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Paper 45
Entered: October 8, 2021

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*.

PER CURIAM

JUDGMENT

Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying Petitioner's Request to Strike
37 C.F.R. § 42.5

Denying Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c)

Granting Petitioner's Motion to Submit Supplemental Information
37 C.F.R. § 42.123(b)

I. 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"). We instituted trial to review the challenged claims. Paper 7 ("Dec." or "Decision to Institute"). Thereafter, United Therapeutics Corporation ("Patent Owner") filed a Response to the Petition (Paper 12, "PO Resp."), Petitioner filed a Reply (Paper 15), and Patent Owner filed a Sur-reply (Paper 25).

The parties filed a Joint Paper Concerning Petitioner's Request to Strike Portions of Patent Owner's Paper Nos. 12 and 25 and Exhibits 2002 and 2025. Paper 29. The parties also briefed the issues of (1) whether we should exclude Exhibits 1002 and 1012 (Papers 31, 32, 37), and (2) whether Petitioner may submit, as supplemental information, the transcript and order from the *Markman* hearing in a parallel district court case (Papers 38, 40). An oral hearing for this proceeding was held on June 23, 2021, and the transcript of that hearing is of record. *See* Paper 44 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–5, 8, and 9 are unpatentable. Petitioner, however, has not established by a preponderance of the evidence that claims 6 and 7 are unpatentable.

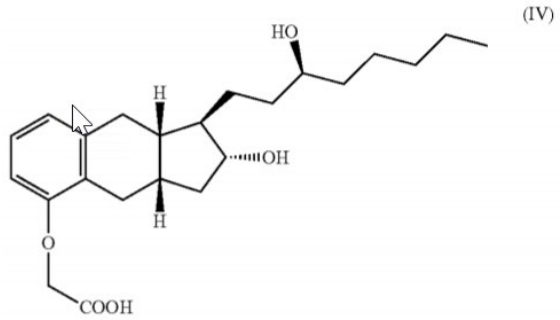
A. The '901 Patent

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.

Prostacyclin derivatives are useful pharmaceutical compounds. *Id.* at 1:23–26. Treprostinil, a known prostacyclin derivative, is the active ingredient in Remodulin. *Id.* at 1:27–32. Before the '901 patent, treprostinil had been prepared as described in Moriarty[1] and other prior-art references. *Id.* 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:

[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 prior-art references asserted in this proceeding.

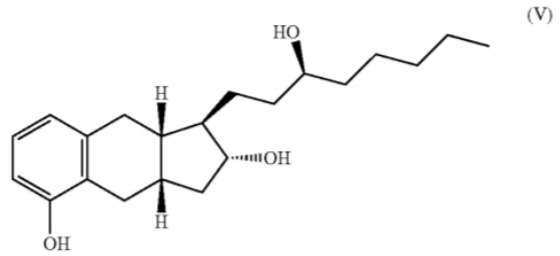


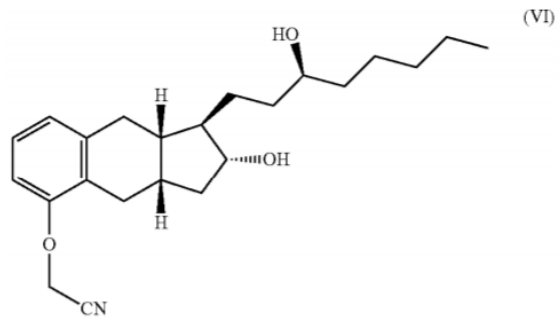
The figure above shows the structure of Formula IV. Ex. 1001, 8:48–63.

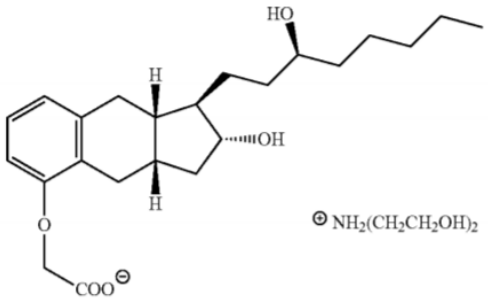
The process of the '901 patent comprises

(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 [sic] 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 simple acidification with diluted hydrochloric acid, and (b) the treprostinil salts can be synthesized from the solution of treprostinil without isolation. This process provides better quality of final product as well as saves significant amount of solvents and manpower in purification of intermediates.

Id. at 16:66–17:12, *see also id.* at 6:4–18 (the same).

B. Illustrative Claim

Claim 1 is the only independent claim. With the Certificate of Correction (Ex. 1006, 2) incorporated, it is reproduced below:

> 1. 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

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