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Fish & Richardson PC P.O.Box 1022 minneapolis, MN 55440			ARNOLD, ERNST V	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/11 has been entered.

Claims 1-30 have been cancelled and claims 31-45 are new.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 1/10/12 was filed after the mailing date of the Office Action on 6/27/11. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Withdrawn rejections:

Applicant's amendments and arguments filed 12/27/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraisse et al. (Cardiol Young 2004; 14: 277-283 IDS filed on 12/27/11) and Atz et al. (Seminars in Perinatology 1997, 21(5), pp 441-455) and Kinsella et al. (The Lancet 1999, 354, 1061-1065) and Loh et al. (Circulation 1994, 90, 2780-2785) and Beghetti et al. (the Journal of Pediatrics 1997 page 844) and Ichinose et al. (Circulation 2004; 109:3106-3111: IDS filed on 1/10/12) and INOmax insert (IDS filed on 1/19/12).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants claims, for example:

31. (New) A method of reducing the risk of occurrence of pulmonary edema associated with a medical treatment comprising inhalation of nitric oxide gas, said method comprising:
- (a) identifying a child in need of inhaled nitric oxide treatment, wherein the child is not known to be dependent on right-to-left shunting of blood;
 - (b) determining that the child identified in (a) has pre-existing left ventricular dysfunction and 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 pre-existing left ventricular dysfunction and so is at particular risk of pulmonary edema upon treatment with inhaled nitric oxide.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Fraisse et al. sought to identify the predictors of extracorporeal membrane oxygenation therapy, death and response to iNO by performing detailed diagnostic screening with Doppler echocardiographic screening of the patient, neonates, with suspected pulmonary hypertension (Abstract; page 278 Patients and methods). The non-invasive technique allows for measurement of ventricular function and estimates both the direction and degree of shunting including bi-directional shunting (page 277 right column; page 278, right column; and pages 279-280, Tables 1 and 2 and appropriate text). Fraisse et al. teach that right to left ductal shunting of blood was found to be an independent predictor of death (Abstract). Fraisse et al. teach that *a left to right*

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