



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.
10/310,232	12/05/2002	William John Curatolo	PC9838B	6606
28523	7590	11/23/2005	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/23/2005

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

Office Action Summary	Application No.	Applicant(s)	
	10/310,232	CURATOLO ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- 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 ____.
- 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) 1-44 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- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.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) 1-44 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) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/03/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time filed 11/04/03, Information Disclosure Statement filed 07/03/03, and Preliminary Amendment filed 12/05/02.

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 negated 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.

Claims 1-15 and 19-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. US 4,708,834, in view of Bacopoulos US 5,130,338.

Cohen teaches a controlled release pharmaceutical unit dosage form comprising a gelatin capsule enclosing a fill, an active agent, a surfactant, a thickener, a co-solvent, and a buffer (column 2, lines 25-40; and column 37-66). The liquid fill can comprise one or more active agents include antidepressant and fatty acids (column 4, lines 17-31).

Art Unit: 1615

The fill comprises solvent, co-solvent, bulking agent, and one or more dispersing agents (column 3, lines 55-67; column 4, lines 1-14, lines 51-68; and column 5, lines 1-14).

Cohen also teaches the use of fatty acid and surfactant such as polysorbate (column 4, lines 51-65).

Cohen does not expressly teach the claimed antidepressant, such as sertraline. However, sertraline is a well-known antidepressant. To be more specific, Bacopoulos teaches sertraline is a known antidepressant (column 1, lines 30). Bacopoulos also teaches oral administering from about 50-200 mg per day of sertraline in oral dosage forms including capsule (column 2, lines 24-68). Bacopoulos further teaches a method of treating a chemical dependency by administering sertraline (column 1, lines 55-58; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release composition of Cohen using sertraline as an antidepressant in view of the teachings of Bacopoulos to obtain the claimed invention, because Bacopoulos teaches sertraline is a known antidepressant, and because Cohen teaches the use of liquid fill capsule composition for a variety active agent including antidepressant that exhibits a number of advantageous including ability to uniformly deliver an accurate dose of the active ingredient, and controlled release of one or more active compounds in vitro or in vivo (column 1, lines 67 through column 2, lines 1-11).

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy et al. US 6,096,338, in view of Bacopoulos US 5,130,338.

Lacy teaches a composition comprising digestible oil, surfactant, carrier, and hydrophobic drug such as antidepressant drug (see abstract; and column 11, line 59). Digestible oil includes vegetable oil, such as corn, olive, coconut, or safflower oil (column 9, lines 35-56). Digestible oil further includes triglycerides (columns 9-10). Surfactant and carrier can be mixture of the disclosed lipophilic surfactant classes 1-8 in columns 4-6, including fatty acid, fatty acid ester, and propylene glycol ester. The composition is liquid at ambient temperatures, and preferably filled into hard or soft gelatin capsule (column 14, lines 53-58).

Lacy does not expressly teach the claimed antidepressant, such as sertraline.

Bacopoulos teaches sertraline is a known antidepressant (column 1, lines 30). Bacopoulos also teaches oral administering from about 50-200 mg per day of sertraline in oral dosage forms including capsule (column 2, lines 24-68). Bacopoulos further teaches a method of treating a chemical dependency by administering sertraline (column 1, lines 55-58; and claims). Thus, it would have been obvious to one of ordinary skill in the art to use sertraline as an antidepressant in view of the teachings of Bacopoulos to obtain the claimed invention, because Bacopoulos teaches sertraline is a known antidepressant, and because Lacy teaches a delivery system that is suitable for a very wide range of drugs (column 11, lines 13-17).

It is noted that the cited references do not explicitly teach the claimed T_{max} , as well as the solubility of sertraline in the water-immiscible vehicle. However, it is noted that where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been

Art Unit: 1615

established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Accordingly, it would have been obvious that the compositions disclosed in the cited references would have the claimed properties, because the references teach the use of similar ingredients in the same delivery system for the same purpose, namely, a gelatin-encapsulated solution of antidepressant for the treatment of condition treatable by sertraline. Furthermore, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In this case, the references cited teach the use of the same active agent, e.g., sertraline.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Finizio, Borkan et al., Mank et al., Yiv, Volicer, and Thompson et al. are cited as of interest for the teachings of liquid fill capsule.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal stroke extending to the right.

S. Tran
Patent Examiner
Art Unit 1615