UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

Moderna Therapeutics, Inc.

Petitioner

v.

Arbutus Biopharma Corporation

Patent Owner

_____

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

Issued: November 15, 2011

Named Inventors: Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, Ian MacLachlan

Title: Lipid Formulations for Nucleic Acid Delivery

_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,058,069

Mail Stop: PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. MANDATORY NOTICES 4

A. Notice of real party-in-interest (37 C.F.R. § 42.8(b)(1)) 4

B. Notice of related matters (37 C.F.R. § 42.8(b)(2)) 4

C. Designation of lead and back-up counsel (37 C.F.R. § 42.8(b)(3)) 4

D. Service information (37 C.F.R. § 42.8(b)(4)) 5

E. Payment of fees (37 C.F.R. § 42.103) 5

F. Certification of grounds for standing (37 C.F.R. § 42.104(a)) 5

III. CHALLENGE AND RELIEF REQUESTED 5

A. Ground 1: Claims 1-22 are anticipated by or obvious in view of Patent Owner's prior disclosures in either the '196 PCT or the '189 publication 5

B. Ground 2: Claims 1-22 are obvious in view of the '196 PCT or the '189 publication in view of Lin and Ahmad 5

C. Ground 3: Claims 1-22 are anticipated by or obvious in view of the '554 publication 5

IV. PRIORITY DATE 5

V. PERSONS HAVING ORDINARY SKILL IN THE ART 6

VI. BACKGROUND 6

A. Lipid carrier particles for nucleic acid payloads 6

B. The '069 patent claims are directed to known lipid components 7

C. The optimal lipid component proportions in a nucleic acid-lipid particle vary 9

D. the '069 patent was granted on alleged unexpected results for a single formulation of lipid components 12

1. '069 patent: The prosecution history confirms patent owner's reliance on unexpected results 14

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

Page

2. '069 patent: Patentee tested only one formulation covered by the claims 15

a) Example 2 shows that *in vitro* the 1:57 SNALP was no more effective than several prior art formulations 16

b) Examples 3-4 show that the 1:57 SNALP was no more effective than the formulations with less than 50% cationic lipid 19

3. The '069 patent: The testing shows that even slight variations of the lipid component proportions and/or the species of lipid component impact efficacy 21

VII. CLAIM CONSTRUCTION 23

A. Claim 1: "Nucleic acid-lipid particle" 23

VIII. PRIOR ART 23

A. Patent owner's prior disclosures are prior art under 35 U.S.C. § 102(b) 23

B. The '554 publication is prior art under 35 U.S.C. § 102(b) 26

C. Lin is prior art under 35 U.S.C. § 102(b) 27

D. Ahmad is prior art under 35 U.S.C. § 102(b) 29

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '069 PATENT IS UNPATENTABLE 31

A. Ground 1: Claims 1-22 are anticipated by or obvious in view of either the '196 PCT or the '189 publication 31

1. Claim 1 32

a) Claim 1(a): a nucleic acid-lipid particle comprising: 32

b) Claim 1(b): a nucleic acid 32

c) Claim 1(c): a cationic lipid comprising from 50 mol% to 65 mol% of the total lipid present in the particle 32

d) Claim 1(d): a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol% to 10 mol% of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol% to 40 mol% of the total lipid present in the particle 38

...

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

e) Claim 1(e): a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol% to 2 mol% of the total lipid present in the particle 39

2. Claim 2: the nucleic acid-lipid particle of claim 1, wherein the nucleic acid comprises a small interfereing RNA (siRNA) 41

3. Claim 3: the nucleic acid-lipid particle of claim 2, wherein the siRNA comprises from about 15 to about 60 nucleotides..... 41

4. Claim 4: the nucleic acid-lipid particle of claim 2, wherein the siRNA comprises at least one modified nucleotide 41

5. Claim 5: the nucleic acid-lipid particle of claim 2, wherein the siRNA comprises at least one 2'-O-methyl (2'OMe) nucleotide 42

6. Claim 6: the nucleic acid-lipid particle of claim 2, wherein said siRNA is about 19 to about 25 base pairs in length 42

7. Claim 7: the nucleic acid-lipid particle of claim 2, wherein said siRNA comprises 3' overhangs 42

8. Claim 8: the nucleic acid-lipid particle of claim 1, wherein the cationic lipid comprises from 52 mol% to 62 mol% of the total lipid present in the particle..... 42

9. Claim 9: the nucleic acid-lipid particle of claim 1, wherein the phospholipid comprises dipalmitoylphosphatidylcholine (DPPC), distearoylphosphatidylcholine (DSPC), or a mixture thereof..... 43

10. Claim 10: the nucleic acid-lipid particle of claim 1, wherein the conjugated lipid that inhibits aggregation of particles comprises a polyethyleneglycol (PEG)-lipid conjugate 43

11. Claim 11: the nucleic acid-lipid particle of claim 10, wherein the PEG-lipid conjugate comprises a PEG-diacylglycerol (PEG-DAG) conjugate, a PEG-dialkyloxypropyl (PEG-DAA) conjugate, or a mixture thereof..... 44

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Page

12. Claim 12: the nucleic acid-lipid particle of claim 11, wherein the PEG-DAA conjugate comprises a PEG-dimyristyloxypropyl (PEG-DMA) conjugate, a PEG-distearyloxypropyl (PEG-DSA) conjugate, or a mixture thereof..... 44
13. Claim 13: the nucleic acid-lipid particle of claim 12, wherein the PEG has an average molecular weight of about 2,000 daltons 44
14. Claim 14: the nucleic acid-lipid particle of claim 10, wherein the nucleic acid-lipid particle comprises about 57.1 mol% cationic lipid, about 7.1 mol% phospholipid, about 34.3 mol% cholesterol or a derivative thereof, and about 1.4 mol% PEG-lipid conjugate 45
15. Claim 15: the nucleic acid-lipid particle of claim 1, wherein the conjugated lipid that inhibits aggregation of particle comprises from 1 mol% to 2 mol% of the total lipid present in the particle..... 45
16. Claim 16: the nucleic acid-lipid particle of claim 1, wherein the nucleic acid in the nucleic acid-lipid particle is not substantially degraded after incubation of the particle in serum at 37°C for 30 minutes 46
17. Claim 17: the nucleic acid-lipid particle of claim 1, wherein the nucleic acid is fully encapsulated in the nucleic acid-lipid particle..... 47
18. Claim 18: the nucleic acid-lipid particle of claim 1, wherein the nucleic acid-lipid particle has a lipid:nucleic acid mass ratio of from about 5 to about 15..... 47
19. Claim 19: the nucleic acid-lipid particle of claim 1, wherein the nucleic acid-lipid particle has a median diameter of from about 40 nm to about 150 nm 48
20. Claim 20: the nucleic acid-lipid particle of claim 1, wherein the phospholipid comprises from 5 mol% to 9 mol% of the total lipid present in the particle..... 48
21. Claim 21: the nucleic acid-lipid particle of claim 1, wherein the cholesterol or derivative thereof comprises

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.