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Paper 11
Entered:September 22, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. and NOxBOX LIMITED,
Petitioner,
v.

MALLINCKRODT HOSPITAL PRODUCTS,
Patent Owner.

Case IPR2016-00777 (8,282,966 B2)
Case IPR2016-00778 (8,431,163 B2)
Case IPR2016-00779 (8,293,284 B2)
Case IPR2016-00780 (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.

I. INTRODUCTION

Praxair Distribution, Inc. ("Praxair") and NOxBOX Limited ("NOxBOX") (collectively, "Petitioner") filed Petitions requesting an *inter partes* review of: (1) claims 1–29 of U.S. Patent No. 8,282,966 B2 ("the '966 patent") (Ex. 1001, IPR2016-00777); (2) claims 1–25 of U.S. Patent No. 8,431,163 B2 ("the '163 patent") (Ex. 1001, IPR2016-00778); (3) claims 1–30 of U.S. Patent No. 8,293,284 B2 ("the '284 patent") (Ex. 1001, IPR2016-00779); and (4) claims 1–44 of U.S. Patent No. 8,795,741 B2 ("the '741 patent") (Ex. 1001, IPR2016-00780). Paper 4 (IPR2016-00777) ("Pet.").[2, 3] Mallinckrodt Hospital Products IP Ltd. ("Patent Owner") filed a Preliminary Response to each Petition. Paper 8 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that 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); *see* 37 C.F.R. § 42.108. Upon considering the Petitions and Preliminary Responses, we exercise our discretion and deny each Petition under 35 U.S.C. §§ 314(a) and 325(d).

A. Related Proceedings

The parties state that Patent Owner has asserted the '966 patent against Petitioner in a case pending in the U.S. District Court for the District of Delaware,

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[2] The parties make similar arguments in their papers and cite similar evidence in each of the cases. Accordingly, citations to papers and exhibits in this Decision refer to those filed in IPR2016-00777, unless stated otherwise.

[3] Petitioner filed Petitions as Paper 4 in each of the other proceedings. We refer to those Petitions as "-778 Pet.," "-779 Pet.," and "-780 Pet."

INO Therapeutics LLC v. Praxair Distribution, Inc., No. 1:15-cv-00170 (GMS). Pet. 10; Paper 7, 1.

Praxair previously filed petitions requesting *inter partes* review of the claims of each of the involved patents. Case IPR2015-00522, Paper 1 (the '966 patent); Case IPR2015-00524, Paper 1 (the '284 patent); Case IPR2015-00525, Paper 1 (the '163 patent); Case IPR2015-00526, Paper 1 (the '741 patent). We denied each of those petitions because Petitioner failed to establish a reasonable likelihood that it would prevail in its assertion that any of the claims of the involved patents are unpatentable. Cases IPR2015-00522, IPR2015-00524, IPR20150-00525, IPR2015-00526, Paper 12 ("-522 Dec. Inst.").

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 9:20–30, 43–44. Initially, the study protocol did not include a baseline pulmonary

capillary wedge pressure ("PCWP") value as an exclusion criterion.[4] *Id.* at 12:25–26. During the study, at least two patients developed signs of pulmonary edema. *Id.* at 13:2–3. The Specification states "[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 (IPR2016-00777); (2) claims 1–25 of the '163 patent (IPR2016-00778); (3) claims 1–30 of the '284 patent (IPR2016-00779); and (4) claims 1–44 of the '741 patent (IPR2016-00780). 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:

[4] 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.

> (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 child 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 the '966 patent claim 1 above, which excludes a child 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),[5] 6(c), 13(e), and 22(e) of the '966 patent (Ex. 1001, IPR2016-00777); claims 1(c) and 6(e) of the '163 patent (Ex. 1001, IPR2016-00778); claims 1(c), 6(c), 13(e), and 23(e) of the '284 patent (Ex. 1001, IPR2016-00779); claims 1(e) and 34(e) of the '741 patent (Ex. 1001, IPR2016-00780).

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

[5] 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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