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Foley & Lardner LLP 3000 K STREET N.W. SUITE 600 WASHINGTON, DISTRICT OF COLUMBIA 20007-5109			VALENROD, YEVGENY	
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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.

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PTOL-90A (Rev. 04/07)

IPR2020-00770

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Withdrawn Rejections

Rejection of claim 12 under 35 USC 112(b) is withdrawn in view of applicants' amendment to the claims.

Rejection of claim 6 under 35 USC 102(b) over Phares et al is withdrawn in view of applicants' amendment to the claims.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Rejection of claims 1-3 under 35 USC 102(b) over Moriarty et al is withdrawn in view of amendments to the claims.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 directed 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Rejection of claim 12 under 35 USC 103(a) over Phares is withdrawn in view of applicants' amendments.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Rejection of claims 6 and 8 under 35 USC 103(a) over Moriarty et al is withdrawn in view of applicants' amendments to the claims.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.

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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 claimed 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

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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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