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.

Protiva Biotherapeutics, Inc.

Patent Owner

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

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DECLARATION OF ANDREW S. JANOFF, PH.D. IN SUPPORT OF MODERNA THERAPEUTICS, INC.'S PETITIONER'S OPPOSITION TO PATENT OWNER'S CONTINGENT MOTION TO AMEND

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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"). *See* EX1007.

3. On December 21, 2018, Patent Owner Protiva Biotherapeutics, Inc. ("Patent Owner") filed its response to Moderna's petition. I have been asked to provide additional opinions in response to Patent Owner's response that are relevant to Moderna's reply. My opinions concerning Moderna's reply are put forth in a separate declaration.

4. Also on December 21, 2018, Patent Owner filed its Contingent Motion to Amend ("MTA"). Patent Owner thereafter filed a Corrected Patent Owner's Contingent Motion to Amend on January 30, 2019. I have been asked to provide additional opinions in response to Patent Owner's MTA. The opinions discussed herein are my own.

5. 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

6. The issued claims of the ’435 patent cover disparate nucleic acid payloads, any of a host of potential lipid components, and ranges for lipid component concentrations for nucleic acid-lipid particles. As written, these claims overlap with the prior art, including the Patent Owner’s own prior disclosures rendering them *prima facie* obvious. The set of substitute claims presented in Patent Owner’s MTA do not remedy the invalidity issues raised. The proposed substitute claims purport to add “limitations” to the preamble, are based upon mischaracterizations of the knowledge in the art, and lack written description support and an enabling disclosure for the different nucleic acid payloads recited therein.

III. QUALIFICATION AND EXPERIENCE

7. I am formally trained as a membrane biophysicist. I obtained my Ph.D. degree in Biophysics from Michigan State University in 1980. Before that, I received my MS in Biophysics from Michigan State University in 1977, and my BS in Biology from The American University in 1971. I received postdoctoral training in Pharmacology at the Harvard Medical School and in Anesthesia at the Massachusetts General Hospital.

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