Trials@uspto.gov
Tel: 571-272-7822

Paper 18
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2021-00406
Patent 10,716,793 B2

Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER, and DAVID COTTA, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge*.

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

INTRODUCTION

A. Background

Liquidia Technologies, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, "the '793 patent"). United Therapeutics Corporation ("Patent Owner") filed a Preliminary Response. Paper 13 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2020). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), 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."

After considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one challenged claim. Accordingly, we institute an *inter partes* review of all challenged claims on all asserted grounds.

B. Related Matters

The parties identify *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1:20-cv-00755-RGA (D. Del.) ("the District Court proceeding"), as a related matter. Pet. 1; Paper 3, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–8 of the '793 patent are unpatentable based on the following grounds (Pet. 30–68):[1]

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–8	103	'212 patent,[3] Voswinckel JESC,[4] Voswinckel JAHA[5]
1–8	103	'212 patent, Voswinckel JESC
1	102	Ghofrani[6]
1, 3, 8	103	Voswinckel JAHA, Ghofrani
1, 3	102	Voswinckel 2006[7]

[1] Petitioner also relies on declarations from Nicholas Hill, M.D., and Igor Gonda, Ph.D. Ex. 1002; Ex. 1004.

[2] The '793 patent claims a priority date of May 15, 2006, and Petitioner "assumes the relevant priority date . . . is May 15, 2006." Pet. 12; Ex. 1001, code (60). Accordingly, patentability is governed by the versions of 35 U.S.C. §§ 102 and 103 preceding the amendments in the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011).

[3] US 6,521,212 B1, issued Feb. 18, 2003 (Ex. 1006) (alleged to be prior art under 35 U.S.C. §§ 102(a), (b), (e)).

[4] Voswinckel, R., et al., *Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension*, 25 EUROPEAN HEART J. 22 (2004) (Ex. 1007) (alleged to be prior art under 35 U.S.C. § 102(b)).

[5] Robert Voswinckel, et al., *Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension*, in Abstracts from the 2004 Scientific Sessions of the American Heart Association, 110 CIRCULATION III-295 (Oct. 26, 2004) (Ex. 1008) (alleged to be prior art under 35 U.S.C. § 102(b)).

[6] Hossein Ardeschir Ghofrani, et al., *Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie*, 30 HERZ 296–302 (June 2005) (Ex. 1010) (alleged to be prior art under 35 U.S.C. § 102(a)). We rely on the English translation that follows the German original article as part of Ex. 1010.

[7] Robert Voswinckel, et al., *Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension*, 144 ANNALS OF INTERNAL MEDICINE

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
2, 4–8	103	Voswinckel 2006, '212 patent

D. The '793 Patent

The '793 patent, titled "Treprostinil Administration by Inhalation," issued on July 21, 2020. Ex. 1001, codes (45), (54). The patent "relates to methods and kits for therapeutic treatment and, more particularly, to therapeutic methods involving administering treprostinil using a metered dose inhaler and related kits." *Id.* at 1:20–23.

Treprostinil "is a prostacyclin analogue" that may be used to treat pulmonary hypertension. *Id.* at 5:37–41. According to the '793 patent, it was previously known to administer treprostinil by intravenous, subcutaneous, or inhalation routes to treat any of several conditions, including pulmonary hypertension. *Id.* at 5:42–58.

The '793 patent relates to the administration of treprostinil in high concentrations over a short inhalation time. *Id.* at 16:61–63, 17:44–46. This method of administration is described as reducing pulmonary vascular resistance and pulmonary artery pressure, as well as increasing cardiac output. *Id.* at 16:32–42, Fig. 10.

E. Illustrative Claim

Claims 1–8 of the '793 patent are challenged. Claim 1 is independent and illustrative; it recites:

> 1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a

149–50 (January 2006) (Ex. 1009) (alleged to be prior art under 35 U.S.C. § 102(a)).

> formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

Ex. 1001, 18:23–31.

ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim in an unexpired patent "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2020). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.*

Neither party presents any terms for construction. Pet. 12–13; Prelim. Resp. 1–56. Accordingly, we determine that no express construction of any claim term is necessary in order to decide whether to institute trial. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

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