

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2023-00462
Patent 10,464,992

**PETITIONER'S OBJECTIONS
TO PATENT OWNER'S RESPONSE EVIDENCE**

I. INTRODUCTION

Petitioner (Celltrion) objects to Patent Owner's (Regeneron) exhibits EX2047, EX2049, EX2050, EX2054, EX2055, EX2056, EX2064, EX2066, EX2071, EX2075, EX2077, EX2079, EX2082, EX2085, EX2091, EX2092, EX2093, EX2094, and EX2095 for failure to comply with the Federal Rules of Evidence (FRE). 37 C.F.R. §42.62(a). These objections are filed under §42.64(b)(1).

II. OBJECTIONS

A. EX2047

Grounds for Objection: FRE 401 (Relevance); FRE 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); FRE 701, 702, 703 (Expert Foundation and Opinions); FRE 802 (Hearsay).

EX2047 is the Declaration of Dr. Alexander M. Klibanov. Because Dr. Klibanov has not yet been deposed, EX2047 should be excluded as presenting opinion testimony, including on an ultimate issue, from witnesses without qualification or proper basis. FRE 701-FRE 705. EX2047 should be excluded as hearsay without exception, including hearsay within hearsay. FRE 802. EX2047 should be excluded as any possible probative value is substantially outweighed by the danger of confusion of the issues and misleading the fact finder, to the extent they rely on information not published before the priority date of the '992 patent. FRE 403; FRE 802.

Celltrion further objects to paragraphs 1-26; 33-34; 63; 66; 68; 70-71; 90-92; 97; 103-104; 107-108; 110; 119; 123-125; 127-128; 130-134; 138; 144-145; 152-154; 159; 162; 174; 185; 189-190; 201-219, as Patent Owner does not rely on or even cite these paragraphs in its Patent Owner Response, rendering the discussion in these paragraphs irrelevant. FRE 401. Celltrion also objects to paragraphs 30, 31, 45, 46, 60, 102, 154, and 171, as relying on post-filing date exhibits, and thus irrelevant. FRE401. And, to the extent that the post-filing date exhibits are deemed relevant, Celltrion submits that any probative value is minimal and is substantially outweighed by the risk of confusing the issues, wasting time, and needlessly presenting cumulative evidence. FRE 403.

B. EX2050

Grounds for Objection: FRE 106 (incomplete document).

EX2050 purports to be the unsealed portions of a trial transcript from a separate proceeding. Celltrion objects to EX2050 under FRE 106 because the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document.

C. EX2054

Grounds for Objection: FRE 401 (Relevance); FRE 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); FRE 611 (scope of cross-examination).

EX2054 is the deposition transcript of Dr. Ralph Tarantino. Celltrion objects to pages 22, ll. 6-9, 11-16, 19-25; 23, ll. 2-6, 9-21, 24-25; 24, ll. 2-9, 12; 27, ll. 16-25; 28, ll. 2-6, 8-14, 24-25; 29, ll. 1-2, 5-7, 9-13, 15-18, 21-25; 30, ll. 2-5, 7-10, 12-13; 33, ll. 2-3, 6-13, 16-25; 34, ll. 4-13, 16-18, 20-25; 35, ll. 3-17, 20-25, 36, ll. 2-11, 14-22, 24-25; 37, ll. 2-8, 10-25; 38, ll. 2-4; 61, ll. 22-25; 66, ll. 4-9; 63, ll. 21-25; 65, ll. 4-5, 7-14, 16-18, 21-25; 66, ll. 2-3, 6-11, 14-25; 67, ll. 1, 5-9, 16-21; 81, ll. 10-13, 16-24; 82, ll. 2-10, 14-24; 83, ll. 4-5; 84, ll. 9-11, 15-24; 85, ll. 4-18, 22-25; 86, ll. 2-7, 11-16, 18-22, 24-25; 87, ll. 2-11, 15-24; 88, ll. 5-17, 21-24; 89, ll. 4-11, 13-14, 16-19, 22-25; 90, ll. 2-3, of EX2054. These portions of the transcript are beyond the scope of Dr. Tarantino's Declaration (EX1002) and are thus irrelevant.

D. EX2055

Grounds for Objection: FRE 106 (incomplete document); FRE 401 (Relevance); FRE 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

EX2055 purports to be an FDA Approval Letter. EX2055 presents redactions regarding the stability and dates of the formulated product. Celltrion objects to EX2055 under FRE 106 because the redactions render the document incomplete. EX2055 includes only a select portion of a larger document that in fairness should be considered along with this document.

To the extent that the redacted dates are after the priority date of the

challenged claims of the '992 patent, Celltrion objects to EX2055 as irrelevant. FRE 401. And, to the extent that EX2055 is deemed relevant, Celltrion submits that any probative value is minimal and is substantially outweighed by the risk of confusing the issues, wasting time, and needlessly presenting cumulative evidence. FRE 403.

E. EX2064 and EX2094

Grounds for Objection: FRE 106 (incomplete document).

Each of EX2064 and EX2094 purport to be a portion of a larger text. Celltrion objects to EX2064 and EX2094 under FRE 106 as the documents are incomplete and include only select portions of larger documents that in fairness should be considered along with the presented exhibits.

F. EX2071

Grounds for Objection: FRE 401 (Relevance); FRE 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

EX2071 purports to be a label. No date appears on the face of EX2017. In fact, the document lists its copyright year as “© 20XX” and its issue date as “Issue Date: XX/XX/XX.” EX2017, 17. Lacking a discernible publication date, EX2071 is irrelevant as it cannot be used to prove any fact relevant to the resolution of this case. FRE 401. To the extent that EX2071 is deemed relevant, its admissions would be unduly prejudicial, misleading, and a waste of time in view of the fact it

cannot prove facts relevant to the resolution of this case. FRE 403.

G. EX2049, EX2066, EX2075, EX2077, EX2079, EX2082, EX2085, EX2091, and EX2092

Grounds for Objection: FRE 401 (Relevance); FRE 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

Each of EX2049, EX2066, EX2075, EX2077, EX2079, EX2082, EX2085, EX2091, and EX2092 purports to be a document published or otherwise made available after the priority date of the challenged claims of the '992 patent. These exhibits should be excluded as irrelevant as they cannot be used to prove any fact relevant to the resolution of this case. FRE 401. To the extent that any of EX2049, EX2066, EX2075, EX2077, EX2079, EX2082, EX2085, EX2091, and EX2092 are deemed relevant, their admissions would be unduly prejudicial, misleading, and a waste of time in view of the fact that none of these exhibits can prove facts relevant to the resolution of this case. FRE 403.

H. EX2092, EX2093, EX2094, and EX2095

Grounds for Objection: FRE 401 (Relevance)

Celltrion objects to EX2092, EX2093, EX2094, and EX2095 as Patent Owner does not rely on or even cite to these exhibits in its Patent Owner Response, rendering these exhibits irrelevant. FRE 401.

I. Each Regeneron exhibit should be restricted to the purpose for which Regeneron offered the exhibit

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Regeneron offered the exhibit. FRE 105. Should Regeneron rely on an exhibit for a different purpose than the one for which it has been offered, Celltrion reserves the right to make additional objections.

III. CONCLUSION

Regeneron exhibits EX2047, EX2049, EX2050, EX2054, EX2055, EX2056, EX2064, EX2066, EX2071, EX2075, EX2077, EX2079, EX2082, EX2085, EX2091, EX2092, EX2093, EX2094, and EX2095 should be excluded; if not excluded, they should be given no weight.

Respectfully submitted,

Dated: November 9, 2023

/Lora M. Green/

Lora M. Green, Reg. No. 43,541
Counsel for Celltrion, Inc.

CERTIFICATE OF SERVICE

I certify that on November 9th, 2023, I caused a true and correct copy of this paper to be served on the Patent Owner at the email correspondence addresses of the Patent Owner as follows:

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Respectfully submitted,

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