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14/575,566	12/18/2014	Sunil GUPTA	FR2009/121 US CNT2	3758
5487	7590	06/09/2016	EXAMINER	
ANDREA Q. RYAN			ANDERSON, JAMES D	
SANOFI			ART UNIT	
55 Corporate Drive			PAPER NUMBER	
MAIL CODE: 55A-505A			1629	
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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):

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Office Action Summary	Application No. 14/575,566	Applicant(s) GUPTA, SUNIL	
	Examiner JAMES D. ANDERSON	Art Unit 1629	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 5/3/2016.
☐ 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) 1,6,9,17,19,24 and 34-40 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,6,9,17,19,24 and 34-40 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. ____.
 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)
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

Art Unit: 1629

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Formal Matters

Applicants' response, filed 5/3/2016, is acknowledged and entered.

No claims have been amended, cancelled, or added.

Claims 1, 6, 9, 17, 19, 24, and 34-40 are pending and under examination pursuant with the latest claim set filed 8/31/2015.

Response to Arguments

Applicants' arguments, filed 5/3/2016, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 5/3/2016 and 5/20/2016. The Examiner has considered the references cited therein

Art Unit: 1629

to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Declaration under Rule 1.132

The Examiner acknowledges receipt of the Rule 1.132 Declaration of Dr. Alton Oliver Sartor ("Sartor" Declaration) and has carefully considered the information provided therein. The Examiner's response to the Sartor Declaration is set forth below in response to Applicants' arguments pertaining to the 35 U.S.C. 103 rejection.

The Examiner also notes Applicants' citation of the Mylan Petition of *Inter Partes* Review of U.S. Patent No. 8,927,592, which includes a Declaration of Dr. Rahul Seth. As the Seth Declaration is directly applicable to the instant claims and refutes points raised in the Sartor Declaration, the Sartor Declaration will be considered in light of the Seth Declaration, particularly those matters that are a matter of opinion and not fact, *e.g.*, predictability of the art and reasonable expectation of success.

Claim Rejections - 35 USC § 103

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

Art Unit: 1629

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.

This application currently names joint inventors. In considering patentability of the claims under 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 under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 17, 19, 24, and 34-40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **BOUCHARD *ET AL.*** (USP No. 5,847,170; Issued Dec. 8, 1998) and **PIVOT *ET AL.*** (Annals of Oncology, September 2008, vol. 19, pages 1547-1552) in view of **BEARDSLEY *ET AL.*** (Curr. Opin. In Supportive and Palliative Care, September 2008, vol. 2, pages 161-166), **RODRIGUES *ET AL.*** (The Canadian J. of Urology, December 2007, vol. 14, no. 6, pages 3779-3786), **MITA *ET AL.*** (Clin. Cancer Res., 2009, vol. 15, no. 2, pages 723-730) (Published Online January 15, 2009), **NATIONAL HORIZON SCANNING CENTRE (“NHSC”)** (University of Birmingham, April 2009, pages 1-6), and **BERTHOLD *ET AL.*** (J. Clin. Oncol., January 2008, vol. 26, no. 2, pages 242-245).

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