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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER, NOTIFICATION DATE, DELIVERY MODE. Includes details for application 14/575,566 filed 12/18/2014 by Sunil GUPTA, inventor ANDREA Q. RYAN, examiner ANDERSON, JAMES D, art unit 1629, notified 06/09/2016 electronically.

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):

- andrea.ryan@sanofi.com
eFlow@frasappmoss112.pharma.aventis.com
GlobalPatent.eFlow@Sanofi.com



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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 Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.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 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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