Trials@uspto.gov
571.272.7822

Paper 12 (IPR2015-00522)
Paper 12 (IPR2015-00524)
Paper 12 (IPR2015-00525)
Paper 12 (IPR2015-00526)
Entered: July 29, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner,

v.

INO THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-00522 (8,282,966 B2)
Case IPR2015-00524 (8,293,284 B2)
Case IPR2015-00525 (8,431,163 B2)
Case IPR2015-00526 (8,795,741 B2)[1]

Before LORA M. GREEN, TINA E. HULSE, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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[1] This Decision addresses issues that are common to each of the above-referenced cases. We, therefore, issue a single Decision that has been entered in each case. The parties may use this style caption when filing a single paper in multiple proceedings, provided that such caption includes a footnote attesting that "the word-for-word identical paper is filed in each proceeding identified in the caption."

I. INTRODUCTION

Petitioner, Praxair Distribution, Inc., filed Petitions requesting an *inter partes* review of: (1) claims 1–29 of U.S. Patent No. 8,282,966 ("the '966 patent") (Ex. 1001, IPR2015-00522); (2) claims 1–30 of U.S. Patent No. 8,293,284 B2 ("the '284 patent") (Ex. 1001, IPR2015-00524); (3) claims 1–25 of U.S. Patent No. 8,431,163 B2 ("the '163 patent") (Ex. 1001, IPR2015-00525); and (4) claims 1–44 of U.S. Patent No. 8,795,741 B2 ("the '741 patent") (Ex. 1001, IPR2015-00526). Paper 1 (IPR2015-00522) ("-522 Pet.").[2] Patent Owner, INO Therapeutics LLC, filed a Preliminary Response to each Petition. Paper 8 (IPR2015-00522) ("-522 Prelim. Resp.").[3]

We have jurisdiction 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). Upon considering the Petitions and Preliminary Responses, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any of the challenged claims in any of the proceedings. Accordingly, the Petition in each proceeding is *denied*.

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[2] Petitioner filed Petitions as Paper 1 in each of the other proceedings. We refer to those Petitions as "-524 Pet.," "-525 Pet.," and "-526 Pet."

[3] Patent Owner filed Preliminary Responses as Paper 8 in each of the other proceedings. We refer to those Preliminary Responses as "-524 Prelim. Resp.," "-525 Prelim. Resp.," and "-526 Prelim. Resp."

A. Related Proceedings

Petitioner states that it is not aware of any current litigation involving any of the involved patents. -522 Pet. 7.[4]

B. The Involved Patents

The involved patents are all related and share substantially the same Specification. The Specification discloses methods of reducing the risk of an adverse event, such as pulmonary edema, associated with treating a patient with inhaled nitric oxide gas ("iNO"). Ex. 1001, Abstract. Nitric oxide is a lung-specific vasodilator that significantly improves blood oxygenation and reduces the need for extracorporeal oxygenation. *Id.* at 3:33–42. INOmax®—nitric oxide for inhalation—is an FDA-approved drug for treatment of term and near term (>34 weeks gestation) neonates who have hypoxic respiratory failure associated with evidence of pulmonary hypertension, known as persistent pulmonary hypertension in the newborn ("PPHN"). *Id.* at 1:18–22, 6:23–29.

The Specification also describes the INOT22 Study, which was conducted, in part, to assess the safety and effectiveness of INOmax® in patients four weeks to eighteen years of age undergoing assessment of pulmonary hypertension. *Id*. at 9:18–30, 43–44. Initially, the study protocol did not include a baseline pulmonary capillary wedge pressure ("PCWP") value as an exclusion criteria.[5] *Id.* at 12:25–26. During the study, at least

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[4] Petitioner makes similar arguments in its papers and cites similar evidence in each of the cases. Accordingly, citations to papers and exhibits in this Decision refer to those filed in IPR2015-00522, unless stated otherwise.

[5] PCWP provides an estimate of left atrial pressure, which may be used to diagnose the severity of left ventricular dysfunction and to measure pulmonary hypertension. Ex. 1001, 5:9–18.

two patients developed signs of pulmonary edema. *Id.* at 13:2–3. The Specification states that "[t]his is of interest because pulmonary edema has previously been reported with the use of iNO in patients with LVD [left ventricular dysfunction], and may be related to decreasing PVR [pulmonary vascular resistance] and overfilling of the left atrium." *Id.* at 13:3–6. The Specification further states that "after the surprising and unexpected identification of SAEs [serious adverse events] in the early tested patients, it was determined that patients with pre-existing LVD had an increased risk of experiencing an AE or SAE [such as pulmonary edema] upon administration." *Id.* at 12:26–30, 13:62–64. The study protocol was amended to exclude patients with a baseline PCWP greater than 20 mmHg, which was selected to avoid enrolling children with LVD who "would be most likely at-risk for these SAEs." *See id*. at 12:32–38.

C. Illustrative Claim

Petitioner challenges: (1) claims 1–29 the '966 patent (IPR2015-00522); (2) claims 1–30 of the '284 patent (IPR2015-00524); (3) claims 1–25 of the '163 patent (IPR2015-00525); and (4) claims 1–44 of the '741 patent (IPR2015-00526). The challenged claims are all similar. Claim 1 of the '966 patent is illustrative and is reproduced below:

> 1. A method of reducing the risk of occurrence of pulmonary edema associated with a medical treatment comprising inhalation of 20 ppm nitric oxide gas, said method comprising:
>
> (a) performing echocardiography to identify a child in need of 20 ppm inhaled nitric oxide treatment for pulmonary hypertension, wherein the child is not dependent on right-to-left shunting of blood;
>
> (b) determining that the child identified in (a) has a pulmonary capillary wedge pressure greater than or equal to 20 mm Hg and thus has left ventricular dysfunction, so

> is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide; and
>
> (c) excluding the child from inhaled nitric oxide treatment, based on the determination that the patient has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide.

Common among almost all the independent claims of all the involved patents is a limitation like step (c) of claim 1 above, which excludes a patient from treatment with inhaled nitric oxide based on a determination that the patient has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide. *See* claims 1(c),[6] 6(c), 13(e), and 22(e) of the '966 patent (Ex. 1001, IPR2015-00522); claims 1(c), 6(c), 13(e), and 23(e) of the '284 patent (Ex. 1001, IPR2015-00524); claims 1(c) and 6(e) of the '163 patent (Ex. 1001, IPR2015-00525); claims 1(e) and 34(e) of the '741 patent (Ex. 1001, IPR2015-00526).

However, not all of the independent claims recite the exact language as claim 1(c) above. Certain claims recite excluding a patient from treatment with inhaled nitric oxide or, despite the patient's ongoing need for treatment for hypoxic respiratory failure, discontinuing treatment with inhaled nitric oxide after it has begun, where the exclusion or discontinuation is based on a determination that the patient has left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide. *See* claims 12(c) and 20(e) of the '163 patent (Ex. 1001, IPR2015-00525); claims 9(e) and 37(e) of the '741 patent

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[6] For ease of reference, we refer to particular steps of particular claims, e.g., step (c) of claim 1, as "claim 1(c)."

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