

1611

 NOTIFICATION DATE
 DELIVERY MODE

 05/02/2013
 ELECTRONIC

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

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| Office Action Summary | Application No. 11/520,479 | | Applicant(s) DESAI ET AL. | |
|--|---|---|--|--|
| | Examiner TREVOR LOVE | Art Unit 1611 | AIA (First Inventor to File) Status No | |
| The MAILING DATE of this communication a Period for Reply | appears on the cover sheet w | with the corresponden | ce address | |
| A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory perio Failure to reply within the set or extended period for reply will, by stat Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN 1.136(a). In no event, however, may a od will apply and will expire SIX (6) MO rute, cause the application to become A | ICATION. reply be timely filed NTHS from the mailing date o BANDONED (35 U.S.C. § 13 | f this communication. | |
| Status | | | | |
| Responsive to communication(s) filed on <u>27</u> A declaration(s)/affidavit(s) under 37 CFR | | <u>.</u> | | |
| | nis action is non-final. | | | |
| 3) An election was made by the applicant in res | sponse to a restriction requi | irement set forth duri | ng the interview on | |
| ; the restriction requirement and election | ion have been incorporated | into this action. | | |
| 4) Since this application is in condition for allow | vance except for formal mat | tters, prosecution as t | to the merits is | |
| closed in accordance with the practice unde | r <i>Ex parte Quayle</i> , 1935 C.I | D. 11, 453 O.G. 213. | | |
| Disposition of Claims | | | | |
| 5) 🛛 Claim(s) <u>66-68,70-72 and 74-94</u> is/are pend | ing in the application. | | | |
| 5a) Of the above claim(s) <u>79-84</u> is/are withdr | | | | |
| 6) Claim(s) is/are allowed. | | | | |
| 7)X Claim(s) <u>66-68,70-72,74-78 and 85-94</u> is/are | e rejected. | | | |
| 8) Claim(s) is/are objected to. | | | | |
| 9) Claim(s) are subject to restriction and | l/or election requirement. | | | |
| * If any claims have been determined <u>allowable</u> , you may be | - | - | way program at a | |
| participating intellectual property office for the corresponding | | • | | |
| <u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> or se | nd an inquiry to <u>PPHfeedback</u> | @uspto.gov. | | |
| Application Papers | | | | |
| 10) The specification is objected to by the Exami | ner. | | | |
| 11) The drawing(s) filed on is/are: a) a | ccepted or b) displayed to | by the Examiner. | | |
| Applicant may not request that any objection to the | ne drawing(s) be held in abeya | ince. See 37 CFR 1.85 | (a). | |
| Replacement drawing sheet(s) including the corr | ection is required if the drawing | g(s) is objected to. See | 37 CFR 1.121(d). | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for forei | gn priority under 35 U.S.C. | § 119(a)-(d) or (f). | | |
| Certified copies: | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of the: | | | | |
| 1. Certified copies of the priority docume | | | | |
| 2. Certified copies of the priority docum | | | | |
| 3. Copies of the certified copies of the p | = | n received in this Nat | tional Stage | |
| application from the International Bure | | | | |
| * See the attached detailed Office action for a list | of the certified copies not rece | eived. | | |
| Interim copies: a) All b) Some c) None of the: In: | terim copies of the priority c | locuments have beer | received. | |
| | | | | |
| Attachment(s) | 🗖 | _ | | |
| 1) Notice of References Cited (PTO-892) | | Summary (PTO-413) | | |
| 2) 🕅 Information Disclosure Statement(s) (PTO/SB/08) | Paper No | (s)/Mail Date | | |
| OCKET | | | | |
| LARM Find authenticated court d | ocuments without waterm | arks at <u>docketalarm.</u> | <u>com</u> . | |
| | | | | |

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DETAILED ACTION

Acknowledgement is made to Applicant's response filed 01/27/2012.

Claims 66-68, 70-72, and 74-94 are pending.

Claims 79-84 remain withdrawn.

Claims 85-94 are newly added.

Claims 66, 72, and 74-78 are currently amended.

Claims 66-68 and 70-72, 74-78, and 85-94 are currently under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/27/2012 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the Examiner.

Withdrawn Rejections

DOCKE.

The rejection of claim 73 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) is <u>withdrawn</u> in view of Applicant's cancellation of said claim.

Rejections Maintained and Made Again in view of Applicant's amendments and newly added claims 85-94.

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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).

DOCKE

Claims 66-68, 70-72, 74-77, and 85-94 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 (and subsequently 9) 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 (example 4) and a solid taxol with a shell of protein (example 9), wherein 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 between 5 mg/ml and 15 mg/ml (claim 66) or 5mg/ml (claim 68).

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).

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