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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/423,021	02/02/2017	Hitesh Batra	080618-1718	8815

22428 7590 01/11/2018

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EXAMINER
VALENROD, YEVGENY

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
01/11/2018	ELECTRONIC

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.** 15/423,021	**Applicant(s)** Batra et al.	
	Examiner YEVGENY VALENROD	**Art Unit** 1621	**AIA 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 9/29/17 .

☐ 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) 1,3-7 and 9-13 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) 1,3-7 and 9-13 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) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☑ Other: 3rd party IDS.

DETAILED CORRESPONDENCE

Notice of Pre-AIA or AIA Status

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

Withdrawn Rejections

Rejection of claim 12 under 35USC 112(b) is withdrawn in view of applicants" amendment to the claims.

Rejection of claim 6 under 35 USC 102(b) over Phares et al is withdrawn in view of applicants' amendment to the claims. Claim 6 is now directed to a pharmaceutical product that is obtained by acidification of the salt of claim 1. Since rejection over Phares was based on the art's disclosure of the treprostinil salt, said rejection no longer applies to the amended claim 6.

Rejection of claims 1-3 under 35 USC 102(b) over Moriarty et al is withdrawn in view of amendments to the claims. Rejection over Moriarty was based on the art's disclosure of treprostinil free acid. Since the amended claims are now dir3ected to the salt of treprostinil the rejection of the free acid no longer applies.

Rejection of claim 12 under 35 USC 103(a) over Phares is withdrawn ion view of applicants' amendments. Claim 12 now depends from claim 11.

Rejection of claims 6 and 8 under 35 USC 103(a) over Moriarty et al is withdrawn in view of applicants' amendments to the claims. Claim 8 has been canceled and claim 6 is now directed to a pharmaceutical product that is obtained by acidification of the salt of claim 1.

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 -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1,3, 4, 5 and 7 is/are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Phares et al (WO 2005/007081).

Phares discloses crystal forms of treprostinil diethanolamine salt (pages 85-90). On page 87 polymorph of Form A is described as anhydrous.

Claims 1, 3, 4, 5 and 7 are treated as product by process claims. While Phares does not disclose the instantly claimed purity the product of Phares inherently meets the purity limitation because it is a crystalized form of the instantly clamed product. The product of Phares is the same as the instantly claimed product. Since the product is the same it inherently meets the limitation directed to product stability at an ambient temperature. A compound's stability is the property of the product and is therefore inseparable from the product itself.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113).

Reply to applicants' remarks

Applicants have argued that Pares fails to disclose the limitation directed to product's stability at ambient temperature.

Examiner has considered applicants' remarks and found them to be not sufficient to overcome the rejection of record. The stability of the diethanol amine salt of treprostinil is an inherent property of the product. "A compound and its properties are inseparable" *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Since the rejection of record stipulates that the product of Phares is the same as the instantly claimed product, stability of the product disclosed by Phares is the same as that of the instantly claimed product.

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, 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

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