

EXHIBIT 2018

U.S. Patent No. 8,546,449 Office Action
(April 1, 2013)



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/065,553	03/24/2011	Michael S. Harvey	8568/17669	2262

7590 04/01/2013
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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1628

MAIL DATE	DELIVERY MODE
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04/01/2013

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.	Applicant(s)	
	13/065,553	HARVEY ET AL.	
	Examiner	Art Unit	
	REI-TSANG SHIAO	1628	

-- 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 14 February 2013.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ 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

- 5) ☒ Claim(s) 1-91 is/are pending in the application.
- 5a) Of the above claim(s) 1-6, 26-27, 30-31, 34-38, and 40-91 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 7-25, 28, 29, 32, 33 and 39 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 3/24/2011 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).

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) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/10/12</u> . | 4) ☐ Other: ____. |

DETAILED ACTION

1. Applicant's remarks filed on February 14, 2013 are acknowledged. Claims 1-91 are pending in the application.

Responses to Election/Restriction

2. Applicant's election without arguments of Group III claim 7-25, 28-29, 32-33 and 39, in the reply filed on February 14, 2013 is acknowledged. Election of a compound triacetin of the acetyl precursor as the single species is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-91 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claim 7-25, 28-29, 32-33 and 39 are drawn to processes of making, and prosecuted in the case. Claims 1-6, 26-27, 30-31, 34-38, and 40-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and therefore is made FINAL.

Claim Rejections - 35 USC § 112

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

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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.

Claim 7-25, 28-29, 32-33 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the acetyl precursor represents triacetin, does not reasonably provide enablement for the acetyl precursor without limitation, see claim 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Dependent claims 8-25, 28-29, 32-33 and 39 are also rejected along with claim 7 under 35 U.S.C. 112, first paragraph.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

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The nature of the invention

The nature of the invention of claims 7-25, 28-29, 32-33 and 39 is drawn to processes of making peracetic acid solution, wherein the acetyl precursor is without limitation (i.e., no named compounds), see claim 7.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is DiCosimo et al. US 2007/0082832. DiCosimo et al. '832 discloses a similar process for preparing peracetic acid solution, see column 27.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the acetyl precursor representing triacetin, see pages 9-10 of the specification. There are no working examples present for “acetyl precursor” without limitation (i.e., no named compounds)” of the instant invention found in the specification.

The breadth of the claims

The breadth of the claims is the instant processes comprising any “acetyl precursor” without limitation (i.e., no named compounds).

The quantity of experimentation needed

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The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what “acetyl precursor” without limitation (i.e., no named compounds) would be used by the instant invention, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physical characteristics to determine which acetyl precursor are used. Thus, the specification fails to provide sufficient support of the broad scope of the compounds of the instant claims for the “acetyl precursor”.

As a result necessitating one of skill to perform an exhaustive search for which “acetyl precursor”, can be prepared of the instant claims in order to practice the claimed invention. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed compounds. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed “acetyl precursor” without limitation, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that “ a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling

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disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by incorporation of the limitation "acetyl precursor" into claim 7 (i.e., see claim 9) respectively would obviate the rejection.

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

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-25, 28-29, 32-33 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "acetyl precursor" without named specific compounds is indefinite and ambiguous, i.e., see line 3. It is unclear what the scope of "acetyl precursor" is. The "acetyl precursor" is from any organic compounds having multiple functionality. Such breadth in view of the limited exemplification and the lack of scope of subject matter resulted from a search of the prior art indicated that the "scope" of claim 7 cannot be ascertained. In view of the high degree of unpredictability of the chemical art and "acetyl precursor" must be made available at the time the invention was made, i.e., filing of application, the broad scope cannot be supplemented with future discovery of new "acetyl precursor". It is recommended that "acetyl precursor" be limited to the specific disclosure in the specification, i.e., triacetin of claim 9. Dependent

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claims 8-25, 28-29, 32-33 and 39 are also rejected along with claim 7 under 35

U.S.C. 112, second paragraph.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf, can be reached on (571)272-2919. 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.

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/REI-TSANG SHIAO/

Rei-tsang Shiao, Ph.D.
Primary Examiner, Art Unit 1628

March 14, 2013