

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*.

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

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.”).

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the ’793 patent on all grounds set forth in the Petition. Paper 18 (“Inst. Dec.”). After institution of trial, Patent Owner filed a Response (Paper 29, “PO Resp.”), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents’ Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which has been entered into the record. Paper 77 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the challenged claims of the ’793 patent. For the reasons discussed below, we determine Petitioner has established by a preponderance of the evidence that each of claims 1–8 of the ’793 patent is unpatentable.

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(a)	'212 patent, ³ Voswinckel JESC, ⁴ Voswinckel JAHA ⁵
1–8	103(a)	'212 patent, Voswinckel JESC
1	102(a)	Ghofrani ⁶
1, 3, 8	103(a)	Voswinckel JAHA, Ghofrani
1, 3	102(a)	Voswinckel 2006 ⁷

¹ Petitioner also relies on declarations from Nicholas Hill, M.D., and Igor Gonda, Ph.D. Exs. 1002, 1004, 1106, 1107.

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(a)	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 (“Petitioner does not believe construction of any claim term is required”); PO Resp. 7 (not proposing construction of any terms). 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)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.