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ELECTRONIC

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The provisional double patenting rejection is withdrawn in view of the conflicting patent application being abandoned.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