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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/739,180	04/24/2007	Thomas Kellcher	C062-02/03 US	8837
34103	7590	02/19/2008	EXAMINER KAM, CHIH MIN	
Intellectual Property Department Cubist Pharmaceuticals, Inc. 65 Hayden Avenue Lexington, MA 02421			ART UNIT	PAPER NUMBER
			1656	
			MAIL DATE	DELIVERY MODE
			02/19/2008	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.

CUBIST 2000

Office Action Summary	Application No. 11/739,180	Applicant(s) KELLEHER ET AL.	
	Examiner CHIH-MIN KAM	Art Unit 1656	

-- 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) 1-53 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4a) Of the above claim(s) _____ is/are withdrawn from consideration.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, 8, 9, 11-30, 37, 38, 45, 46 and 53 is/are rejected.
- 7) Claim(s) 2-7, 10, 31-36, 39-44 and 47-52 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 24 April 2007 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 type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
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)
Paper No(s)/Mail Date <u>8/11/07</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Claims

1. Claims 1-53 are pending and examined.

Information Disclosure Statement (IDS)

2. The references on IDS filed August 14, 2007 have been considered and signed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 8, 9, 11-30, 37, 38, 45-46 and 53 are rejected under 35 U.S.C. 102(e) as anticipated by Baker *et al.* (US RE39,071 E, reissue of U.S. Patent 5,912,226, filed December 16, 1991).

Baker *et al.* teach an antibacterial composition comprising daptomycin (LY146032) in substantially pure form, which refers to daptomycin that contains less than 2.5% of a combined total of anhydro-daptomycin and beta-isomer of daptomycin (column 8, lines 50-60; Example 4;

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claims 1(g), 30), where daptomycin is purified by a procedure using Diaion HP-20 resin column and HPLC (Examples 1-3, claim 8). A pharmaceutical formulation comprising the purified daptomycin (LY146032) with pharmaceutical carriers or excipients can also be prepared (column 9, lines 47-59; claims 9, 37, 38, 45-46 and 53). The reference also anticipates claims 11-29 because although the product by process claims are limited by and defined by the process, determination of patentability is based on the product itself, and the patentability of a product does not depend on its method of production (see MPEP 2113). In the instant case, the composition comprising daptomycin that is substantially free of anhydro-daptomycin and beta-isomer of daptomycin (< 2.5%) as indicated in the patent is the same as the claimed composition comprising substantially pure daptomycin (>95% daptomycin), even though the daptomycin of reference is purified by a different process.

Claim Objections

4. Claims 2-7, 10, 31-36, 39-44 and 47-52 are objected to because the claims are dependent from a rejected claim.

Conclusion

5. Claims 1, 8, 9, 11-30, 37, 38, 45-46 and 53 are rejected; and claims 2-7, 10, 31-36, 39-44 and 47-52 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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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).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

February 14, 2008