

Petitioner Liquidia Technologies, Inc.

Oral Argument Demonstratives

Liquidia

U.S.

Overview of the Claims

Product by Process Claims	Method Claims
Claim 1	Claim 6
<p>A pharmaceutical batch consisting of treprostinil or a salt thereof and impurities resulting from (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the salt of treprostinil with an acid to form treprostinil, and</p> <p>wherein the pharmaceutical batch contains at least 2.9 g of treprostinil or its salt.</p>	<p>A method of preparing a pharmaceutical product from a pharmaceutical batch as claimed in claim 1, comprising storing a pharmaceutical batch of a salt of treprostinil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the pharmaceutical batch after storage.</p>
Claims 2-5 depend from it.	Claim 7 depends from it.

The Claims of the '901 Patent are Product

- Process limitations are not accorded any weight for determining validity.
- In determining validity of a product-by-process claim, the focus is on the product, not on the process of making it (*Amgen Inc. v. F. Hoffmann-Laurie*, 582 F.3d 1369 (Fed. Cir. 2009)).
- The process claim elements do nothing to impart structure to the claimed treprostinil or salt thereof, and thus, do not preclude the claimed pharmaceutical composition.
- The Examiner withdrew the rejection based on product-by-process claims. Patent Owner argued that the resulting products of the '901 Patent have different pharmacokinetic profiles.

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“Instead, for purposes of this Decision, level of ordinary skill in the art is reflected including Phares and Moriarty. *See In re* F.3d 1573, 1579 (Fed. Cir. 1995) (“The p skill in the art is a hypothetical person v know the relevant prior art.’).”

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