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Paper 7
Date: October 13, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2020-00770
Patent 9,604,901 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

INTRODUCTION

Liquidia Technologies, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–9 of U.S. Patent No. 9,604,901 B2 (Ex. 1001, "the '901 patent"). United Therapeutics Corporation ("Patent Owner") filed a Preliminary Response (Paper 6 ("Prelim. Resp.")).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision under § 314 may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). In addition, the Federal Circuit has interpreted the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition." *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, we institute an *inter partes* review of claims 1–9 of the '901 patent.

Related Matters

Patent Owner asserted the '901 patent against Petitioner in *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, Case No. 1:20-cv-00755 (D. Del.). Paper 5, 1.

Petitioner filed IPR2020-00769, challenging the claims of U.S. Patent No. 9,593,066, a patent in the same family as the '901 patent. *Id.* Together with this Decision, we concurrently issue a decision in that case, denying the Petition. IPR2020-00769, Paper 7.

U.S. Patent No. 8,497,393 (Ex. 1004, "the '393 patent") is a parent of the '901 patent. Ex. 1001, Code (63). The '393 patent was the subject of *SteadyMed Ltd. v. United Therapeutics Corp.*, IPR2016-00006 ("the '393 IPR"). In that case, the Board held that claims 1–22 of the '393 patent are unpatentable (IPR2016-00006, Paper 82 (PTAB March 31, 2017) ("the '393 Decision" or "the '393 Dec."), and the Federal Circuit affirmed (*United Therapeutics Corp. v. SteadyMed Ltd.*, 702 Fed.App'x. 990 (Fed. Cir. 2017)).

The '901 Patent

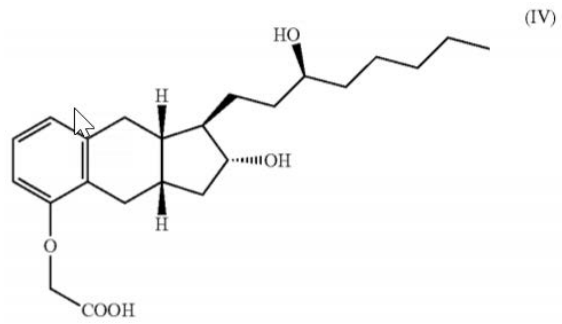
The '901 patent relates to "an improved process to convert benzindene triol to treprostinil via salts of treprostinil and to purify treprostinil." Ex. 1001, Abstract.

Treprostinil was a known, useful pharmaceutical compound. *Id.* at 1:35–65, *see also id.* at 27 ("Treprostinil [is] the active ingredient in Remodulin®."). Before the '901 patent, treprostinil had been prepared as described in Moriarty[1] and other prior-art references. *Id.* at 1:28–32.

[1] Moriarty et al., *The Intramolecular Asymmetric Pauson-Khand Cyclization as a Novel and General Stereoselective Route to Benzindene Prostacyclins: Synthesis of UT-15 (Treprostinil)*, 69 J. ORG. CHEM. 1890–1902 (2004) (Ex. 1009). Moriarty is one of the two prior-art references asserted in this proceeding.

According to the ’901 patent, because treprostinil is “of great importance from a medicinal point of view, a need exists for an efficient process to synthesize th[is] compound[] on a large scale suitable for commercial production.” *Id.* at 1:66–2:3.

The ’901 patent discloses “a process for the preparation of a compound having formula IV, or a hydrate, solvate, or pharmaceutically acceptable salt thereof.” *Id.* at 8:44–46. Petitioner represents that Formula IV is treprostinil. Pet. 11; Ex. 1002 ¶ 30. Formula IV has the following structure:

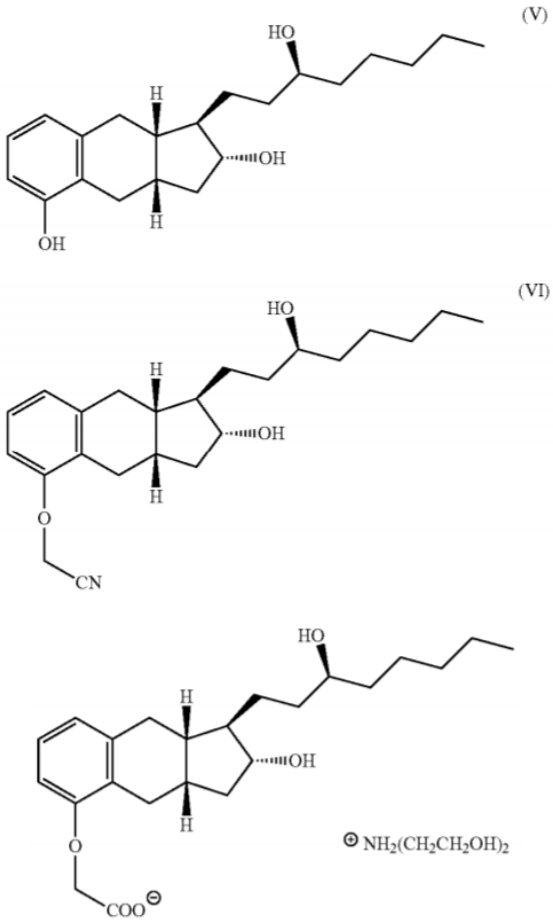


The figure above shows the structure of Formula IV. Ex. 1001, 8:48–63.

The process of the ’901 patent comprises

> (a) alkylating a compound of structure V with an alkylating agent such as $ClCH_2CN$ to produce a compound of formula VI,
> (b) hydrolyzing the product of step (a) with a base such as KOH,
> (c) contacting the product of step (b) with a base B such as diethanolamine to for a salt of the following structure, and
> (d) reacting the salt from step (b) with an acid such as HCl to form the compound of formula IV.

Id. at 8:65–9:48. Structure V, formula VI, and the salt formed in step (c) have the following structures:



The figures above show the structures of structure V, formula VI, and the salt formed in step (c). *Id.* at 9:1–28, 9:33–45. The ’901 patent states that “[i]n one embodiment, the purity of compound of formula IV is at least 90.0%, 95.0%, 99.0%, 99.5%.” *Id.* at 9:49–50.

According to the ’901 patent:

> The quality of treprostinil produced according to this invention is excellent. The purification of benzindene nitrile by column chromatography is eliminated. The impurities carried over from intermediate steps (i.e. alkylation of triol and hydrolysis of benzindene nitrile) are removed during the carbon treatment and the salt formation step. Additional advantages of this process are: (a) crude treprostinil salts can be stored as raw material at ambient temperature and can be converted to treprostinil by

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