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06/09/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
14/575,566	12/18/2014	Sunil GUPTA	FR2009/121 US CNT2	3758	
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5487 ANDREA Q. R	7590 06/09/201 YAN	EXAMINER			
SANOFI		ANDERSON, JAMES D			
55 Corporate Drive					
MAIL CODE: 55A-505A			ART UNIT	PAPER NUMBER	
BRIDGEWATI	ER, NJ 08807	1629			
			NOTIFICATION DATE	DELIVERY MODE	

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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	Application No. 14/575,566	Applicant(s) GUPTA, SUNIL	
Office Action Summary	Examiner JAMES D. ANDERSON	Art Unit 1629	AIA (First Inventor to File) Status No
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the	corresponder	nce address
A SHORTENED STATUTORY PERIOD FOR REPL' THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period or - 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 to will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDON	mely filed In the mailing date of ED (35 U.S.C. § 13	of this communication. 33).
Status			
1) Responsive to communication(s) filed on <u>5/3/2</u> A declaration(s)/affidavit(s) under 37 CFR 1. 1			
2a) ☐ This action is FINAL . 2b) ☐ This	action is non-final.		
3) An election was made by the applicant in resp	·		ing the interview on
 the restriction requirement and election Since this application is in condition for allowated closed in accordance with the practice under Exercise 	nce except for formal matters, pr	osecution as	
Disposition of Claims*			
5a) Of the above claim(s) is/are withdraw 6) Claim(s) is/are allowed. 7) Claim(s) is/are allowed. 7) Claim(s) is/are objected to. 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 exparticipating intellectual property office for the corresponding antito://www.uspto.gov/patents/init_events/pph/index.jsp or send application Papers 10) The specification is objected to by the Examine 11) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct	ted. or election requirement. ligible to benefit from the Patent Pro pplication. For more information, ple d an inquiry to <u>PPHfeedback@uspto</u> er. epted or b) objected to by the drawing(s) be held in abeyance. Se	ease see gov. Examiner. ee 37 CFR 1.85	5(a).
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign Certified copies: a) All b) Some** c) None of the: 1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority documen application from the International Bureaut See the attached detailed Office action for a list of the certification.	ts have been received. ts have been received in Applica prity documents have been recei u (PCT Rule 17.2(a)).	ition No	
Attachment(s)			
Notice of References Cited (PTO-892)	3) Interview Summar		
P) X Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/	SB/08b) — Paper No(s)/Mail [)ate	



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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

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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

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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 negatived by the manner in which the invention was made.

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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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