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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/520,479	09/12/2006	Neil P. Desai	638772000109	8972

25226 7590 12/29/2010
MORRISON & FOERSTER LLP
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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/29/2010	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	11/520,479	DESAI ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- 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 *30 September 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) *66-68 and 70-84* is/are pending in the application.

4a) Of the above claim(s) *79-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-68 and 70-78* 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 *09/30/2010*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 09/30/2010.

Claims 66-68 and 70-84 are pending.

Claims 79-84 remain withdrawn.

Claims 66-68 and 70-78 are currently under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 09/30/2010 has been considered except where references are lined through. It is noted that Applicant stated in a transmittal letter (09/30/2010) that copies of the pending U.S. Patent Applications was not provided in conformity with the requirements under 37 CFR 1.98, however, 37 CFR 1.98 (a)(2)(iii) states that Applicant must provide a legible copy "For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion".

Maintained Rejections

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.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 66-68 and 70-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al (U.S. Patent number 5,439,686, Patent issued Aug. 8, 1995) in view of Shively (U.S. Patent number 5,407,683, Patent issued Apr. 18, 1995).

Desai teaches a pharmaceutical suspension comprising taxol (paclitaxel) and albumin (see example 4). Said taxol composition of example 4 comprises 13mg of taxol (2 mg/ml * 6.5ml) and 3ml of 5% human serum albumin (2.85ml water). Desai further teaches that a higher loading of taxol can be achieved by utilizing an additional solvent

such as ethyl acetate, which is removed. Said taxol suspension is taught as being protein walled polymeric shells enclosing an oil/taxol solution, said core is not taught as comprising a substantial amount of polymer. Desai teaches that the composition of Desai is stable for 27 days at temperatures of 4°C, 25°C, and 38°C (see example 5). Desai teaches that the crystalline taxol can be ground to a size less than 1 micron, which allows for intravenous delivery, wherein preferred particle radii for the invention of Desai are 0.1 to 5 microns (see column 6, lines 14-16). It is noted that the albumin is taught as being substantially crosslinked by way of disulfide bonds (see claim 1), wherein it is further noted that the remaining (free) albumin would necessarily associate with the taxol.

Desai fails to directly teach that the concentration of taxol (paclitaxel) is 5 mg/ml.

Shively teaches that "[f]or therapeutic use, emulsions containing between about 0.5 and about 5 mg/ml taxol [...] are [...] administered orally or intravenously" (see column 9, lines 51-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize 5 mg/ml of taxol in the invention of Desai. One would have been motivated to do so since Shively teaches that 5 mg/ml is a therapeutically effective amount, wherein Desai directly teaches methods of obtaining "higher loading of drug". There would be a reasonable expectation of success since Desai teaches how to achieve higher amounts of taxol, and Desai teaches the amount (5 mg/ml) one would desire.

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