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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/893,537	05/14/2013	Heidi Lane	031671-US-CNT05 167-62 C5	6198
28249 7590 01/19/2016 DILWORTH & BARRESE, LLP Dilworth & Barrese, LLP 1000 WOODBURY ROAD SUITE 405 WOODBURY, NY 11797			EXAMINER KLINKEL, KORTNEY L	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 01/19/2016	DELIVERY MODE 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. 13/893,537	Applicant(s) LANE ET AL.	
	Examiner Kortney L. Klinkel	Art Unit 1611	AIA (First Inventor to File) Status No

-- 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 MONTHS 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 10/13/2015.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) 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*

- 5) Claim(s) 1-9 is/are pending in the application.
5a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 6) Claim(s) ____ is/are allowed.
- 7) Claim(s) 1-7 is/are rejected.
- 8) Claim(s) ____ is/are objected to.
- 9) Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) 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).

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).

Certified copies:

- a) All b) Some** c) None of the:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/468,520.
 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) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) Other: ____.

DETAILED ACTION

Claims 1-9 are pending in the instant Office action. The present application is being examined under the pre-AIA first to invent provisions.

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Election/Restriction

Applicant's election without traverse of the species of method directed to the administration of everolimus and lymphatic cancer which is non-Hodgkin's lymphoma in the response 10/13/2015 is acknowledged. The requirement is still deemed proper and is therefore made FINAL. Claims 1-7 encompass the elected species.

Claims 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/13/2015.

Information Disclosure Statement

Acknowledgement is made of applicant's submitting information disclosure statements on 5/14/2013, 9/11/2014, and 7/2/2015. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Priority

Acknowledgement is made of applicant's priority claim that the instant application is a CON of 13/546686 filed 7/11/2012 which is a CON of 10/468520 filed 1/27/2004 which is a 371 of PCT/EP02/01714 filed 2/18/2002 which claims priority to foreign applications UK 0104072.4 filed 2/19/2001 and UK 0124957.2 filed 10/17/2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 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 –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under both pre-AIA 35 U.S.C. 102(a) and 102(e) as being anticipated by Wasik et al. (WO 01/51049 published July 19, 2001 and having an international filing date of January 12, 2001 (which is after November 29, 2001) and claiming priority to US provisional application 60/176086 filed January 14, 2000). Thus the 102(a) date of Wasik et al. is July 19, 2001 and the 102(e) date is January 14, 2000, see MPEP 706.02(f)(1)(I)(C).

Wasik et al. teach a method for treating lymphatic cancer, including non-Hodgkin's lymphoma, comprising administering to a subject a therapeutically effective

amount of everolimus (referred to throughout the document as SDZ RAD) (p. 2 final paragraph, p. 8 lines 1-2, Fig. 7, p. 12 first full paragraph, claims 1, 5 and 16). The preferred daily dose is 1 to 10 mg which falls within and thereby anticipates the ranges of claims 3 through 5 (p. 16 lines 18-24). Also Wasik et al. teach a preferred unit dose ranging from about 0.5 to 10 mg (p. 14 lines 23-24). The SDZ RAD (everolimus) can be administered orally (p. 14 line 4).

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:

(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 negated by the manner in which the invention was made.

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 pre-AIA 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.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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