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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/310,232	12/05/2002	William John Curatolo	PC9838B	6606

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/09/2006

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 *22 May 2006*.

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4a) Of the above claim(s) _____ is/are withdrawn from consideration.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) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 44 is objected to for being in an incomplete form. For examining purpose, claim 44 is interpreted as being depending in claim 23. See Preliminary Amendment dated 12/05/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties (solubility) recited in the claims. It appears from the specification that, only certain water-immiscible solvents are useful in the claimed invention. Specification at page 7 bridging page 8, discloses single solvent vehicles in which the solvent dissolves in water as molecular monomers are not useful as vehicles in this invention. The examples clearly demonstrate that polysorbate-80 is a sertraline vehicle that prevents precipitation. Accordingly, not all type of water-

immiscible solvents can be used. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the structure which makes up the formulation must be clearly and positively specified.

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.

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).

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

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). It this case, the references cited teach the use of the same active agent, *e.g.*, sertraline.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson EP 0 768 083, in view of Lacy et al. US 6,096,338.

Johnson teaches a composition comprising sertraline or salt thereof, and pharmaceutically acceptable carrier for tablet, capsules, troches, and aqueous suspension (page 4, lines 1-24).

Johnson does not explicitly teach the claimed water-immiscible vehicle (carrier).

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). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the carrier system in view of the teaching of Lacy to obtain the claimed invention, because Lacy teaches a carrier system suitable for a wide range of hydrophobic drugs to improve the bioavailability of the hydrophobic drugs.

It is noted that the cited references do not teach the property being claimed, namely the solubility of sertraline in the water-immiscible vehicle. However, absence of evidence to the contrary, it would have been obvious that the sertraline taught by the cited prior arts would have the claimed solubility, because the prior arts teach the use of similar water-immiscible carrier. Products of identical chemical composition can not 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).

Response to Arguments

Applicant's arguments filed 05/22/06 have been fully considered but they are not persuasive.

Applicant argues that the office action does not establish a prima facie case of obviousness, since no suggestion or motivation has been established to modify the controlled release composition of Cohen using sertraline as an antidepressant as taught by Bacopoulos. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Cohen clearly teaches a liquid fill capsule suitable for one or more active agents include *antidepressant* (column 4, lines 17-31). Bacopoulos teaches sertraline is a well-know antidepressant in the art.

Applicant argues that the office action does not establish a prima facie case of obviousness, since no suggestion or motivation has been established to modify the carrier vehicle of Lacy using sertraline as an antidepressant as taught by Bacopoulos. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Lacy clearly teaches a carrier system suitable for a wide variety of hydrophobic drugs including *antidepressant* (see abstract; and column 11, line 59). Bacopoulos teaches sertraline is a well-know antidepressant in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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 M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. 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). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615