



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
13/902,132 05/24/2013 Giorgio Calderari 23278.2.US.10 2532

53449 7590 08/08/2013
PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER

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

Art Unit: 1628

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).

Art Unit: 1628

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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.