

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

PROTIVA BIOTHERAPEUTICS, INC.,
Patent Owner.

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

**CORRECTED DECLARATION OF DAVID H. THOMPSON, PH. D. IN
SUPPORT OF PATENT OWNER'S CONTINGENT MOTION TO AMEND**

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 A. “serum-stable”16

 B. “a cationic lipid comprising from 50 mol % to 75 mol % of the total lipid present in the particle”20

 C. “wherein the particle is formulated such that the nucleic acid is not substantially degraded after exposure of the particle to a nuclease at 37°C for 20 minutes”21

VII. CONCLUDING STATEMENTS.....23

I, David H. Thompson, declare as follows:

I. QUALIFICATIONS

1. I am a Professor of Chemistry at Purdue University and Director of the Medicinal Chemistry Group in the Purdue Center for Cancer Research. My primary research interests include development of transiently-stable carrier systems for drug and nucleic acid delivery.

2. I received my Ph.D. in Organic Chemistry from Colorado State University in 1984. I also hold a Bachelor of the Arts in Biology and a Bachelor of Science in Chemistry from the University of Missouri, Columbia.

3. I have been a visiting professor at numerous institutions including, Chulalongkorn University, Department of Pharmaceutics; Technical University of Denmark, Department of Micro & Nanotechnology; Japan Advanced Institute of Science & Technology, Department of Biomaterials; Osaka University, Department of Applied Chemistry; University of Florida, Department of Pharmaceutics; and University of British Columbia, Department of Biochemistry.

4. I am listed as a co-inventor on 7 United States patents. I have also published more than 140 peer reviewed scientific papers.

5. I have studied, taught, practiced, and conducted research involving the formulation, use, characterization, and delivery of lipid particles. I have expertise with the delivery of therapeutic agents using lipid particles.

6. A copy of my Curriculum Vitae, attached as EX2010, contains further details on my education, experience, publications, and other qualifications to render an expert opinion in this matter.

II. SCOPE OF WORK

7. I understand that a petition was filed with the United States Patent and Trademark Office for inter partes review of U.S. Patent No. 9,364,435 (“the ’435 patent,” EX1001).

8. I further understand that the Patent Trial and Appeal Board (“PTAB” or the “Board”) has decided to institute inter partes review of claims 1-20 of the ’435 patent based on the disclosures of WO2005/007196 (“the ’196 PCT,” EX1002); U.S. Patent Publication No. 2006/134189 (“the ’189 PCT,” EX1003); Lin, Alison J. et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 BIOPHYSICAL JOURNAL 3307 (2003) (“Lin,” EX1005); Ahmad, Ayesha et al., *New multivalent cationic lipids reveal bell curve for transfection efficiency versus membrane charge density: lipid-DNA complexes for gene delivery*, 7 J GENE MED 739 (2005) (“Ahmad,” EX1006); and U.S. Patent Publication No. 2006/0240554 (“the ’554 publication,” EX1004).

9. I have been specifically asked to provide my expert opinions on the patentability of the claims of the ’435 patent in view of the asserted Grounds in the

petition. I have also been asked to provide my opinion on the patentability of substitute claims that have been submitted to the Board in Patent Owner's Contingent Motion to Amend. In connection with this analysis, I have reviewed the '435 patent and the prior art cited against the patentability of claims 1-20. I have also reviewed and considered the petition, Dr. Janoff's Declaration and deposition transcript, and the Board's Decision on Institution of Inter Partes Review, and may cite these documents in this declaration.

10. I am being compensated at a rate of \$600 per hour for my work in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

III. LEGAL STANDARDS

11. I have been advised that a claimed invention is not patentable under an anticipation theory (35 U.S.C. § 102) if all claim elements are found in a single prior art reference. I further understand that anticipation is about prior invention and therefore the single prior art reference must be found to disclose all elements of the claimed invention arranged as in the claim. I also understand that picking, choosing, and combining various embodiments disclosed within a single reference is not proper under an anticipation theory.

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