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13/902,132	05/24/2013	Giorgio Calderari	23278.2.US.10	2532
53449	7590	08/08/2013	EXAMINER	
PATENT CORRESPONDENCE ARNALL GOLDEN GREGORY LLP 171 17TH STREET NW SUITE 2100 ATLANTA, GA 30363			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1628	
			NOTIFICATION DATE	DELIVERY MODE
			08/08/2013	ELECTRONIC

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):

patents@agg.com

Dr. Reddy's Laboratories, Ltd., et al.
v.
Helsinn Healthcare S.A., et al.

DETAILED ACTION

Status of Claims

Claims 10-15 are pending and are under examination in this office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/24/13 is acknowledged and has been reviewed.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

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 10-15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claim 10, the word "means" is preceded by the word(s) "making" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by

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35 U.S.C. 112(f) or 35 U.S.C. 112 (pre-AIA), sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

The term “making” has no functional meaning, therefore it is confusing what Applicant is referring to.

However to accelerate prosecution Examiner has interpreted the claim as a formulation comprising palonosetron.

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status

Claim Rejections - 35 USC § 102

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 –

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Baroni et al. (WO 2004/073714).

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Baroni et al. teach a Palonosetron has surprisingly been found to exhibit an efficacy plateau as a single dose (see pg 8, lines 20+) and can be in a concentration of 0.25 mg (see pgs 11, lines 14-16 and 13, lines 20-25) for the treatment of emesis induced by chemotherapy (see pg 13, lines 18-20, as required by instant claims 10-11) in a single intravenous unit (see pg 13, lines 3-5).

With regards to the limitations means for making said formulation stable for 24 months or 18 months, Baroni teaches their formulation prepared as shown in Example 3, Table 8, therefore it is expected that the aqueous formulation of palonosetron will be stable for 24 or 18 months. Additionally Baroni teaches that their formulation is stable for extended times ranging from 1 yr, 18 months, 6 months (see pg 18, lines 21-24, as required by instant claim 10)

Therefore Baroni anticipates instant claims 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

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