reasonably relied upon by experts in the field

T: FRE 1006 (improper summary)

U: FRE 105 (limited purpose) to the extent that any portion of this exhibit may be deemed admissible, such admissibility should be for a limited purpose

V: FRE 705 and/or 37 C.F.R. § 42.65 the exhibit includes expert testimony that does not disclose the underlying facts or data

| Ex. No. | Description | Objections |
|---|---|---|
| 2048 | Expert Declaration of Dr. Lucian V. Del Priore, M.D., Ph.D. - CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER | A, C, D, E, F, G, H, J, M, N, O, Q, R, S, T, U |
| 2049 | Expert Declaration of Dr. Alexander M. Klibanov, Ph.D. - CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER | A, C, D, E, F, G, H, J, M, N, O, Q, R, S, T, U |
| 2050 | Expert Declaration of David M. Brown, M.D.<br>(including at least ¶¶150-181 for Patent Owner's failure to comply with 37 CFR § 42.6(a)(3)) | C, D, E, F, G, J, N, O, and S,<br>A, H, M, Q, R, T, U |
| 2051 | Expert Declaration of Dr. Diana V. Do, M.D.<br>(including at least ¶¶98-170 for Patent Owner's failure to comply with 37 CFR § 42.6(a)(3)) | C, D, E, F, G, J, N, O, and S,<br>A, H, M, Q, R, T, U |
| 2052 | Expert Declaration of Richard Manning, Ph.D. - CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER<br>(including at least ¶¶29-42, 48-117 for Patent Owner's failure to comply with 37 CFR § 42.6(a)(3)) | C, D, E, F, G, J, N, O, Q, R and S,<br>A, H, M, Q, R, T, U |
| 2053 | A Study of Aflibercept Administered in Combination With Pemetrexed and Cisplatin in Patients With Advanced Carcinoma, NCT00794417, ClinicalTrials.gov (Posted Nov. 20, 2008), https://clinicaltrials.gov/ct2/history/NCT00794417?A=1&B=1 | A, B, C, D, E, F, G, H, M, N, O, T, U |
| 2054 | A Study of Intravenous Aflibercept With Docetaxel in Chinese Patients With Solid Tumors, NCT01148615, ClinicalTrials.gov (Posted Jun. 22, 2010), https://clinicaltrials.gov/ct2/history/NCT01148615?A=1&B=1 | A, B, C, D, E, F, G, H, M, N, O, T, U |

| Ex. No. | Description | Objections |
|---|---|---|
| 2055 | Ferrara et al., *Development of ranibizumab, an anti-vascular endothelial growth factor antigen binding fragment, as therapy for neovascular age-related macular degeneration.* 26 RETINA 859 (2006) | A, C, D, E, F, G, H, M, N, O, U |
| 2056 | Kim et al., *A Brief History of Anti-VEGF for the Treatment of Ocular Angiogenesis*, 181 THE AMERICAN JOURNAL OF PATHOLOGY 376 (2012) | A, C, D, E, F, G, H, M, N, O, U |
| 2057 | Ramazi et al., *Post-translational modifications in proteins: resources, tools and prediction methods*, 2021 DATABASE 1 (2021) | A, C, D, E, F, G, H, M, N, O, U |
| 2058 | Bork et al., *Increasing the Sialylation of Therapeutic Glycoproteins: The Potential of the Sialic Acid Biosynthetic Pathway*, 98 J. PHARM. SCI. 3499 (2009) | A, C, D, E, F, G, H, M, N, O, U |
| 2059 | Regeneron Sample Analysis Report: PK06005-9-SA-01V1 (2006) ("Koehler-Stec Report") - CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER | A, B, C, D, E, F, G, H, M, N, O, Q, R, S, U |
| 2060 | Regeneron Pharmaceuticals Protocol VGFT-OD-0605, Table 14.2.3/2a - Summary of Proportion of Vision Loss from Baseline to Week 96, Last Observations Carried Forward (Full Analysis Set) ("VGFT-OD-0605 Analysis Summary") – CONFIDENTIAL MATERIAL - SUBJECT TO PROTECTIVE ORDER | A, B, C, D, E, F, G, H, I, M, N, O, Q, R, S, T, U |
| 2061 | Kim et al., *Eyes that Do Not Meet the Eligibility Criteria of Clinical Trials on Age-Related Macular Degeneration: Proportions of the Real-World Patient Population and Reasons for Exclusion*, 2021 JOURNAL OF OPHTHALMOLOGY1 (2021) | A, C, D, E, F, G, H, M, N, O, U |

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