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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 13/034,340, inventor Alan H. Auerbach, and examiner HUI, SAN MING R.

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 13/034,340	Applicant(s) AUERBACH ET AL.	
	Examiner SAN-MING HUI	Art Unit 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 03 July 2012.
- 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) 37-56 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 37-56 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) 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).
- 12) 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

- 13) 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 type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's response filed 7/3/2012 has been entered.

Claims 37-56 are pending.

The provisional double patenting rejection is withdrawn in view of the conflicting patent application being abandoned.

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 negated by the manner in which the invention was made.

Claims 37-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell et al., British Journal of Cancer, 2004;90:2317-2325 in view of Tannock et al., J. Clin. Oncol., 1996;14:1756-1764. All of the references are of record in the parent application.

O'Donnell et al. teaches abiraterone acetate is known to be an inhibitor of 17 α -hydroxylase/C17,20-lyase, which can be used to suppress testosterone level in prostate cancer patients (see the abstract for example). O'Donnell et al. teaches 800mg of abiraterone acetate as useful in suppressing the serum testosterone level (See the abstract for example). O'Donnell et al. also teaches that concomitant glucocorticoid therapy may be needed for continuous use of abiraterone acetate (See the abstract and page 2323, col.2 for example).

O'Donnell et al. does not expressly teach the use of prednisone in the method of treating prostate cancer. O'Donnell et al. does not expressly teach the use of the herein claimed dosage and regimen for prednisone and abiraterone acetate.

Tannock et al. teaches 10mg of prednisone in combination with other anti-cancer drug as effective in treating refractory hormonal-resistance prostate cancer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer.

One of ordinary skill in the art would have been motivated to employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method of treating prostate cancer, including refractory prostate cancer. Since abiraterone acetate provide a new mechanism of action in treating prostate cancer and prednisone is known to be useful in treating refractory prostate cancer, concomitant employment of both compounds into a single method useful for the very same purpose, treating prostate cancer, would be considered *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)). Treating refractory prostate cancer with abiraterone acetate would be reasonably expected to be effective since abiraterone provides a new mechanism of action against prostate cancer. O'donnell et al. provides an additional motivation to concomitantly employ prednisone since employing replacement glucocorticoid such as prednisone would ensure the safety and effectiveness of abiraterone acetate.

Furthermore, the optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. The optimization of known effective amounts of known active agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). It is also noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 7/3/2012 averring the presence of unexpected results because abiraterine plus prednisone being more effective than prednisone alone have been fully considered but they are not persuasive. The examiner notes that it is expected because abiraterone and prednisone are known to be individually effective in treating prostate cancer. At least additive effective is expected.

Applicant's arguments filed 7/3/2012 averring the presence of commercial success have been considered, but are not found persuasive. The examiner notes that applicant bears the burden to provide evidence of commercial success. Furthermore, gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to

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