

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. IPR2019-00554

U.S. Patent No. 8,058,069

**DECLARATION OF THOMAS J. ANCHORDOQUY, PH.D.
IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S
RESPONSE**

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I, Dr. Thomas J. Anchordoquy, PhD, declare as follows:

I. INTRODUCTION

1. I am a tenured Professor in the Department of Pharmaceutical Sciences at the University of Colorado Anschutz Medical Campus in Aurora, Colorado. I have been retained by counsel for ModernaTX, Inc. (“Moderna”) as an expert in the relevant art.

2. I understand that Moderna formerly engaged Dr. Andrew Janoff as an expert in this matter and that he submitted a declaration dated January 2, 2019 (“Janoff Declaration”) in support of Moderna’s Petition for Inter Partes Review (“IPR”) of U.S. Patent No. 8,058,069 (the “’069 patent”) (“Petition”). EX1008. I understand that Dr. Janoff passed away in December 2019 and that I have been engaged to replace him as Moderna’s expert in this proceeding.

3. I have reviewed Dr. Janoff’s declaration and, while I may have emphasized different points or stated things differently, I agree with the general premises set-forth regarding the invalidity of the ’069 patent as stated therein.

4. On November 13, 2019, Patent Owner Protiva Biotherapeutics, Inc. (“Patent Owner”) filed its response to Moderna’s Petition (“Response”). I have been asked to provide additional explanation regarding the prior art and the state of the art in response to Patent Owner’s arguments in its Response.

While counsel for Moderna has assisted in the preparation of this declaration (*e.g.*, aiding in formatting and providing introductory language and legal standards), the substantive 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. I understand that the Board ordered an IPR over the '069 patent with respect to the following grounds of unpatentability for claims 1-22:

- A. Under §102 and §103 in view of either 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.

7. The '069 patent is directed to a nucleic acid-lipid particle comprising four lipid components (*i.e.*, a cationic lipid, cholesterol, a phospholipid and a conjugated lipid), each of which fall within a claimed proportion with regard to the total lipid in the particles. *See, e.g.*, EX1001, cl.

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1. In my opinion, Moderna has shown that the cited prior art in Grounds 1-3 renders each of the claims in the '069 patent invalid by a preponderance of the evidence.

III. QUALIFICATION AND EXPERIENCE

8. I possess the knowledge, skills, experience, training and the education to form an expert opinion and testimony in this case.

9. I received a bachelor of science in biology from Oregon State University in 1982. I received my master's and doctoral degrees from the University of California Davis in Zoology in 1988 and 1989, respectively. I did my doctoral thesis work under the direction of Dr. John Crowe at the University of California Davis. Dr. Crowe is an expert in the stability of liposomes during freezing and drying, and this was the main topic of my thesis work.

10. I continued my studies at the University of Colorado as a post-doctoral researcher with Dr. John Carpenter in the University of Colorado School of Pharmacy, where I joined the faculty as an Assistant Professor in Pharmaceutical Sciences in 1998. I was promoted to Associate Professor in Pharmaceutical Sciences in 1998. I was promoted to Associate Professor in Pharmaceutical Sciences with Tenure in 2005, and then to Full Professor in 2011.

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