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 *04 February 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) *1,3-31,39,43,46,47,52-60,78-80,83-97 and 99* 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4a) Of the above claim(s) _____ is/are withdrawn from consideration.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) *1,3-31,39,43,46,47,52-60,78-80,83-97 and 99* 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 *09/06/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of the amendment filed on 02/04/2008. Upon entering the amendment, claims 1, 3, 12, 60 and 99 are amended and claim 2 is cancelled. The pending claims are 1, 3-31, 39, 43, 46-47, 52-60, 78-80, 83-97 and 99 and presented for examination.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. 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 –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nemeth et al. (US 6,031,003).

With respect to claims 1-5 and 7-11, Nemeth discloses pharmaceutical composition and use of molecules able to modulate the activity of an inorganic ion receptor, preferably a calcium receptor (see cool 1, lines 26-29). And also, the inorganic ion receptor-modulating agents include ionomimetics, ionolyitcs, calcimimetics, and calcilytics. Preferably, calcimimetics are ionomimetics, which affect one or more calcium receptor activities and bind to a calcium receptor (see col. 5, line 48-56). Further, the molecule is a substituted R-phenypropyl-of- phenethylamine derivative, or a substituted

R-benzyl-ot-phenethylamine derivate, having the structure as recited in claim 4 (see col 8, line 21-40). And also the molecule, calcimimetic or calcilytic having an ECs0 or IC 50 at a calcium receptor of less than or equal to 5 μM, preferably less than or equal to 1 μM, 100 nmolar, 10 nmolar, or 1 nmolar (see col 8, lines 58-65). And also, the agents can be formulated as pharmaceutically acceptable salts such as hydrochlorides, acetate, citrate, methanesulfonate, ethanesulfonate and the like (see col. 62, lines 28-32). And also, to facilitate administration of the agent, composition includes carriers and excipients such as calcium phosphate, various sugars, cellulose derivatives, vegetable oils, and physiologically compatible solvents (see col, 62, lines 47-53). And for oral administration, the agents are formulated into conventional oral administration dosage forms such as capsules, tablets, and liquid preparations (see col 63, lines 8-10).

With respect to claims 1 and 7-11, it is the examiner's position that, inherently, the composition advanced by Nemeth provides pharmaceutically acceptable salts of various concentrations to facilitate the pharmacological use by altering the physical characteristic of the agent without preventing it from exerting its physiological effect. Since the essential elements of the Nemeth composition are identical to the instant compositions (that is, excipients like cellulose derivatives, starch, oral dosage forms such as capsules, tablets and further modulation of calcium receptor activity can be used to treat diseases such as primary hyperparathyroidism and Secondary hyperparathyroidism0, the composition would inherently have the same physiochemical properties (e.g. dissolution profile) as the composition set forth in the instant application.

As such, it is the examiner's position that the composition advanced by Nemeth anticipates the composition enumerated in the instant claim set.

3. Claims 12, 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by William G.Goodman et al. (J. Am: Soc. Nephrology 13, 1017-1024, 2002).

Goodman discloses calcimimetic agents such as AMG 073 agent (cinacalcet HC1) for lowering the plasma parathyroid hormone levels in hemodialysis patients suffering from secondary hyperparathyroidism due to ESRD (see abstract). And also, repeated daily orally administered doses of the calcimimetic agent AMG 073 effectively reduce plasma PTH levels, decrease serum phosphorus concentrations, and lower the calcium-phosphorus ion product in hemodialysis patients with secondary hyperparathyroidism (see page 1023). The bioavailability of AMG 073 after oral administration is greater and it exhibits a more consistent pharmacokinetic profile. Cinacalcet HC1 has demonstrated efficacy in controlling the hypercalcemia of severe primary HPT and in reducing parathyroid hormone levels in patient with secondary HPT Since all critical elements as required by instant claims are taught by the cited reference and claims are anticipated.

Applicant’s arguments filed on 02/04/2008 have been fully considered but they are not persuasive.

Applicant asserts that Nemeth and William G. Goodman’s reference does not disclose pharmaceutical composition having a dissolution profile.

This is found not persuasive because, firstly the claims are directed to a composition comprising and any composition comprising the active ingredients recited

in the claims will inherently meet that composition. Therefore the composition advanced by Nemeth reference provides pharmaceutically acceptable salts of (calcimimetics and calcilytics) various concentrations to facilitate the pharmacological use by altering the physical characteristic of the agent without preventing it from exerting its physiological effect. Since the essential elements of the Nemeth composition are identical to the instant compositions (that is, active agent, excipients like cellulose derivatives, starch, oral dosage forms such as capsules, tablets and further modulation of calcium receptor activity can be used to treat diseases such as primary hyperparathyroidism and secondary hyperparathyroidism, the composition would inherently have the same physiochemical properties (e.g. dissolution profile for releasing the calcimimetic compound or calcilytic compound from the composition) as the composition set forth in the instant application. And also, it is known in the art that a pharmaceutical salt exhibits a higher dissolution rate than the corresponding conjugate acid or base at an equal pH, even though they may have the same equilibrium solubility. Salts often speed dissolution by effectively acting as their own buffers to alter the pH of the diffusion layer, thus increasing the solubility of the parent compound in that layer over its inherent solubility at the pH of the dissolution medium.

Claim Rejections - 35 USC § 103

4. 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.

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