IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Lawrence Glen GARY, et al.
Title:	RAPID DISSOLUTION FORMULATION OF A CALCIUM RECEPTOR-ACTIVE COMPOUND
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This submission accompanies Applicants' Request for Continued Examination and it is in further response to the Non-Final Office Action dated April 30, 2009, concerning the above-referenced patent application.

Applicant has enclosed with this amendment a Petition for Extension of Time to make this response timely.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document.

Remarks/Arguments begin on page 6 of this document.

Please amend the application as follows:

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-77. (Cancelled).

78. (Previously presented) A pharmaceutical composition comprising

(a) from about 10% to about 40% by weight of cinacalcet HCl;

(b) from about 40% to about 75% by weight of microcrystalline cellulose;

(c) from about 1% to about 5% by weight of povidone;

(d) from about 5% to about 35% by weight of starch;

(e) from about 1% to about 10% by weight of crospovidone;

(f) from about 0.05% to about 1.5% by weight of colloidal silicon dioxide; and

(g) from about 0.05% to about 1.5% by weight of magnesium stearate;

wherein the percentage by weight is relative to the total weight of the composition.

79. – 82. (Cancelled).

83. (Original) The composition according to Claim 78 further comprising at least one ingredient chosen from lubricants and clear and color coating materials.

84. (Original) The composition according to Claim 78 further comprising from about 1% to about 6% by weight of at least one coating material chosen from clear and color coating materials relative to the total weight of the composition.

85. (Original) The composition according to Claim 78, wherein the cinacalcet HCl is in a form chosen from amorphous powders, crystalline particles, matrix particles, and mixtures of any of the foregoing.

86. (Original) The composition according to Claim 78, wherein the cinacalcet HCl is in a form chosen from needle-shape particles, rod-shape particles, plate-shaped particles, and mixtures of any of the foregoing.

87. (Original) The composition according to Claim 78, wherein the particle D_{50} of the cinacalcet HCl particles is less than or equal to about 50 μm.

88. (Original) The composition according to Claim 78, wherein the composition is in the form of granules.

89. (Original) The composition according to Claim 78, wherein the composition is in a form chosen from tablets, capsules, and powders.

90. (Original) The composition according to Claim 88, wherein the granules have a granule D_{50} measured using a sieve analysis ranging from about 50 μm to about 150 μm.

91. (Original) The composition according to Claim 90, wherein the granules have a granule D_{50} measured using a sieve analysis ranging from about 80 μm to about 130 μm.

92. (Original) The composition according to Claim 78, wherein the cinacalcet HCl is present in a therapeutically effective amount for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

93. (Original) The composition according to Claim 78, wherein the cinacalcet HCl is present in an effective dosage amount for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

94. (Original) The composition according to Claim 92, wherein the hyperparathyroidism is chosen from primary hyperparathyroidism and secondary hyperparathyroidism.

95. (Original) The composition according to Claim 93, wherein the hyperparathyroidism is chosen from primary hyperparathyroidism and secondary hyperparathyroidism.

96. (Original) The composition according to Claim 78, wherein the cinacalcet HCl is present in an amount ranging from about 10% to about 30% by weight relative to the total weight of the composition.

97. (Original) The composition according to Claim 96, wherein the cinacalcet HCl is present in an amount ranging from about 15% to about 20% by weight relative to the total weight of the composition.

98. – 102. (Cancelled).

103. (Previously presented) The composition according to claim 78, wherein crospovidone is present intergranularly, intragranularly, or a combination thereof.

104. (Previously presented) The composition according to Claim 78, wherein crospovidone is present intergranularly.

105. (Previously presented) The composition according to Claim 78, wherein crospovidone is present intragranularly.

106. (Previously presented) The composition according to Claim 78, wherein the microcrystalline cellulose and starch are present in a weight ratio ranging from about 1:1 to about 15:1.

107. (Previously presented) The composition according to Claim 106, wherein the weight ratio is about 10:1.

108. (Previously presented) The composition according to Claim 106, wherein the weight ratio ranges from about 1:1 to about 10:1.

109. (Previously presented) The composition according to Claim 108, wherein the weight ratio is about 5:1.

110.-118. (Cancelled).

119. (Previously presented) A method for the treatment of at least one disease chosen from hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product, comprising administering to a patient in need thereof a pharmaceutical composition according to claim 78.

120. (Previously presented) The method according to Claim 119, wherein the patient is human.

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