UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/424,367	04/15/2009	Edward Yaworski	020801-007710US	1406

20350 7590 07/30/2010

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
PITRAK, JENNIFER S	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
07/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/424,367	YAWORSKI ET AL.	
	Examiner	Art Unit	
	JENNIFER PITRAK	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9,14,17-26,38,47,48 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,14,17-26,38,47,48 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____ .

DETAILED ACTION

Election/Restrictions

The requirement for election of species presented in the Office Action mailed 3/31/2010 has been withdrawn. Upon further consideration, the species are deemed to be patentably indistinct.

Claims 1-5, 9, 14, 17-26, 38, 47, 48, and 55 are pending and are under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 61/045228, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112

for one or more claims of this application. Application No. 61/046228 does not provide adequate support for claim 55. **Therefore, claim 55 is afforded the benefit of the instant filing date, 04/15/2009.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

MacLachlan, *et al.* (US 2006/0008910, copending application 11/148152)

Claims 1-4, 9, 14, 17-26, 38, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLachlan, *et al.* (US 2006/0008910, of record, item 10 on 06/08/2010 IDS) ("MacLachlan").

The claims are to a nucleic acid lipid particle comprising a nucleic acid, a cationic lipid, a noncationic lipid mixture of phospholipid and cholesterol, and a conjugated lipid. The claims are further directed to the particle wherein the nucleic acid is an siRNA, the relative amounts of components are specified, and the lipids are specified.

MacLachlan teaches lipid encapsulated interfering RNA in the form of stable nucleic acid-lipid particles ("SNALP") comprising an siRNA, a cationic lipid, phospholipid, cholesterol,

and a conjugated lipid (page 4, paragraph 56; pages 7-11, paragraphs 84-119; claim 5) wherein the siRNA is from about 15-60 nucleotides (claim 6), the conjugated lipid is PEG-DMA and has an average molecular weight of about 2000 daltons (claim 13; paragraphs 91, 95, and 96), and the phospholipid is DSPC (paragraphs 62 and 91). MacLachlan also teaches the SNALP wherein the cationic lipid is from about 2 mol % to about 60 mol % of the total lipid present in the particle (paragraph 85), the phospholipid is from about 5% to about 90% or from about 10% to about 85% of the total lipid present in the particle (paragraph 85), the cholesterol is from about 20% to about 55% of the total lipid present in the particle (paragraph 85, top of page 8), and the conjugated lipid is from about 1% to about 20% of the total lipid present in the particle (paragraph 85). MacLachlan teaches that it will be readily apparent to one of skill in the art that the proportions of the components of the nucleic acid lipid particles may be varied (p.8, paragraph 85). MacLachlan teaches that the particles can be formulated in pharmaceutically acceptable carriers (page 18, paragraphs 205-7). MacLachlan teaches the particles having a lipid:nucleic acid mass ratio of from 12.5-100 (nucleic acid:lipid ratio from 0.01-0.08, page 15, paragraph 162) and having a median diameter of less than about 150 nm (claims 4 and 20). MacLachlan also teaches that the nucleic acids of the particles can comprise modified nucleotides (page 6, paragraph 73).

It would have been obvious to one of skill in the art at the time the instant invention was made to make a nucleic acid lipid particle comprising an siRNA, a cationic lipid, a phospholipid, cholesterol, and a PEG-conjugate because MacLachlan teaches such a particle. It would have been obvious to make the particle comprising the instantly claimed components and having the instantly claimed physical properties of claims 23-25 because MacLachlan teaches the particles

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.