Paper No. ___
Filed: December 21, 2018

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

PATENT OWNER'S CONTINGENT MOTION TO AMEND

TABLE OF CONTENTS

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;

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.