

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MODERNA THERAPEUTICS, INC.,  
Petitioner,

v.

ARBUTUS BIOPHARMA CORPORATION,  
Patent Owner.

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Case IPR2018-00739  
Patent No. 9,364,435

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**PATENT OWNER'S NOTICE OF OBJECTION TO EVIDENCE**

## I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner submits the following objections to evidence submitted in the Petitioner's Reply. Patent Owner's objections apply the Federal Rules of Evidence ("FRE").

## II. OBJECTIONS

### A. Reply Declaration of Dr. Andrew S. Janoff (EX1021)

Patent Owner objects to the admissibility of EX1021.

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

For example, paragraphs 23, 24, 25, and 28 are not relevant to arguments made in the petition materials. Further, to the extent this exhibit is deemed relevant, admission of the exhibit would be unduly prejudicial, misleading, and a waste of time because the opinion is not based on record evidence. Moreover, EX1021 is not admissible because it is not based on facts or data that the expert has been made aware of or personally observed.

### B. *Kauffman, et al. Optimization of Lipid Nanoparticle Formulations for mRNA Delivery in Vivo with Fractional Factorial and Definitive Screening Designs (EX1024)*

Patent Owner objects to the admissibility of EX1024 and any document relying on EX1024.

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); F.R.E. 106 (Remainder of or Related Writings).

EX1024 is not cited in the petition and is not prior art to the '435 patent. Accordingly, this exhibit is not relevant to the proceeding. Further, to the extent this exhibit is deemed relevant, admission of the exhibit would be unduly prejudicial, misleading, and a waste of time because the opinion is not based on record evidence.

**C. Decision on Appeal, Appeal No. 2016-008388 (PTAB July 18, 2018) (EX1025)**

Patent Owner objects to the admissibility of EX1025 and any document relying on EX1025.

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

EX1025 is a Board decision addressing patentability of claims in an application not owned by Protiva. Accordingly, this exhibit is not relevant to the proceeding. Further, to the extent this exhibit is deemed relevant, admission of the exhibit would be unduly prejudicial, misleading, and a waste of time because the opinion is not based on record evidence.

**D. Declaration of Dr. Andrew S. Janoff (EX1007)**

Patent Owner objects to the admissibility of EX1007.

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); F.R.E. 703 (Bases of an Expert).

The Petitioner's Reply confirms that Dr. Janoff's opinions were based on the petition. Paper 28 at 24. That is, Dr. Janoff's opinions are not based on evidence, but rather attorney argument. Accordingly, this exhibit is not relevant to the proceeding. Further, to the extent this exhibit is deemed relevant, admission of the exhibit would be unduly prejudicial, misleading, and a waste of time because the opinion is not based on record evidence. Moreover, EX1007 is not admissible because it is not based on facts or data that the expert has been made aware of or personally observed.

**III. CONCLUSION**

Exhibits 1021, 1024 and 1025 were filed and served on March 22, 2019.

These objections are made within five business days of service.

Respectfully submitted,

Dated: March 29, 2019

/ Michael T. Rosato /  
Michael T. Rosato, Lead Counsel  
Reg. No. 52,182

**CERTIFICATE OF SERVICE**

This is to certify that I caused to be served a true and correct copy of the foregoing Patent Owner's Objection to Evidence was served on March 29, 2019, on the Petitioner at the correspondence address of the Petitioner as follows:

Michael Fleming  
C. Maclain Wells  
IRELL & MANELLA LLP  
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Respectfully submitted,

Dated: March 29, 2019

/ Michael T. Rosato /  
Michael T. Rosato, Lead Counsel  
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