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11/739,180	04/24/2007	Thomas Kelleher	C062-02/03 US	8837

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Intellectual Property Department
Cubist Pharmaceuticals, Inc.
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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	
MAIL DATE	**DELIVERY MODE**
11/17/2008	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 2210

Office Action Summary	Application No.	Applicant(s)	
	11/739,180	KELLEHER ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	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 *18 August 2008*.

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) *1-29,31-36,38-44 and 46-52* 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4a) Of the above claim(s) _____ is/are withdrawn from consideration.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) *1-5,8-29,31-34,38-42 and 46-50* is/are rejected.

7)☒ Claim(s) *6,7,35,36,43,44,51 and 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) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 1-29, 31-36, 38-44 and 46-52 are pending.

Applicants' amendment filed August 18, 2008 is acknowledged. Claim 1 has been amended, and claims 30, 37, 45 and 53 have been cancelled. Therefore, claims 1-29, 31-36, 38-44 and 46-52 are examined.

Withdrawn Claim Objections

2. The previous objection to claims 2-7, 10, 31-34, 39-42 and 47-50 is withdrawn in view of a new ground of rejection made on these claims.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 1, 8, 9, 11-30, 37, 38, 45-46 and 53 under 35 U.S.C. 102(e) as being anticipated by Baker *et al.* (US RE39,071 E, reissue of U.S. Patent 5,912,226), is withdrawn in view of applicants' amendment to the claim, and applicant's response at pages 8-9 in the amendment filed August 18, 2008.

New 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.

4. Claims 1-5, 8-29, 31-34, 38-42 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over 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), where daptomycin is purified by a procedure using Diaion HP-20 resin column and HPLC (Examples 1-3, claim 8). Baker *et al.* also teach a pharmaceutical formulation comprising the purified daptomycin (LY146032) with pharmaceutical carriers or excipients can also be prepared (column 9, lines 47-59; claims 9, 38, 46). Although Baker *et al.* do not specifically disclose the daptomycin (LY146032) that is essentially pure (i.e., at least 98% of a sample being daptomycin as defined at page 11, lines 23-26 of the instant specification); that is substantially free of anhydro-daptomycin (no more than 1%; page 11, lines 27-29) and substantially free of β-isomer of daptomycin (no more than 1%); that is essentially free of anhydro-daptomycin (no more than 0.5%; page 12, lines 1-3) and substantially free of β-isomer of daptomycin (no more than 1%); that is free of anhydro-daptomycin (no more than 0.1%; page 12, lines 4-6) and substantially free of β-isomer of daptomycin (no more than 1%), the reference does indicate the daptomycin (LY146032) contains less than 2.5% of a combined total of anhydro-daptomycin and beta-isomer of daptomycin, thus it is obvious that LY146032 is at least 97.5% pure, which encompass the embodiments at least 98% pure (claims 1(a), 2, 31, 39, 47), the embodiments of substantially free of anhydro-daptomycin (no more than 1%) and substantially free of β-isomer of daptomycin (no more than 1%; claims 1(b), 3, 32, 40, 48), the embodiments of essentially free of anhydro-

daptomycin (no more than 0.5%) and substantially free of β-isomer of daptomycin (no more than 1%; claims 1(c), 4, 33, 41, 49), and the embodiments of free of anhydro-daptomycin (no more than 0.1%) and substantially free of β-isomer of daptomycin (no more than 1%; claims 1(d), 5, 34, 42, 50). It is also obvious that claims 11-29 are not patentable because 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 (less than 2.5% impurity, or at least 97.5% pure) as indicated in the patent is the similar to the claimed composition comprising essentially pure daptomycin (>98% daptomycin), even though the daptomycin of reference is purified by a different process. Baker *et al.* also disclose an antibiotic composition comprised of a combination of a compound of formula 1 (i.e., anhydro-A21978C; column 1, lines 14-21), a compound of formula 2 (isomer of A21978C) and a compound of formula 3 (the parent cyclic peptide of A21978C; LY146032) or pharmaceutically acceptable salts (Reissue:claim 18; claim 10 of instant application).

Claim Objections

5. Claims 6-7, 35-36, 43-44 and 51-52 are objected to because the claims are dependent from a rejected claim.

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