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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/937,870	09/10/2004	Glen Gary Lawrence	038923-0304	1696

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	10/937,870	LAWRENCE ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- 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 *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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

4)☒ Claim(s) *78,83-97,103-109,119 and 120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78,83-97,103-109,119 and 120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ 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).

11)☐ 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

12)☐ 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) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Request for Continued Examination filed on 12/12/2008.

Claims 78, 103-109 and 119 have been amended.

Claims 1-77, 79-82, 98-102 and 110-118 have been cancelled.

Claims 78, 83-97, 103-109, 119 and 120 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/2008 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 86 recites the cinacalcet HCl is in a form chosen from needle-shaped particles, rod-shaped particles, plate-shaped particles, and mixture as originally filed. The specification only discloses the cinacalcet HCl, the crystalline powders can be in forms including polymorphs, psuedopolymorphs, crystal habits,

micromeretics, and particle morphology. As such, the disclosure of the instant specification is not sufficient to support the claimed cinacalcet HCl forms chosen from needle-shaped particles, rod-shaped particles, plate-shaped particles, and mixtures.

Claim Rejections - 35 USC § 103

3. 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 negatived by the manner in which the invention was made.

4. 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(a) 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.

5. Claims 78, 83-97, 103-109 and 119-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Wagenen et al (US 6,211,244 B1) as evidenced by Kajiyama et al (US 6,656,492) in view of Creekmore et al (US 6,316,460 B1) and Hsu et al (US 2005/0147670).

Van Wagenen discloses a pharmaceutical composition comprising inorganic ion receptor-modulating compounds able to modulate the activity of an inorganic ion receptor that will have beneficial effect (col. 5 lines 25-30). Compound is a calcimimetic

(which would read on cinacalcet HCl) acting on a parathyroid cell calcium receptor and reduces the level of parathyroid hormone in the serum of the patient and can be used to treat diseases such as primary hyperparathryroidism and secondary hyperparathyroidism (col. 6 lines 48-51 and col. 11 lines 30-53). Composition can also be formulated as pharmaceutically acceptable salts such as hydrochloride and composition further includes carrier or excipients like microcrystalline cellulose in about 15%; colloidal silicon dioxide in about 0.44 %; starch, various sugars to facilitate administration of the compounds (col. 19 lines 44+ and col. 44 lines 15-25). Further, composition can be formulated into conventional oral administration dosage forms such as capsules, tablets and liquid preparations and generally, a therapeutically effective amount is between about 1 nmole and 3 micro mole of the compound, preferably 0.01 and 20 mg/kg of the animal to be treated, which would read on from about 10% to about 40% by weight of cinacalcet HCl compound (col. 20 lines 32-41). Additional disclosure includes that the pharmaceutical composition contains a sufficient amount of a calcium receptor modulating compound in proper pharmaceutical form (which would read on particulate or granular form) to exert a therapeutic effect on a human and also the preparation of pharmaceutically acceptably salts can facilitate the pharmacological use of a compound by altering its physical characteristics without preventing it from exerting a physiological effect (col. 5 lines 32-47).

Note: Van Wagenen does not disclose cinacalcet HCl is in a form of amorphous powders, crystalline particles (needle, rod, plate-shaped particles) or granules having D50 ranging from about 50 microns to about 150 microns.

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