

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONTIER THERAPEUTICS, LLC
Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE
SPEZIALPRÄPARATE MBH
Patent Owner

Inter Partes Review Case No. IPR2016-00649
Patent Number 8,664,231

Before the Honorable TONI R. SCHEINER, ERICA A. FRANKLIN, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

**PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED WITH
PETITIONER'S *INTER PARTES* REVIEW PETITION**

Pursuant to 37 C.F.R. § 42.64(b)(1), the undersigned, on behalf of and acting in a representative capacity for Patent Owner Medac Gesellschaft Für Klinische Spezialpräparate MBH ("Patent Owner"), hereby submit the following objections to Petitioner Frontier Therapeutic LLC's ("Petitioner") Exhibits as indicated below, and any reference thereto/reliance thereon, without limitation. Patent Owner's objections below apply the Federal Rules of Evidence ("F.R.E.") as required by 37 C.F.R § 42.62.

These objections address evidentiary deficiencies in the material served by

Petitioner with the Petition on February 22, 2016.

The following objections apply to the Exhibits indicated below as they are actually presented by Petitioner, in the context of Petitioner's February 22, 2016 Petition (Paper 1, "Petition") and not in the context of any other substantive argument on the merits of the instituted grounds in this proceeding. Patent Owner expressly objects to any other purported use of these Exhibits, including as substantive evidence in this proceeding, which would be untimely and improper under the applicable rules, and Patent Owner expressly asserts, reserves, and does not waive any other objections that would be applicable in such a context.

I. Objections to Exhibit 1004 And Any Reference to/Reliance Thereon

Grounds for objection: F.R.E. 106 (Incomplete Document); F.R.E. 1002 ("Requirement of the Original"); F.R.E. 1003 ("Admissibility of Duplicates"); and F.R.E. 801, 802 (Impermissible Hearsay).

Patent Owner objects to the use of Exhibit 1004 under F.R.E. 106, 1002, and 1003 because Petitioner fails to provide the complete document. Exhibit 1004 appears to be missing at least page 648.

Patent Owner objects to Exhibit 1004 as impermissible hearsay under F.R.E. 801 and 802 to the extent to which the out of court statements therein, or the out of court statements referenced therein, are offered for the truth of the matters asserted and constitute impermissible hearsay for which Petitioner has not demonstrated

any exception or exclusion to the rule against hearsay (F.R.E. 801, 802).

II. Objections to Exhibits 1005, 1007-1010, 1018-1030 And Any Reference to/Reliance Thereon

Grounds for objection: F.R.E. 901 (“Authenticating or Identifying Evidence”); F.R.E. 902 (“Evidence That is Self-Authenticating”); F.R.E. 1002 (“Requirement of the Original”); F.R.E. 1003 (“Admissibility of Duplicates”); and 37 C.F.R. § 42.61 (“Admissibility”).

Patent Owner objects to the use of Exhibits 1005, 1007-1010, 1018-1030 under F.R.E. 901, 1002, 1003, and 37 C.F.R. § 42.61 because Petitioner fails to provide the authentication required for these documents, and has not established that the Exhibits are self-authenticating under F.R.E. 902.

III. Objections to Exhibits 1006, 1011, 1014, 1015, And Any Reference to/Reliance Thereon

Grounds for objection: F.R.E. 901 (“Authenticating or Identifying Evidence”); F.R.E. 1002 (“Requirement of the Original”); F.R.E. 1003 (“Admissibility of Duplicates”); F.R.E. 801, 802 (Impermissible Hearsay); and 37 C.F.R. § 42.61 (“Admissibility”).

Patent Owner objects to the use of Exhibits 1006, 1011, 1014, and 1015 under F.R.E. 901, 1002, 1003, and 37 C.F.R. § 42.61 because Petitioner fails to provide the authentication required for these documents, and the has not established that the Exhibits are self-authenticating under F.R.E. 902.

Patent Owner further objects to Exhibits 1006, 1011, 1014, and 1015 as impermissible hearsay under F.R.E. 801 and 802 to the extent to which the out of court statements therein, or the out of court statements referenced therein, are offered for the truth of the matters asserted and constitute impermissible hearsay for which Petitioner has not demonstrated any exception or exclusion to the rule against hearsay (F.R.E. 801, 802).

IV. Objections to Exhibits 1012 and 1013 And Any Reference to/Reliance Thereon

Grounds for objection: F.R.E. 801 and 802 (Impermissible Hearsay).

Further, Drs. Gershwin and Gammon purport to make use of statements contained within the exhibits they cite for the truth of the matter contained therein, but they have not demonstrated that any hearsay exception applies, which violates FRE 801, 802. (*See, e.g.*, Ex. 1012 ¶¶ 71, 75, 78) and Ex. 1013 ¶¶ 41, 42, 48, 51, 55, 62).

V. Objections to Exhibit 1017 And Any Reference to/Reliance Thereon

Grounds for objection: F.R.E. 106 (Incomplete document) F.R.E. 1002 (“Requirement of the Original”); and F.R.E. 1003 (“Admissibility of Duplicates”).

Patent Owner objects to the use of Exhibit 1017 under F.R.E. 106, 1002, and 1003 because Petitioner fails to provide the complete document.

IPR2016-00649
U.S. Patent No. 8,664,231

Attorney Docket No.
110670-0010-651

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Respectfully submitted,

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