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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/608,644	01/29/2015	Peter Wayne Marks	PAT034678-US-CNT	8815
* * * * * * * * * * * * * * * * * * * *	14/608,644 01/29/2015 Peter Wayne Marks	EXAMINER		
INTELLECTUAL PROPERTY DEPARTMENT			JEAN-LOUIS, SAMIRA JM	
EAST HANOV	EAST HANOVER, NJ 07936-1080		ART UNIT	PAPER NUMBER
			1627	
			NOTIFICATION DATE	DELIVERY MODE
			12/18/2015	EI ECTRONIC

## 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):

phip.patents@novartis.com



	<b>Application No.</b>		Applicant(s) MARKS ET AL.	
Office Action Summary	Examiner SAMIRA JEAN-LOUIS	Art Unit 1627	AIA (First Inventor to File) Status No	
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with th	e corresponder	ce address	
A SHORTENED STATUTORY PERIOD FOR REPLY THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDC	e timely filed com the mailing date on ONED (35 U.S.C. § 13	of this communication. 3).	
Status				
1) Responsive to communication(s) filed on 12/0:  A declaration(s)/affidavit(s) under 37 CFR 1.1	<del></del>	<u>.</u>		
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.			
3) An election was made by the applicant in response	onse to a restriction requireme	nt set forth duri	ng the interview on	
the restriction requirement and election	•			
4) Since this application is in condition for allowar closed in accordance with the practice under E	•	'		
Disposition of Claims*				
5) Claim(s) <u>1-9</u> is/are pending in the application. 5a) Of the above claim(s) <u>5-7</u> is/are withdrawn	from consideration.			
6) Claim(s) is/are allowed.				
7) Claim(s) 1-4,8 and 9 is/are rejected.				
8) Claim(s) is/are objected to.				
9) Claim(s) are subject to restriction and/or	•			
* If any claims have been determined allowable, you may be el			nway program at a	
participating intellectual property office for the corresponding as				
http://www.uspto.gov/patents/init_events/pph/index.isp or send	an inquiry to PPHreedback@usp	<u>ro.dov</u> .		
Application Papers				
10) The specification is objected to by the Examine 11) The drawing(s) filed on is/are: a) □ acce		o Evaminar		
Applicant may not request that any objection to the			5(2)	
Replacement drawing sheet(s) including the correct				
Priority under 35 U.S.C. § 119		,	· · · · · · · · · · · · · · · · · · ·	
12) Acknowledgment is made of a claim for foreign	priority under 35 H.S.C. & 119	(a)-(d) or (f)		
Certified copies:	priority and or or or or or grind	(a) (a) 01 (1).		
a) ☐ All b) ☐ Some** c) ☐ None of the:				
1.☐ Certified copies of the priority document	ts have been received.			
2. Certified copies of the priority document				
3. Copies of the certified copies of the prio	•	eived in this Na	tional Stage	
application from the International Bureau				
** See the attached detailed Office action for a list of the certific	ea copies not receivea.			
Attachment(s)				
1) Notice of References Cited (PTO-892)	3) Interview Summ	ary (PTO-413)		
2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SPaper No(s)/Mail Date 01/29/15, 02/04/15, 04/01/15.	Paper No/s\/Mai			
U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13)  Office Action 9	Summary	Part of Paper N	o./Mail Date 20151211	
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The present application is being examined under the pre-AIA first to invent provisions.

#### **DETAILED ACTION**

### **Election/Restrictions**

Claims 1-9 are currently pending in the application.

Applicant's election of Group I (i.e. claims 1-4 and 8-12) in the reply filed on 12/01/15 and election of everolimus as the m-TOR inhibitor is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 5-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 1-4 and 8-9 are examined on the merits herein.

#### **IDS**

The information disclosure statements (IDS) submitted on 01/29/15, 02/04/15, and 04/01/15 are acknowledged and have been entered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.



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### Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will



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determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp.

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. patent No. 9,006,224 (hereinafter Marks US Patent Application No. '224). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating endocrine tumors comprising administering an mTOR inhibitor. The claimed invention and U.S. patent Marks '224 are rendered obvious over another as the claimed invention teaches a broad genus of a method for treating endocrine tumors by administering a broad genus of mTOR inhibitors whereas Marks '224 teaches a subgenus of treatment of pancreatic neuroendocrine tumors by administering everolimus. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of U.S. Patent No. 9,006,224.

### Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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