

Amendments to the Claims:

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

Listing of Claims:

Claim 1. (Original): A method for treating endocrine tumors, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 2. (Original) A method for inhibiting growth of endocrine tumors, comprising administering to a subject in need thereof a therapeutical effective amount of an mTOR inhibitor.

Claim 3. (Original) A method for inhibiting or controlling endocrine tumors, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 4. (Original) A method for inducing endocrine tumor regression, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 5. (Original) A method for treating endocrine tumor invasiveness or symptoms associated with such tumor growth, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 6. (Original) A method for preventing metastatic spread of endocrine tumors or for preventing or inhibiting growth of micrometastasis, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 7. (Original) A method for the treatment of a disorder associated with endocrine tumors, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

Claim 8. (Currently Amended) A method according to ~~any one of claims 1 to 7~~claim 1, comprising administering in addition a therapeutically effective amount of at least one second drug substance.

Claim 9. (Original) A method according to claim 8, wherein a second drug substance is somastatin or a somastatin analogue.

Claim 10. (Currently Amended) The use of an mTOR inhibitor for the manufacture of a medicament for use in a method according to ~~any one of claims 1 to 9~~claim 1.

Claim 11. (Currently Amended) A method according to ~~any one of claims 1 to 9~~claim 1, or ~~the use according to claim 10~~, wherein an mTOR inhibitor is selected from rapamycin or a rapamycin derivative.

Claim 12. (Original) A method according to claim 10, wherein an mTOR inhibitor is 40-O-(2-hydroxyethyl)-rapamycin.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/094,173	05/19/2008	Peter Wayne Marks	34678-US-PCT	9572
1095	7590	11/30/2010	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 101/2 EAST HANOVER, NJ 07936-1080			JEAN-LOUIS, SAMIRA JM	
			ART UNIT	PAPER NUMBER
			1627	
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			11/30/2010	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. 12/094,173	Applicant(s) MARKS ET AL.	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1627	

-- 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 1 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 ____.
- 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) 1-12 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) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-12 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) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Claim 10 provides for the use of an mTOR inhibitor for the manufacture of a medicament for use in a method according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to claim. Given that the claim may have dual interpretation either as a method of preparation or as a method of treatment, the claim is being interpreted herein as optionally both a method of making and a method of treating.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claims 1-3 and 8-12 are drawn to a method for treating endocrine tumors, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

II. Group II, claim 4 is drawn to a method for inducing endocrine tumor regression, comprising administering to a subject in need thereof a therapeutically effective amount of an mTOR inhibitor.

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