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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 11/739,180, 04/24/2007, Thomas Kelleher, C062-02/03 US, 8837
Row 2: 34103, 7590, 08/11/2009, [EXAMINER: KAM, CHIH MIN], [ART UNIT: 1656, PAPER NUMBER]
Row 3: [MAIL DATE: 08/11/2009, DELIVERY MODE: 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.	11/739,180	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 15 May 2009.
- 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) 1-29,31-36,38-44,46-52 and 54-57 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- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.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) 1-5,8-29,31-34,38-42,46-50 and 54-57 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:
- 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 type="checkbox"/> Notice of References Cited (PTO-892)                                     | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>20090808</u> |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date | 6) <input type="checkbox"/> Other:   |

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

All participants (applicant, applicant's representative, PTO personnel):

- (1) CHIH-MIN KAM. (3) William DeVaul.  
(2) Jill Mandelblatt. (4) \_\_\_\_\_.

Date of Interview: 14 May 2009.

Type: a)  Telephonic b)  Video Conference  
c)  Personal [copy given to: 1)  applicant 2)  applicant's representative]

Exhibit shown or demonstration conducted: d)  Yes e)  No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: pending claims.

Identification of prior art discussed: Baker et al. (US RE39,071E).

Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussing the Baker reference regarding the purity of daptomycin (LY 146032). applicants would present the arguments and evidence indicating the purity of LY146032 in Baker's reference is best 93% in the coming amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

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## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-29, 31-36, 38-44, 46-52 and 54-57 are pending.

Applicants' amendment filed May 15, 2009 is acknowledged. Claim 1 has been amended, and new claims 54-57 have been cancelled. Therefore, claims 1-29, 31-36, 38-44, 46-52 and 54-57 are examined.

### *Claim Rejections - 35 USC § 102/103*

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)).

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.

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2. Claims 1-5, 8-29, 31-34, 38-42, 46-50 and 54-57 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as 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) obtained 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; Examples 4 and 5; claim 1(g), 54), where daptomycin is purified by a procedure using Diaion HP-20 resin column, followed by HPLC and another HP-20 resin column (Examples 1-5, claim 8). Baker *et al.* also teach the preparation of a pharmaceutical formulation comprising the purified daptomycin (LY146032) with pharmaceutical carriers or excipients (column 9, lines 47-59; claims 9, 38, 46 and 55-57). 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  $\beta$ -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  $\beta$ -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  $\beta$ -isomer of daptomycin (no more than 1%), the reference does indicate the daptomycin (LY146032) is in substantially pure form and contains less than 2.5% of a combined total of anhydro-daptomycin and beta-isomer of daptomycin. Furthermore, Baker *et al.* discloses a composition or pharmaceutical composition comprising substantially pure daptomycin, which meets the criteria of claim 1(a)-1(d) and 1(g), and its dependent claims because the term

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