

# Exhibit 1021



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/698,739	01/25/2007	S. George Kottayil	50695.0100	4756

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1646

MAIL DATE DELIVERY MODE

09/15/2010

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.**

11/698,739

**Applicant(s)**

KOTTAYIL ET AL.

**Examiner**

SANDRA WEGERT

**Art Unit**

1646

-- 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 31 August 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) 1-8 and 10-38 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 12-19, 24-29 and 33-138 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-4, 10, 11, 20-23, 31 and 32 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:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 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)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/10, 8/31/10</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1646

### **Detailed Action**

#### ***Status of Application, Amendments, and/or Claims***

Applicant's remarks and the Information Disclosure Statements sent 21 June 2010 and 31 August 2010, have been entered into the record.

Claims 1-8, 10-29 and 31-138 are pending. Claims 1 and 20 are amended. Claims 5-8, 12-19, 24-29 and 33-138 are withdrawn. Claims 9 and 30 are cancelled.

Claims 1-4, 10, 11, 20-23, 31 and 32 are under examination in the Instant Application.

### **Maintained/New Claim Rejections/Objections**

#### **Claim Rejections: Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 10, 11, 20-23, 31 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11, 30-32, 127, 128 and 139 of copending Application No. 12/221,333 (Pub No. 2009/0176834). Although the conflicting claims are not identical, they are not patentably distinct from each other because each application describes almost identical inventions, and the claims to those inventions use nearly identical language in describing them.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Instant claims 1-4, 10, 11, 20-23, 31 and 32 are directed to formulations of fentanyl and fentanyl derivatives that are at least about 10 microns in diameter and produce  $C_{max}$  blood concentrations of 127pg/ml to about 213 pg/ml or 142pg/ml to 195pg/ml or 158pg/ml to 177 pg/ml after sublingual administration to humans. Claims 9-11, 30-32, 127, 128 and 139 of copending application 12/221,333 are directed to formulations of fentanyl and fentanyl derivatives that are at least about 10 microns in diameter- as recited in the independent claims from which claims 9-11, 30-32, 127, 128 and 139 depend- and produce  $C_{max}$  blood concentrations of 127pg/ml to about 213 pg/ml or 142pg/ml-195pg/ml or 158pg/ml-177 pg/ml after sublingual administration to humans.

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