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.

_____

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

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CORRECTED PATENT OWNER'S CONTINGENT MOTION TO AMEND

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I. PRELIMINARY STATEMENT

This Contingent Motion to Amend is submitted in IPR2018-00739 involving U.S. Patent No. 9,364,435 ("the '435 patent"), pursuant to 37 C.F.R. §42.121 and the Board's authorization via email on December 11, 2018. In the event that the Board finds any of claims 1-20 of the '435 patent unpatentable, Patent Owner Protiva Biotherapeutics, Inc. requests that the unpatentable claim(s) be replaced with the corresponding substitute claim(s) 21-40.

II. FACTS

A. Claims of the '435 Patent

Claims 1-20 of the '435 patent were issued on June 14, 2016. Of the 20 claims, claim 1 is the only independent claim. The issued claims of the '435 patent are directed to a nucleic acid-lipid particle comprising a nucleic acid and specific concentrations of a cationic lipid (50-85 mol %), a non-cationic lipid (13-49.5 mol %), and a conjugated lipid (0.5-2 mol %).

B. The Instituted Grounds

The Board instituted "all grounds as set forth in the Petition." Paper 15, at 33. The petition set forth three grounds of alleged unpatentability. As presented by the petition, Ground 1 alleges obviousness based on the combination of the '196 PCT (EX1002) and '189 Publication (EX1003); Ground 2 alleges obviousness based on the combination of patent owner's prior disclosure, Lin (EX1005), and

Ahmad (EX1006); Ground 3 alleges anticipation or obviousness based on the '554

Publication (EX1004). Pet. 5.

C.   Burden of Persuasion

In a motion to amend, the burden of persuasion rests on the petitioner to

demonstrate that the substitute claims are unpatentable. *Aqua Products, Inc. v.*

Matal, 872 F.3d 1290, 1327 (Fed. Cir. 2017). The Federal Circuit has held that:

"(1) the PTO has not adopted a rule placing the burden of persuasion with respect

to the patentability of amended claims on the patent owner that is entitled to

deference; and (2) in the absence of anything that might be entitled deference, the

PTO may not place that burden on the patentee." *Id*. Accordingly, Patent Owner

respectfully submits that this paper and supporting evidence provided herewith

meets the requisite burden of production.

III.   ARGUMENT

A.   Contingent Nature of the Motion

This motion is contingent upon a finding that any of original claims 1-20 are

unpatentable. Patent Owner is not surrendering the original claims, and if they are

all found to be patentable, then this motion need not be considered. *See Corning*

Optical Communications RF LLC v. PPC Broadband, Inc., IPR2014-00441, Paper

19 at 3 ("[T]he request to substitute claims is always contingent."). Any claims

found not unpatentable should not be replaced.

B. Proposed Amendments

Proposed substitute claims for each of claims 1-20 are submitted in the claim listing attached as **Appendix A**. Claims 21-40 are claim-for-claim substitutions of claims 1-20 and thus are presumptively reasonable under 37 C.F.R. § 42.121(a)(3).

In response to the grounds on which trial was instituted by the Board, substitute claim 21 amends independent claim 1 by reciting a narrower range for the concentration of the cationic lipid, and a narrower range for the concentration of non-cationic lipid. Also in response to the instituted grounds, substitute claim 21 further recites the term "serum stable" in reference to the claimed nucleic acid-lipid particle, as well as the language "wherein the particle is formulated such that the nucleic acid is not substantially degraded after exposure of the particle to a nuclease at 37ºC for 20 minutes."

Specifically, substitute claim 21 is shown below in mark-up form relative to independent claim 1:

21.   (Substitute for claim 1) A <u>serum-stable</u> nucleic acid-lipid particle comprising:

(a) a nucleic acid;

(b) a cationic lipid comprising from 50 mol % to [[85]] <u>75</u> mol % of the total lipid present in the particle;

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