

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VALNEVA AUSTRIA GMBH,
Petitioner

v.

TAKEDA VACCINES, INC.,
Patent Owner

Case IPR2025-00776
U.S. Patent No. 11,730,802

PATENT OWNER'S OBJECTIONS TO EVIDENCE

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Patent Owner, Takeda Vaccines, Inc., objects under the Federal Rules of Evidence (F.R.E.) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 1002, 1003, 1035, and 1037 (the “Challenged Evidence”), filed by Petitioner Valneva Austria GmbH on March 31, 2025, with its Petition for *inter partes* review and on July 18, 2025, with its Petitioner’s Brief Against Discretionary Denial. Patent Owner timely files its Objections within ten business days of the date of the Board’s Decision on Institution. 37 C.F.R. § 42.64(b)(1). Patent Owner files these Objections to provide notice to Petitioner that Patent Owner may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c), unless cured by Petitioner.

I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS

A. Exhibit 1002

Exhibit 1002 is the Declaration of Dr. Farshad Guirakhoo. Patent Owner objects to paragraphs 1–37, 530, and 531 of Exhibit 1002 under F.R.E. 401, 402, and 403. Petitioner does not rely on or even cite these declaration paragraphs in its Petition, rendering Dr. Guirakhoo’s testimony in these paragraphs irrelevant under F.R.E. 401. Patent Owner therefore also objects to the foregoing paragraphs under F.R.E. 402. Patent Owner also objects to this testimony under F.R.E. 403 because it has no probative value, creates unfair prejudice to Patent Owner, and will only confuse the issues and waste the Board’s time.

Patent Owner also objects to paragraphs 113–161 and 202–396 of Exhibit 1002 under F.R.E. 401, 402 and 403 because those paragraphs discuss Grounds and claims that are no longer at issue in this proceeding due to Patent Owner disclaiming claims 1–8, 10, 12–31, 59, and 63 of U.S. Patent No. 11,938,201 (“the ’201 patent”) (*see* Exhibit 2005), rendering Dr. Guirakhoo’s testimony in these paragraphs irrelevant under F.R.E. 401. Patent Owner therefore also objects to the foregoing paragraphs under F.R.E. 402. Patent Owner also objects to this testimony under F.R.E. 403 because it has no probative value, creates unfair prejudice to Patent Owner, and will only confuse the issues and waste the Board’s time.

Patent Owner also objects to paragraphs 46–67 of Exhibit 1002 because those paragraphs rely on evidence that is inadmissible under at least F.R.E. 106 and 1001(e). *See infra*.

B. Exhibit 1003

Exhibit 1003 purports to be excerpts of the file history of the ’201 patent. Patent Owner objects to Exhibit 1003 because it is incomplete. Petitioner has not submitted the complete file history for the ’201 patent. Therefore, Exhibit 1003 is not a “duplicate” as defined by F.R.E. 1001(e) insofar as the exhibit is not “a counterpart ... that accurately reproduces the original.” Patent Owner also objects to Exhibit 1003 under F.R.E. 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. Exhibit 1035

Exhibit 1035 purports to be the Declaration of Dan H. Barouch, M.D., Ph.D., submitted in IPR2023-00354. Patent Owner objects to Exhibit 1035 under F.R.E. 401, 402, and 403. Petitioner does not rely on or even cite this declaration in its Petition and Exhibit 1035 discusses a patent not at issue in this proceeding, rendering Exhibit 1035 irrelevant under F.R.E. 401. Patent Owner therefore also objects to Exhibit 1035 under F.R.E. 402. Patent Owner also objects to Exhibit 1035 under F.R.E. 403 because it has no probative value, creates unfair prejudice to Patent Owner, and will only confuse the issues and waste the Board's time.

D. Exhibit 1037

Exhibit 1037 purports to be an article from *Immunity* by Barouch, D.H., et al., entitled "Prospect for a Zika Virus Vaccine." Patent Owner objects to Exhibit 1037 under F.R.E. 401, 402, and 403. Petitioner does not rely on or even cite this declaration in its Petition, rendering Exhibit 1037 irrelevant under F.R.E. 401. Patent Owner therefore also objects to Exhibit 1037 under F.R.E. 402. Patent Owner also objects to Exhibit 1037 under F.R.E. 403 because it has no probative value, creates unfair prejudice to Patent Owner, and will only confuse the issues

and waste the Board's time.

II. CONCLUSION

To the extent Petitioner fails to correct the defects associated with the Challenged Evidence in view of Patent Owner's objections herein, Patent Owner may file a motion to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/Eldora L. Ellison/

Date: October 30, 2025

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Lead Attorney for Patent Owner

CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned **PATENT OWNER'S OBJECTIONS TO EVIDENCE** was served in its entirety on October 30, 2025, upon the following parties via electronic mail:

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