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EXAMINER

GEMBEH, SHIRLEY V

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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):

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



### **DETAILED ACTION**

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

### **Status of Claims**

Claims 12-41 are pending and are under examination in this office action. Claims 1-11 have been cancelled. Claims 16-41 are newly added.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/25/13 is acknowledged and has been reviewed.

1. The response filed on **10/9/13** has been entered.
2. Applicant's arguments filed 10/9/13 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 10-15 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

The rejection of Claims 10-11 under 35 U.S.C. 102(b) as being anticipated by Baroni et al. (WO 2004/073714). Is withdrawn due to Applicant's amendment to the claims.

The rejection of Claims 12-15 under 35 U.S.C. 103 as being obvious over Baroni et al. (WO 2004/073714) is withdrawn due to Applicant's amendment to the claims.

### ***Claim Objections***

Claim 27 is objected to because of the following informalities: claim 27 is a duplicate of claim 26. Appropriate correction is required.

### ***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.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 12, 14-16, 18-24, 26-33, 35-41 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US 5,202,333) in view of Barton (Citrate Buffer Calculation, 2000, 2pgs and Castillo et al., US 6,284,749 further in view of Gambhir, US 5,854,270 and as evidenced by Matsumoto (All references have already been made of record).

With regards to claims 12, 16, 24 and 33, Berger et al. teaches a method of treating and or reducing chemotherapy induced nausea and vomiting with a pharmaceutical solution for reducing emesis in cancer patients (see col. 1, lines 33-40, as required by instant claims 14, 18, 26-26, 35), comprising palonosetron in a pharmaceutical acceptable carrier (see col. 2, lines 20 to 25 and col. 12, lines 41-52 and col. 3, lines 17-21) in a single unit dosage form (see col. 13, lines 1-5) for intravenous

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