

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Moderna Therapeutics, Inc.

Petitioner

v.

Protiva Biotherapeutics, Inc.

Patent Owner

Case No. IPR2018-00739

U.S. Patent No. 9,364,435

**DECLARATION OF ANDREW S. JANOFF, PH.D.
IN SUPPORT OF MODERNA THERAPEUTICS, INC.'S
PETITIONER'S REPLY TO PATENT OWNER RESPONSE**

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I, Dr. Andrew S. Janoff, PhD, declare as follows:

I. INTRODUCTION

1. My name is Andrew S. Janoff. I am a consultant in biotechnology and drug delivery, primarily focusing on lipid and liposome technology. I have been retained by counsel for Moderna Therapeutics, Inc. (“Moderna”) as an expert in the relevant art.

2. I submitted a declaration dated March 5, 2018 in support of Moderna’s Initial Petition for Inter Partes Review of U.S. Patent No. 9,364,435 (the “’435 patent”) (“Petition”). *See* EX1007.

3. On December 21, 2018, Patent Owner Protiva Biotherapeutics, Inc. (“Patent Owner”) filed its response to Moderna’s Petition (“Response”). I have been asked to provide additional opinions in response to Patent Owner’s Response that are relevant to Moderna’s reply. The opinions discussed herein are my own.

4. This declaration is based on the information currently available to me. To the extent that additional information becomes available, I reserve the right to continue my investigation and study, which may include a review of documents and information that may be produced, as well as testimony from depositions.

II. SUMMARY OF OPINIONS

5. The Board ordered an IPR over the '435 patent with respect to the following grounds of unpatentability for claims 1-20:

- a) Under § 103 in view of the '196 PCT and '189 publication;
- b) Under § 103 in view of each of the '196 PCT and '189 publication in view of Lin and/or Ahmad; and,
- c) Under § 102 or § 103 in view of the '554 publication.

6. The '435 patent is directed to a composition of nucleic acid-lipid particles comprising three lipid components (*i.e.*, cationic lipid, non-cationic lipid and conjugated lipid), each of which fall within a claimed proportion with regard to the total lipid in the particles. *See, e.g., id.*, cl. 1. The cited prior art in Grounds 1-3 renders the claims invalid by a preponderance of the evidence.

III. QUALIFICATION AND EXPERIENCE

7. I possess the knowledge, skills, experience, training and the education to form an expert opinion and testimony in this case. A detailed record of my professional qualifications and relevant experience, including a list of patents and academic and professional publications, is set forth in my declaration dated March 5, 2018 (EX1007), and my curriculum vitae submitted therewith (EX1018).

8. I am being compensated by Moderna for my time spent in developing this declaration at a rate of \$750 per hour, and for any time spent

testifying in connection with this declaration at a rate of \$750 per hour. My compensation is not contingent upon the substance of my opinion, the content of this declaration or any testimony I may provide, or the outcome of the *inter partes* review or any other proceeding.

9. I have no financial interest in Moderna.

10. My opinion expressed in this declaration are based on the Petition and exhibits cited in the Petition, Patent Owner's Response and exhibits cited in the Response, the exhibits attached to Moderna's reply to Patent Owner's Response, and other documents and materials identified in this declaration, including the '435 patent (EX1001) and its prosecution history (EX1016), the prior art references and materials discussed in this declaration, and any other references specifically identified in this declaration.

11. I am aware of information generally available to, and relied upon by, persons of ordinary skill in the art at the relevant times, including technical dictionaries and technical reference materials (including, for example, textbooks, manuals, technical papers, articles, and relevant technical standards).

12. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information that comes to light throughout this proceeding.

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